Original

Elena Huerta-Ramos*[1,2,3]
Silvia Marcó-García*[1]
Maria Soledad Escobar-Villegas*[1]
Elena Rubio-Abadal[1,2,3]
Susana Ochoa[1,2,3]
Eva M. Grasa Bello[4]
Anna Alonso Solís[4]
Mireia Rabella[4]
Jesús Berdun[5]
Margarita Hospedales[5]
m-RESIST group**
Iluminada Corripio***[4]
Judith Usall*** [1,2,3]

m-RESIST, a complete m-Health solution for patients with treatment-resistant schizophrenia: a qualitative study of user needs and acceptability in the Barcelona metropolitan area

[1]Parc Sanitari Sant Joan de Déu, Barcelona, Spain
[2]Instituto de Salud Carlos III, Centro de Investigación en Red de Salud Mental (CIBERSAM), Madrid, Spain
[3]Catalan Group in Women's Mental Health Research (GTRDSM), Barcelona, Spain
[4]Fundació e Institut de Recerca del Hospital de la Santa Creu i Sant Pau, CIBERSAM G21 Barcelona, Spain
[5]Fundació TicSalut, Barcelona, Spain
* Both authors contributed equally to this study and should be considered co-first authors
**m-RESIST is a multidisciplinary research group:

Elena Huerta-Ramos (neuropsychologist), Judith Usall (psychiatrist), Susana Ochoa (psychologist), Elena Rubio-Abadal (psychiatrist), Marisol Escobar (sociologist), Marta Ferrer Quintero (psychologist) Iluminada Corripio (psychiatrist), Eva Grasa (psychologist), Anna Alonso-Solís (neuropsychologist), Mireia Rabella (neuropsychologist), Maria J Portella (psychologist), Anna Díaz (psychiatrist), Alejandro Keymer-Gausset (psychiatrist), Alexandra Roldán (psychiatrist), Margarita Hospedales (senior project manager), Jesús Berdún (telecommunications engineer), Katya Rubinstein (psychologist), Asaf Caspi (psychiatrist), Matti Isohanni (professor emeritus psychiatry, psychiatrist), Erika Jääskeläinen (researcher), Jouko Miettunen (professor of clinical epidemiology), Jussi Seppälä (psychiatrist), Hannu J. Koponen (professor of psychiatry of aging), Nina Rautio (post-doctoral researcher, gerontologist), Jani Moilanen (psychiatric resident), Annika Seppälä (doctoral student), Teija Juola (project researcher), Zsolt Szabolcs Unoka (psychiatrist, psychotherapist), István Bitter (psychiatrist), Kata Fazekas (psychologist), Kinga Farkas (psychiatrist), Alena Samsonova (consultant), Anna Triantafillou (project senior manager), Panagiotis Kokkinakis (software engineer), Garifalia Sebú (project director), Shenja van der Graaf (user research), Tanguy Coenen (designer/developer), Wouter Vandenbosch (designer/developer), Johanna Caro (researcher/epidemiologist), Vincenzo Vella (researcher/economist), Cari Almazán (e-health unit manager), Enrico d'Amico (CEO), María Bugheroni (R&D director), Ilaria de Vita (international projects director), Vittorio Tauro (application development administrator), Chiara Bonizzi (chief of technical projects), Walter Baccinelli (researcher), Valentina Simonetti (researcher), Gregoris Mentzas (professor), Fotis Paraskevopoulos (researcher).
*** Both authors contributed equally to this study and should be considered co-final authors

Background. Despite the theoretical potential of m-health solutions in the treatment of patients with schizophrenia, there remains a lack of technological solutions in daily practice. The aim of this study was to measure the receptivity of patients, informal carers, and clinicians to an integral intervention model focused on patients with persistent positive symptoms: Mobile Therapeutic Attention for Patients with Treatment Resistant Schizophrenia (m-RESIST).

Methods. A qualitative study of the needs and acceptability of outpatients with treatment-resistant schizophrenia was carried out in Parc Sanitari Sant Joan de Déu (Barcelona). We analyzed the opinions of patients, informal carers, and clinicians concerning the services initially thought to be part of the solution. Five focus groups and eight interviews were carried out, using discourse analysis as the analytical approach.

Results. A webpage and a virtual forum were perceived as suitable to get reliable information on both the disease and support. Data transmission service, online visits, and instant messages were evaluated as ways to improve contact with clinicians. Alerts were appreciated as reminders of daily tasks and medical appointments. Avoiding stressful situations for outpatients, promoting an active role in the management of the disease, and maintaining human contact with clinicians were the main suggestions for improving the effectiveness of the solution.

Conclusions. Positive acceptance of m-RESIST services is related to its usefulness in meeting user needs, its capacity to empower them, and the possibility of maintaining human contact.

Keywords: m-health, Treatment-resistant Schizophrenia, Integral Intervention Model, Qualitative Study, Users' Needs

Correspondence:
Judith Usall
Parc Sanitari Sant Joan de Déu
C/Doctor Antoni Pujadas, 42
08830 Sant Boi de Llobregat (Spain)
Tel.: 0034 936406350
E-mail: jusall@pssjd.org

Elena Huerta-Ramos, et al.

m-RESIST, a complete m-Health solution for patients with treatment-resistant schizophrenia: a qualitative study of user needs and acceptability in the Barcelona metropolitan area

m-RESIST, una solución m-Health integral para personas con Esquizofrenia Resistente: estudio cualitativo de necesidades y aceptabilidad de usuarios en el área de Barcelona

Introducción. A pesar del creciente potencial teórico de las soluciones m-Health en el tratamiento de pacientes con esquizofrenia, siguen faltando soluciones tecnológicas a nivel práctico. El objetivo de este estudio fue medir las necesidades y aceptabilidad de pacientes, familiares y profesionales hacia un modelo m-Health de intervención integral: Salud Móvil para pacientes con esquizofrenia resistente al tratamiento (m-RESIST).

