

A survey of eMedia-delivered interventions for schizophrenia used in randomized controlled trials

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Background: Randomized trials evaluating electronic Media (eMedia) delivery of interventions are increasingly frequent in mental health. Although a number of reviews have reported efficacy of these interventions, none has reviewed the type of eMedia interventions and quality of their description. We therefore decided to conduct a survey of eMedia-delivered interventions for schizophrenia.

Methods: We surveyed all relevant trials reliably identified in the Cochrane Schizophrenia Group's comprehensive register of trials by authors working independently. Data were extracted regarding the size of the trial, interventions, outcomes and how well the intervention was described.

Results: eMedia delivery of interventions is increasingly frequent in trials relevant to the care of people with schizophrenia. The trials varied considerably in sample sizes (mean =123, median =87, range =20–507), and interventions were diverse, rarely evaluating the same approaches and were poorly reported. This makes replication impossible. Outcomes in these studies are limited, have not been noted to be chosen by end users and seem unlikely to be easy to apply in routine care. No study reported on potential adverse effects or cost, end users satisfaction or ease of use. None of the papers mentioned the use of CONSORT eHealth guidelines.

Conclusion: There is a need to improve reporting and testing of psychosocial interventions delivered by eMedia. New trials should comply with CONSORT eHealth guidance on design, conduct and reporting, and existing CONSORT should be updated regularly, as the field is constantly evolving.

Keywords: randomized trials, survey, eMedia, information technology, schizophrenia, methodology

Background

The use of technology to advance psychological treatment is a developing professional reality.¹ The digital revolution has the potential to transform mental health care by connecting patients, services and health data in new ways.² There has been extensive research on the use of electronic Media (eMedia) technologies for a variety of emotional and mental health problems. A number of literature reviews of interventions delivered through eMedia have been published. These include reviews of interventions for anxiety disorders in adults,³ behavior problems in children,⁴ treatment of alcohol-related problems⁵ and patient education and support for people with schizophrenia.⁶

Numerous mobile phone-based telemedicine solutions for remote patient monitoring and disease management in schizophrenia have been tested.⁷ The eMedia-delivered interventions for this population group range from simple telephone reminders to attend follow-up appointments⁸ to complex medication monitoring systems to improve compliance.⁹ The virtual reality (VR) programs are being used to teach people various skills, most notably vocational and the social competencies,^{10,11} but novel approaches have been developed to help people with chronic psychotic symptoms.¹²

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eMedia

eMedia can be defined as the media that use electronics or electromechanical energy for end users (audience) to access content (this is in contrast to static media, mainly print). The eMedia sources most familiar to the general public are video recordings, audio recordings, multimedia presentations, slide presentations, CD-ROM and online content. Most new eMedia are now in a digital Media form (dMedia). Numerous terms are used to describe interventions delivered through dMedia, including mobile health and mobile psychosocial interventions (mPSI) (Table 1).

Reviews in this area address the effects of specific forms of eMedia,^{3,13,14} but we know of no definitive overview of how eMedia has been used and described in a defined group of randomized controlled trials (RCTs). In order to replicate the findings, the interventions should be clearly described. This should involve details of their development and initial testing.¹⁵ The CONSORT guidelines recommend that in reporting of an RCT, the authors should describe each intervention thoroughly, including control interventions. The description should allow a clinician to know exactly how to administer the intervention that was evaluated in the trial. If the control group is