Métodos. Se llevó a cabo un estudio cualitativo en el Parc Sanitari Sant Joan de Déu (Barcelona) de las necesidades y aceptabilidad de pacientes con esquizofrenia resistente. Se analizaron sus opiniones, junto con las de familiares y profesionales, relativas a los servicios inicialmente pensados para formar parte del m-RESIST. Se realizaron cinco grupos focales y ocho entrevistas, usando el análisis del discurso como aproximación analítica.

Resultados. Se consideró adecuada la creación de una página web y un foro virtual para obtener información fiable sobre la enfermedad y como apoyo entre usuarios. Para mejorar el contacto con los profesionales, se valoró positivamente el servicio de transmisión de datos, visitas "*online*" y mensajes instantáneos. Las alertas fueron consideradas útiles como recordatorios de tareas diarias y citas médicas. Las principales sugerencias para mejorar la eficacia fueron: evitar el exceso de alertas para no generar estrés, promover un papel activo del paciente en el manejo de la enfermedad y mantener contacto personal con los profesionales.

Conclusiones. La buena aceptabilidad hacia el m-RESIST se relaciona con su utilidad para satisfacer las necesidades del usuario, su capacidad para empoderarles y la posibilidad de mantener contacto humano.

Palabras clave: m-Health, Esquizofrenia Resistente, Intervención Integral, Estudio Cualitativo, Necesidades de Usuarios

INTRODUCTION

In the European Union (UE), approximately 5 million people (0.2-2.6%) suffer from psychotic disorders[1]. Of these disorders, schizophrenia is the most common sub-group. Up to 30-50% of patients present treatment-resistant schizophrenia (TRS)[2,3]. Standard intervention is complex due to the presence of persistent positive symptoms, extended periods of hospitalization, and increased risk of morbidity. This scenario generates a high level of suffering for both patients and their family members, and a heavy financial burden for the healthcare system[4,5].

Study of the needs of these patients is warranted in order to better understand their psychosocial functioning and to develop rehabilitation objectives so as to offer them improved attention[6]. According to the published literature, the needs most commonly identified by patients include a reduction of psychotic symptoms and psychological distress, development of daily routines and interests, maintaining of social contact, and obtaining information about the illness and its treatment[7,8]. This diversity of needs is similar to that expressed by family members of patients and professionals[9,10], with some variation from country to country owing to differences in the healthcare systems and the cultural milieu[11,12].

At present it is hard to cover the needs put forward by patients due to the overload of the healthcare system, limited access to certain professionals, and difficulties in adhering to the treatment for this pathology[13]. Nevertheless, in the last decade there has been an increase in m-Health, which may serve to resolve this situation[14].

The concept of m-Health encompasses the practice of medicine and public health with the support of electronic devices such as mobile phones, patient monitoring devices, and other wireless devices[15], with the aim of achieving more rapid detection of symptoms, better adherence to treatment, and improved follow-up of the patient's state, among other goals.

The literature is scant on the needs of patients with psychotic disorders, the acceptability of these new technologies, and the ways they may be used to help in the intervention process.

A study by Lal (2015) analyzed the receptiveness of young people with a first psychotic episode toward the use of new technologies as an integral part of healthcare attention. The conclusion was that they could be useful to deal with the need for access to information about the illness, medication, education, and employment. They were also seen as useful to improve self-management of symptoms and to provide reminders of medical appointments[16]. Regarding their acceptability, a meta-analysis in 2016 (Berry) of people with serious mental health problems addressed the differences between hypothetical acceptability and real acceptability. It found the latter to be greater following the experience of patients with interventions via mobile phone[17].

Recently, a number of m-Health applications were designed in order to meet some of the needs mentioned above. These solutions tend to focus on three areas of intervention:

Elena Huerta-Ramos, et al.

m-RESIST, a complete m-Health solution for patients with treatment-resistant schizophrenia: a qualitative study of user needs and acceptability in the Barcelona metropolitan area

psycho-education, monitoring of symptoms, and self-management of the illness[18-22]. The psycho-educational interventions have been used to offer information about the illness and training to patients via the internet[23]. The monitoring of symptoms and improved self-management are helpful in bettering adherence to medication, providing information and feedback on the state of patient health, and improving the efficacy of psychological treatment such as cognitive-behavioral therapy[24,25].

In spite of the theoretical effectiveness of these applications, the technological models that include TRS in an integral fashion are few. There are several explanations for this: the skepticism of professionals concerning the capacity of patients to adhere to a research protocol, the reticence of the patients when it comes to being monitored[26,27], the possible presence of cognitive deficits[19], and the relative unwillingness of the most chronic patients to participate in an intervention with mobile devices[18]. Currently of note are the FOCUS[27] and MATS[18] programs, although their efficacy has yet to be put to the test. Nor have applications been developed that include family members and professionals in the orbit of patients with schizophrenia; they might be in a position to contribute to improved illness management and patient well-being[28].

With the goal of improving the quality of care, an m-Health solution is being set up, within the framework of the program of Research and Innovation of the UE, Horizon 2020. Known as Salud Móvil [Mobile Health], it is designed for patients with treatment-resistant schizophrenia under the aegis of m-RESIST, and is led by the Hospital de la Santa Creu i Sant Pau, in Barcelona. This innovative project has the aim of promoting empowerment, individualizing treatment through the integration of pharmacological and psychosocial focuses, and improving understanding of the illness using real-time predictive models with the patient. A consortium of 12 public and private sector entities has been established, including clinical and technological institutions, in order to create a system based on electronic devices. The program will serve patients, family members, and professionals, and will include the following functions: monitoring, clinical and psychological assessment, therapeutic intervention, psycho-education, and the bases for a predictive model for relapses. Unlike other applications that focus on a single domain (psycho-educational, monitoring, or self-management), m-RESIST is a model of integrated intervention that covers all these areas. m-RESIST is the only telepsychiatric project in the world aimed at patients with resistant schizophrenia.

In this line, in 2015, a study was carried out in a number of countries (Israel, Hungary, and Spain) with the aim of identifying the needs, preferences, and acceptance of patients with TRS in regards to m-Health interventions in general, and specifically to the m-RESIST program[29]. The results were positive, summarizing the overall consensus among the three countries.

As noted above, there are clear differences among the healthcare systems, and indeed the cultures, of different countries. Given that there were no data on these questions on the national level, the present study aimed to specifically develop the opinions and points of view arising from the users' group in the Barcelona area. Subsequently the tool will be tested in terms of its usability at the Hospital de la Santa Creu i Sant Pau in Barcelona as well as in other countries involved in the project.

MATERIAL AND METHODS

With the objective of involving potential users in the design of m-RESIST, a qualitative study was carried out prior to the development and implementation of the program on the needs and preferences of out-patients with TRS. The study was carried out at the Parc Sanitari Sant Joan de Déu (PSSJD), in Barcelona, Spain, from March to June, 2015.

PSSJD was previously a dedicated psychiatric institution. In 2010 it became part of a general hospital. In terms of new technologies, PSSJD has implemented quite a few, including the use of digitized clinical records and the possibility of videoconferences among professionals. In addition, it has taken part in three research projects related to telemedicine, among them m-RESIST.

Study participants

In the sample were included out-patients with TRS, family members with the role of main carer, and mental health professionals.

The inclusion criteria, both those in common for all participants and those specific to each profile, are shown in Table 1. The criteria for the patients, as well as those for their family members, were established through a brief screening process by the referring psychiatrist. For evaluation of the criteria for resistance to treatment the Positive and Negative Symptoms Scale (PANSS) was administered. Two exclusion criteria were established for the patients: having intellectual incapacity and being hospitalized in an acute care unit.

TRS was defined as the prescription of an appropriate antipsychotic treatment without response (not meeting the remission criteria of Andreasen based on the PANSS)[30].

Primary resistant patients are defined as those with auditory hallucinations and/or persistent delirium who have not responded to treatment under three appropriate anti-

Elena Huerta-Ramos, et al.

m-RESIST, a complete m-Health solution for patients with treatment-resistant schizophrenia:
a qualitative study of user needs and acceptability in the Barcelona metropolitan area

Table 1	Specific and common inclusion criteria			
Common inclusion criteria for all the participants				
18 or older			Basic familiarity with new technologies	
Specific inclusion criteria for clinicians				
Profession: psychiatry, psychology, social work, nursing, and case management for the individualized support program			A minimum of 5 years' experience in the treatment of patients with TRS	
Specific inclusion criteria for informal carers				
Family members: parents, siblings, and friends			Main responsibility for patient care	
Specific inclusion criteria for out-patients				
Under 45 years old	Diagnosed with schizophrenia according to DSM-IV-TR	A maximum of 15 years' progression of the illness	More than 6 months since the TRS diagnosis	Positive symptoms ≥4 (at least moderately ill), according to the Global Clinical Impression Scale (GCI)[43]

psychotic pharmaceutical sets of guidelines for a minimum of one year from the initial visit[31]. Appropriate guidelines are defined by two criteria:

a) Appropriate trials of two different antipsychotic medications (other than clozapine) belonging to a different class, for a period of at least 12 weeks, and at least 500 mg/day of chlorpromazine in the five previous years.

b) A trial of clozapine for at least 12 weeks at a dose of at least 400 mg (or a level of clozapine of at least 350 ng/mL).

Also included were patients with persistent psychotic symptoms ('pseudoresistant') for the following reasons: poor adherence, drug abuse, poor vision, tendency to isolation, low involvement of carers in the therapeutic process, or not choosing treatment programs[32].

The selection of participants was carried out using non-random intentional sampling with the aim of obtaining the maximum amount of information. All of the participants were required to be fluent in Spanish in order to guarantee a registry with all needs and opinions duly recorded.

The patients and their family members were referred to the research teams by their psychiatrists. Once the patients and their family members had verbally accepted being participants in the study, their contact information was provided to the personal researcher in order to schedule an interview. The professionals' group was contacted directly by the research team. Before starting with the focus groups and interviews, all participants were requested to provide their written informed consent, after which the nature of the study was explained to them. All participants were required to provide consent for the audio recording of the sessions, and to indicate their willingness to help clarify any problems in the transcription if necessary.

The study was in compliance with the Helsinki Declaration[33] and was approved by the ethics committee of PSSJD.

Procedure

A total of 5 discussion groups -2 with professionals, 2 with patients, and 1 with family members- were formed.

In addition, 8 individual interviews were held -4 with patients and 4 with family members- with the aim of examining questions that had not been sufficiently discussed in the focus groups. This number was needed to reach the point of theoretical saturation.

Owing to the importance of age in the use of information and communication technologies (ICTs), the group of patients with TRS was divided up according to age, with a young patients' group made up of those 18-29, and an older patients' group made up of those aged 30-45. An effort was made to maintain the same ratio of the sexes in the two groups. The family members' group, made up of the main carers, consisted entirely of women, as it is the women who generally assume this role[34]. Nevertheless, owing to the growing importance of men as carers, four individual interviews were carried out with men.

Both the focus group sessions and the interviews were held in a meeting room, at some remove from the area of

Elena Huerta-Ramos, et al.

m-RESIST, a complete m-Health solution for patients with treatment-resistant schizophrenia: a qualitative study of user needs and acceptability in the Barcelona metropolitan area

the hospital where patients are treated, in order to have a more neutral environment. The average length of the sessions was 120 minutes for the focus groups and 60 minutes for the interviews. The participants were asked questions about various subjects, which were organized into the following blocks:

1. Daily necessities of the patients, as identified by them, their family members, and the professionals, and opinions about how they were treated by the healthcare system.

2. Receptiveness toward m-Health solutions and how these might help meet the identified needs.

3. Opinions and suggestions about the solutions contemplated in m-RESIST.

There was a semi-structured set of guidelines with which the moderators checked off the basic topics that emerged in each block. All of the data were recorded and then transcribed for subsequent analysis.

Research team

The focus groups were handled by a moderator and a coordinator. The former, responsible for putting forward the topics and guiding the conversation, was a psychologist with more than five years' experience in qualitative techniques. The latter, a sociologist with more than ten years' experience, was responsible for welcoming the participants, taking notes, recording the conversations, distributing the questionnaires among the participants, and determining when the theoretical saturation point for information had been reached. In addition, both professionals acted as interviewers when needed.

There was no pre-existing relationship between the research team and the participants in the patients' and family members' groups. The researchers had no direct working relationship with any members of the professionals' group, although the moderator had previously collaborated on one occasion with four of them.

Theoretical framework

The study was based on the principle of discourse analysis. This analytical approach holds that there is much more at play when people communicate as equals than the mere exchange of information, and that this communication goes well beyond literal meanings and includes information that emanates from the influence of society and culture.

In this line, the use of language was studied in spontaneous discourse, following a number of sentences, which

involves the interaction of the speaker and the listener in a specific situational context, here mainly interviews and focus groups. The linguistic material obtained is defined as 'performance data' and may include hesitations, clichés and non-conventional forms such as colloquial expressions[35]. Considering these forms of expression is essential in the study of opinions and attitudes of patients with schizophrenia, given that they tend to display a lack of verbal fluency in their discourse.

RESULTS

Participants

Table 2 shows the characteristics of the study participants. In the patients' group there were 6 women and 8 men, of whom 57% had a basic level of education, and with a heterogeneous level of ability to use the ICT devices; 43% used them to communicate with professionals. In the family members' group there were 5 women and 4 men; 55% had an average educational level. The level of ability in using the ICT devices was predominantly average, although only 11% used the devices to communicate with professionals.

In the professionals' group, there were 8 women and 5 men, with different professional specializations. The average length of experience with TRS was 15 years, the ability to use ICT devices was average on the whole, and 46% used the devices to communicate with patients.

Evaluation of receptiveness to the services/ applications of m-RESIST

In this study we focused on the needs that m-RESIST attempts to address through the following intervention modules: psycho-education, monitoring, treatment, and illness self-management (Table 3).

Psycho-education: website and virtual forum

Regarding healthcare, the main needs of both patients and their families were greater information about the treatments, the side effects of the medication, and the symptoms. This was the main reason why we thought it helpful to have a website specialized in TRS (cf. Additional Material, excerpt 1).

The family members requested specific information be provided them with tools for managing day-to-day situations, such as how to respond when the patient refuses medication, how to manage isolation, and so on.

Elena Huerta-Ramos, et al.

m-RESIST, a complete m-Health solution for patients with treatment-resistant schizophrenia:
a qualitative study of user needs and acceptability in the Barcelona metropolitan area

Table 2	Characteristics of the participants in the interviews and in the focus groups of patients, family members, and professionals

Patients

	Age	Sex	Education level	Level of ICT use*	ICT use with professionals**
P1	18	Female	Basic	Basic	No
P2	27	Female	Basic	Average	Yes
P3	28	Male	Basic	Average	No
P4	26	Male	Basic	Good	Yes
P5	28	Male	Mid-level	Average	No
P6	22	Female	Mid-level	Average	No
P7	43	Male	Mid-level	Basic	Yes
P8	45	Male	Basic	Basic	Yes
P9	34	Male	Basic	Average	No
P10	35	Male	Basic	Basic	Yes
P11	32	Female	Basic	Basic	Yes
P12	38	Male	University	Excellent	No
P13	41	Female	Mid-level	Scant	No
P14	44	Female	Mid-level	Basic	No

Family members

	Age	Sex	Education level	Level of ICT use*	ICT use with professionals**
F1	52	Male	Basic	Basic	Yes
F2	56	Female	Mid-level	Average	No
F3	48	Female	University	Average	No
F4	71	Female	Mid-level	Average	No
F5	51	Female	Mid-level	Average	No
F6	47	Female	Mid-level	Good	No
F7	56	Male	University	Good	No
F8	52	Male	University	Average	No
F9	70	Male	Mid-level	Scant	No

Professionals

	Age	Sex	Education level	Level of ICT use*	ICT use with professionals**	Experience with TRS (years)
PF1	41	Male	Case management	Average	Yes	18
PF 2	36	Female	Case management	Good	Yes	12
PF 3	40	Male	Case management	Good	Yes	19
PF 4	41	Female	Nursing	Average	Yes	22
PF 5	49	Male	Social work	Good	No	8

Table 2	Continuation					
Professionals						
	Age	Sex	Education level	Level of ICT use*	ICT use with professionals**	Experience with TRS (years)
PF 6	37	Female	Social work	Average	No	14
PF 7	32	Female	Psychiatry	Average	No	6
PF 8	46	Female	Psychiatry	Average	No	22
PF 9	35	Male	Psychiatry	Good	Yes	10
PF 10	47	Female	Psychology	Average	No	15
PF 11	36	Female	Psychiatry	Average	No	12
PF 12	48	Female	Psychology	Good	Yes	20
PF 13	57	Male	Psychology	Basic	No	20

*ICT is an abbreviation of information and communication technologies. Questionnaire self-evaluated by the individual using an *ad hoc* scale. ** Use of ICT was determined by instant messaging, email, or on-line visits.

Table 3	Relation between perceived needs and m-RESIST services	
AREA	**NEEDS**	**m-RESIST SERVICE**
Personal care	Getting out of bed	Mobile alert
	Daily hygiene	
Illness management	Taking medication	Mobile alert
	Visit reminders	
Medical attention	Appropriate follow-up	On-line visits, data transmission, and instant messaging
	Additional information	Website
Social environment	Company	Virtual forum
	Mutual support	

Both patients and professionals pointed out the lack of a social network providing company and emotional support to meet one of the main needs of patients. This would explain the broad acceptance of a virtual space designed to promote contact among patients.

The patients, in turn, perceived this as an opportunity to feel useful helping others with the same illness; they felt that those recently diagnosed could receive welcome support from patients with greater experience (excerpt 2).

Despite the potential usefulness of the internet in meeting this need, most patients and family members were reticent about sharing personal information.

The need for information expressed by the patients, as well as their desire to increase contact with other people with TRS, demonstrates the potential to play a more active role in the management of the illness.

Monitoring: data transmission

Within the field of healthcare, key complaints that emerged from all three profile groups included the lack of immediacy and continuity in attention as well as the wish for longer visits.

The implementation of a data transmission service by means of an intelligent clock, able to store and transmit physiological patterns to patients and professionals, could help to satisfy this need (excerpt 3).

The three participant profile groups consider this to be appropriate. As the patients have to introduce data automatically, it is seen as less invasive. The chance for follow-up of physical activity, sleep patterns, and medicine-taking are viewed as especially positive (excerpt 4).

Elena Huerta-Ramos, et al.

m-RESIST, a complete m-Health solution for patients with treatment-resistant schizophrenia:
a qualitative study of user needs and acceptability in the Barcelona metropolitan area

Most patients feel that the exchange of data with family members would be useful (excerpt 5). Nonetheless, this would require written approval by the patients be given to the clinical personnel prior to participation.

Clinical treatment: online visits and instant messaging

For patients, online visits and instant messaging are the two services viewed most favorably in order to increase contact with professionals.

Two different observations regarding online visits were made in relation to the age of the patients. For the young patients, more accustomed to new technology, these visits were seen as a chance to have greater contact with the psychiatrist (excerpt 6). For the older patients, these visits were seen as appropriate only in situations in which it was difficult for the patient to keep a face-to-face appointment.

Instant messaging, on the other hand, was viewed very positively by patients in both the younger and the older group (seen as especially helpful at the time of discharge from hospital) and by the professionals (as a means of increasing contact with their patients) (excerpt 7).

To sum up, the three participant profiles felt that having greater contact between them was the main advantage of m-RESIST.

Task self-management: alerts

The possibility of alerts on the mobile was well received by patients and their family members, but the professionals were more reticent, suspecting that it might lead to patients' becoming more passive.

The patients thought it particularly important to record their taking their medication, as well as the date of the next doctor's appointment. The opportunity to share these alerts with their family members (especially mothers) was also well received (excerpt 8). The family members, in turn, saw it very helpful for the patients to be reminded to take their medication, as they are the ones primarily responsible for the supervision of this task.

To sum up, the importance of taking medication, as a crucial part of treatment and a component in self-management of the illness, contributed to broad acceptance of alerts among both the patients and their family members.

Suggestions for improvement

The participants expressed some concerns in the focus groups and interviews; they also offered some solutions for their concerns.

The main risk foreseen was that some of the services and/or applications of m-RESIST might encourage a passive role on the part of the patients. This was particularly the case with the data transmission service, mobile alerts, and online visits.

Individualized data transmission service

The clinicians were particularly worried by this risk (excerpt 9). They suggested adapting this service to the individual needs of each patient, and its application only to those least capable of monitoring their illness and most reluctant to share information about their symptoms with their doctors. In addition, they highlighted the need to periodically confirm acceptance of the service with patients over time.

Regarding smart watches, the possibility of using them would be subject to certain time restrictions; furthermore, it would be up to the patients to decide which alerts and what information should be sent to the professionals.

Flexible number of mobile alerts

For the professionals, it is essential to avoid situations that might be stressful to the patients. Therefore, it is important to determine the correct number of alerts. Both groups stressed this idea (especially the case managers), given their prior experience with the use of alerts (excerpt 10).

Given that alerts are not appropriate for all patients, professionals need to be able to determine those patients who are best suited for the service (for example, only those taking certain medications) and also the number of alerts to be sent (no more than twice a day), bearing in mind that patients can change in terms of the need to keep receiving these reminders.

Alternation of online and face-to-face visits

The greatest reticence was found in the professionals' group, which saw fit to mention that online visits were to be seen as a complement to face-to-face visits. To this end, they would like to be able to recommend when the online visits could be used as an alternative, and they focused on those patients who have problems keeping regular appointments and those who are most reluctant to visit the doctor (excerpt 11).

This idea is shared with patients and family members, who feel that online visits are fine as a means to increase contact between patients and professionals, but they are not to be a substitute for medical visits.

Elena Huerta-Ramos, et al.

m-RESIST, a complete m-Health solution for patients with treatment-resistant schizophrenia: a qualitative study of user needs and acceptability in the Barcelona metropolitan area

DISCUSSION

Despite the theoretical usefulness of new technologies in mental health, to date only a limited number of solutions have been put forward[27,36]. The currently existing tools tend to focus on a specific area of intervention, mainly in the field of psycho-education[19], or on improvement to adherence to medication by means of alert systems[24,37]. The few interventions that are being implemented in a comprehensive way[18,27] continue to overlook aspects as essential as cognitive-behavioral therapy and work with families and professionals. Furthermore, there are as yet no studies evaluating the efficacy of existing programs. As a consequence, today there is no global intervention model articulating the different areas of attention in this group.

Our study provides results concerning the need for and acceptance by TRS patients of new technologies for their treatment—specifically, the services included in the m-RESIST solution. These include online visits, instant messaging, data transmission, alerts, and psycho-education. Although there is a bit of reticence on the part of professionals, the patients' and family members' groups showed broad acceptance of this solution. This is attributable, in large measure, to the capacity of m-RESIST to satisfy the most relevant needs in the lives of the patients[7,9] and to empower them in the management of their illness and daily lives[38,39].

In the case of our study, this acceptability remains hypothetical, until the pilot project is implemented. If the project results are in line with what was put forward by Berry[17], the real acceptability will be greater following the experience of users with this tool.

Nevertheless, given the results obtained, it is important to modify the initial focus of some of the services included in m-RESIST. In the case of data transmission, users indicated the importance of being able to personalize the service in accordance with their capacity to self-manage the illness. Mobile alerts should also be implemented for those patients who in general tend to forget to take their medication or turn up for medical appointments. The number and frequency of the alerts should be agreed upon previously by the patients, as was determined in prior studies[18]. As to online visits, the importance of human contact in the treatment of TRS provides an explanation for the proposal by users that online visits be combined with face-to-face visits.

This study is the first in our country to examine the needs and preferences of patients with TRS, their family members, and professionals with regard to m-Health. However, further studies are needed of the viewpoint of the users, with a greater number of participants and with attention paid to the effects of gender and age[8,40-42]. The reluctance of some professionals to use technological solutions in the treatment of patients with TRS, as noted by Ben-Zeev in earlier studies[26,27], must be considered in the context of future implementations of m-Health treatment; specific training for professionals in this area would be useful. This implies the need to demonstrate to them the advantages of the technology in their daily work, as a means to encourage them to become active users.

Elena Huerta-Ramos, et al.

m-RESIST, a complete m-Health solution for patients with treatment-resistant schizophrenia: a qualitative study of user needs and acceptability in the Barcelona metropolitan area

ADDITIONAL MATERIAL	
Below are several excerpts from the users that are referred to in the text in relation to the topics of the interviews and focus groups	
Psychoeducation: website and virtual forum	**Excerpt 1. Young patients' group** *P1[1]: Information about what schizophrenia is, the medication you are taking…* *P2: Yes, I agree.* *COO[2]: Pardon?* *P1: Yes, the most appropriate medication for you.* *MOD[3]: What else would you like to include?* *P2: the most important thing is … it has to be a secure website … because people get confused and some people include incorrect information…* [1] In the conversations among participants, P is for 'participant'. Numbers are used to distinguish among subsequent participants. [2] Abbreviation for coordinator. [3] Abbreviation for moderator.
	Excerpt 2. Older patients' group *P11: I would like it… for example, talking about the paranoias that I have had … maybe other people have had the same paranoias… I don't know.* *P8: Fine, I think that … basing yourself on the experience that you had… advice is much better when it comes from someone who has been in the same situation. You can say, "Hey, take it easy, do this or that bearing in mind what the other person has gone through …*
Monitoring: Data transmission	**Excerpt 3. Families' group** *F1[4]: The clock could be just the thing for my kid, in case it detects a destabilizing of his heart rate … He spends all day in the house with his computer watching videoclips …* [4] Abbreviation for family member.
	Excerpt 4. Young patients' group *P3: Could be good.* *P4: You have to keep an eye on how long you sleep, your activity level, and everything …* *P3: Watching how long you sleep, the passing of time, and the day when only the clock is necessary …* *P4: The medication at that time.* *MOD: That's all.*
	Excerpt 5. Older patients' group *MOD: Who would you want to share an alarm of this kind with?* *P7: With my mother.* *P8: With my mother, too.* *P9: With nobody.* *P10: In my case … with my mother.* *P11: With my wife.*

Elena Huerta-Ramos, et al.

m-RESIST, a complete m-Health solution for patients with treatment-resistant schizophrenia: a qualitative study of user needs and acceptability in the Barcelona metropolitan area

ADDITIONAL MATERIAL	
Clinical treatment: Online and instant messaging	**Excerpt 6. Young patients' group** *MOD: And … Would you like to have more contact with a specific professional—a nurse, a psychologist, a psychiatrist, a case manager?* *P3: Sure! With my psychiatrist. Why not? But when?* *MOD: When you're at home, for example.* *P3: To talk about your concerns and things like that?* *MOD: For example, if you think it would be helpful to reduce the time between visits.* *P3: Absolutely! More frequent visits!*
	Excerpt 7. Professionals' group *PF1[5]: We always use telephone calls, but there are times when you are too busy to answer the phone, so now we use WhatsApp if we think we can evaluate the situation that way … and if someone has a problem, we call the patients, and if we feel from the message that there is a significant worsening in their condition, then we visit them. So there are different procedures to follow.* *PF2: In my case, since WhatsApp appeared, the number of calls has gone down dramatically. You can handle things using WhatsApp and it's more comfortable for the patients. It's a faster way to look after their needs …* [5] Abbreviation for professional
Self-management of tasks: alerts	**Excerpt 8. Young patients' group** *P4: I'd like to share them with other people, in case something happens to me …* *MOD: Who would you like to share them with?* *P4: I don't know. With my father, my mother … even my brother.* *MOD: So, if you had a visit and received an alert, would you want your mother to receive one as well?* *P4: Yes.* *P3: My father … I wouldn't want to share it with my father … maybe my grandmother, because my father is rude.* *COO: Your grandmother?* *P3: Yeah, my grandmother.* *COO: And you?* *P2: My mother.* *P1: Yeah, my mother.*
Suggestion for improvement: Individualized service for data transmission	**Excerpt 9. Professionals' group** *PF1: I feel the problem is a lack of autonomy. That is, the individual needs to be able to decide … Why does every decision of patients have to be controlled? I mean, it is irrelevant to us, as clinicians, and it might even be counterproductive, to have more information than the patients want to give us.*

Elena Huerta-Ramos, et al.

m-RESIST, a complete m-Health solution for patients with treatment-resistant schizophrenia: a qualitative study of user needs and acceptability in the Barcelona metropolitan area

ADDITIONAL MATERIAL

Suggestions for improvement: Flexible number of alerts	**Excerpt 10. Professionals' group** *PF4: I feel that.... in the case of patients who say "I often forget to take my medication" or "Yeah, so, can I note it on my mobile or set an alarm, OK"? on following visits, they often tell me "I deactivated the alarm because it was buzzing all day. It drove me nuts." So as a professional you have to find another strategy to make patients associate medication with their daily habits. Because in the end an alarm is stressful, isn't it?* *MOD: Yes …* *PF4: Obviously … three or four alarms a day … if the patients have to take a lot of pills … My patients stopped using alerts …* *PF1: Yes, it's like we said earlier … the question of autonomy.*
	Excerpt 11. Professionals' group *PF9: From my point of view it's a bit risky … You could replace the face-to-face sessions. It seems risky. Maybe some patients, with very negative symptoms, might think "Why do I have to go see the doctor if I can talk with him by webcam?"* *PF1: In my opinion, it might be helpful at times, but never as a replacement.* *COO: A complement.* *PF1: Exactly! It's a great idea as a complement!* *COO: And what about the rest?* *PF13: I feel it should be in addition.* *PF7: Yes, yes.* *PF13: And used to bolster the link [between patients and clinicians], because for more reluctant patients … a webcam might be helpful to prevent missing appointments … or phone calls at specific times, if there's a problem with making the visit. And maybe these visits will make it easier. But not exclusively …*

REFERENCES

1. Wittchen HU, Jacobi F, Rehm J, Gustavsson A, Svensson M, Jönsson B, et al. The size and burden of mental disorders and other disorders of the brain in Europe 2010. Eur Neuropsychopharmacol. 2011;21:655-79.

2. Essock SM, Hargreaves WA, Dohm FA, Goethe J, Carver L, Hipshman L. Clozapine eligibility among state hospital patients. Schizophr Bull. 1996;22:15–25.

3. Juarez-Reyes MG, Shumway M, Battle C, Bacchetti P, Hansen MS, Hargreaves WA. Effects of stringent criteria on eligibility for clozapine among public mental health clients. Psychiat Serv. 1995;46:801–6.

4. Kennedy JL, Altar CA, Taylor DL, Degtiar I, Hornberger JC. The social and economic burden of treatment-resistant schizophrenia: a systematic literature review. Int Clin Psychopharmacol. 2014;29:63–76.

5. Olesen J, Gustavsson A, Svensson M, Wittchen, HU, Jönsson B. The economic cost of brain disorders in Europe. Eur J Neurol. 2012;19:155–62.

6. Gandotra S, Paul SE, Daniel M, Kumar K, Raj HA, Sujeetha B. A Preliminary Study of Rehabilitation Needs of In-patients and Out-patients with Schizophrenia. Indian J Psychiatry. 2004; 46:244–55.

7. Ochoa S, Haro JM, Autonell J, Pendàs A, Teba F, Màrquez M; NEDES Group. Met and unmet needs of schizophrenia patients in a Spanish sample. Schizophr Bull. 2003;29:201–10.

8. Hansson L, Björkman T, Svensson, B. The assessment of needs in psychiatric patients. Interrater reliability of the Swedish version of the Camberwell Assessment of Needs instrument and results from a cross-sectional study. Acta Psychiatr Scand. 1995;92:285–93.

9. Grover S, Avasthi A, Shah S, Lakdawala B, Chakraborty K, Nebhinani N, et al. Indian Psychiatric Society multicentric study on assessment of health-care needs of patients with severe mental illnesses as perceived by their family caregivers and health-care providers. Indian J Psychiatry. 2015;57:181–9.

10. Ochoa S, Vilaplana M, Haro JM, Villalta-Gil V, Martínez F, Negredo MC, et al. Do needs, symptoms or disability of outpatients with schizophrenia influence family burden? Soc Psychiatry Psychiatr Epidemiol. 2008;43:612–8.

11. Hansson L, Vinding HR, Mackeprang T, Sourander A, Werdelin G, Bengtsson-Tops A, et al. Comparison of key worker and patient assessment of needs in schizophrenic patients living in the community: a Nordic multicentre study. Acta Psychiatr Scand. 2001;103:45–51.

12. Mulder CL, Ruud T, Bahler M, Kroon H, Priebe S. The availability and quality across Europe of outpatient care for difficult-to-engage patients with severe mental illness: a survey among experts. Int J Soc Psychiatry. 2014;60:304–10.

13. Instituto de Mayores y Servicios Sociales. Modelo de atención a las personas con enfermedad mental grave. 2007.

14. Coffey MJ, Coffey CE. The emerging story of emerging technologies in neuropsychiatry. Dialogues Clin Neurosci. 2016; 18:127–34.

15. World Health Organization. mHealth: New horizons for health through mobile technologies. Observatory. 2011;3:112.

16. Lal S, Dell'Elce J, Tucci N, Fuhrer R, Tamblyn R, Malla A. Preferences of Young Adults With First-Episode Psychosis for Receiving Specialized Mental Health Services Using Technology: A Survey Study. JMIR Ment Heal. 2015;2:e18.

17. Berry N, Lobban F, Emsley R, Bucci S. Acceptability of Interventions Delivered Online and Through Mobile Phones for People Who Experience Severe Mental Health Problems: A

Elena Huerta-Ramos, et al.

m-RESIST, a complete m-Health solution for patients with treatment-resistant schizophrenia:
a qualitative study of user needs and acceptability in the Barcelona metropolitan area

Systematic Review. J Med. Internet Res. 2016;18.

18. Granholm E, Ben-Zeev D, Link PC, Bradshaw KR, Holden JL. Mobile Assessment and Treatment for Schizophrenia (MATS): a pilot trial of an interactive text-messaging intervention for medication adherence, socialization, and auditory hallucinations. Schizophr Bull. 2012;38:414–25.

19. Rotondi AJ, Sinkule J, Haas GL, Spring MB, Litschge CM, Newhill CE, et al. Designing websites for persons with cognitive deficits: Design and usability of a psychoeducational intervention for persons with severe mental illness. Psychol Serv. 2007;4:202–24.

20. Ainsworth J, Palmier-Claus JE, Machin M, Barrowclough C, Dunn G, Rogers A, et al. A comparison of two delivery modalities of a mobile phone-based assessment for serious mental illness: native smartphone application vs text-messaging only implementations. J Med Internet Res. 2013;15,e60 .

21. Alvarez-Jimenez M, Alcazar-Corcoles MA, González-Blanch C, Bendall S, McGorry PD, Gleeson JF. Online, social media and mobile technologies for psychosis treatment: a systematic review on novel user-led interventions. Schizophr Res. 2014;156:96–106.

22. Rotondi AJ, Eack SM, Hanusa BH, Spring MB, Haas GL. Critical design elements of e-health applications for users with severe mental illness: singular focus, simple architecture, prominent contents, explicit navigation, and inclusive hyperlinks. Schizophr Bull. 2015;41:440–8.

23. van der Krieke L, Emerencia AC, Boonstra N, Wunderink L, de Jonge P, Sytema S. A web-based tool to support shared decision making for people with a psychotic disorder: randomized controlled trial and process evaluation. J Med Internet Res. 2013; 15:e216.

24. Frangou S, Sachpazidis I, Stassinakis A, Sakas G. Telemonitoring of medication adherence in patients with schizophrenia. Telemed. J E Health. 2005;11:675–83.

25. Daker-White G, Rogers A. What is the potential for social networks and support to enhance future telehealth interventions for people with a diagnosis of schizophrenia: a critical interpretive synthesis. BMC Psychiatry. 2013;13:279.

26. Ben-Zeev D. Mobile technologies in the study, assessment, and treatment of schizophrenia. Schizophr Bull. 2012;38:384–5.

27. Ben-Zeev D, Brenner CJ, Begale M, Duffecy J, Mohr DC, Mueser KT. Feasibility, acceptability, and preliminary efficacy of a smartphone intervention for schizophrenia. Schizophr Bull. 2014; 40:1244–53.

28. Chien WT, Leung SF, Yeung FK, Wong WK. Current approaches to treatments for schizophrenia spectrum disorders, part II: Psychosocial interventions and patient-focused perspectives in psychiatric care. Neuropsychiatric Disease and Treatment. 2013;9:1463–81.

29. Huerta-Ramos E, Escobar-Villegas MS, Rubinstein K, Unoka ZS, Grasa E, Hospedales M, et al. Measuring Users' Receptivity Toward an Integral Intervention Model Based on mHealth Solutions for Patients With Treatment-Resistant Schizophrenia (m-RESIST): A Qualitative Study. JMIR mHealth uHealth. 2016;4,e112.

30. Kay SR, Fiszbein A, Opler LA. The Positive and Negative Syndrome Scale for schizophrenia. Schizophr Bull. 1987;13:261–76.

31. Peuskens J. The evolving definition of treatment resistance. Journal of Clinical Psychiatry. 1999;60:4–8.

32. Elkis H, Meltzer HY. Refractory schizophrenia. Rev Bras Psiquiatr. 2007;29(Suppl 2):S41–S47.

33. JAVA. Declaration of Helsinki World Medical Association Declaration of Helsinki. Bull world Heal Organ. 2013;79:373–4.

34. Thara R, Kamath S. Women and schizophrenia. Indian J Psychiatry. 2015;57:S246–S251.

35. Have P. Ten. Review Essay: Conversation Analysis Versus Other Approaches to Discourse. Forum Qualitative Sozialforschung / Forum: Qualitative Social Research. 2006;7.

36. Chan S, Torous J, Hinton L, Yellowlees P. Towards a Framework for Evaluating Mobile Mental Health Apps. Telemed J E Health. 2015 Dec;21(12):1038–41

37. Spaniel F, Novak T, Bankovska Motlova L, Capkova J, Slovakova A, Trancik P, et al. Psychiatrist's adherence: A new factor in relapse prevention of schizophrenia. A randomized controlled study on relapse control through telemedicine system. J Psychiatr Ment Health Nurs. 2015;22:811–20.

38. Morozova MA, Rupchev GE. Description and validation of a new scale for assessment of autonomy in patients with schizophrenia. Zh Nevrol Psikhiatr Im S S Korsakova. 2015;115(1):53-7.

39. Hamann J, Kohl S, McCabe R, Bühner M, Mendel R, Albus M, et al. What can patients do to facilitate shared decision making? A qualitative study of patients with depression or schizophrenia and psychiatrists. Soc Psychiatry Psychiatr Epidemiol. 2016 Apr;51(4):617-25.

40. Ochoa S, Usall J, Haro JM, Araya S, Autonell J, Busquets E, et al. Comparative study of the needs of patients with schizophrenia by gender. Actas Esp Psiquiatr. 2001;29:165–71.

41. Archer N, Keshavjee K, Demers C, Lee R. Online self-management interventions for chronically ill patients: cognitive impairment and technology issues. Int J Med Inform. 2014;83:264–72.

42. Arvidsson H. Gender differences in needs and care of severely mentally ill persons: findings from a Swedish cross-sectional and longitudinal study. Int J Soc Psychiatry. 2010;56:424–35.

43. Busner J, Targum SD. The clinical global impressions scale: applying a research tool in clinical practice. Psychiatry (Edgmont). 2007;4:28–37.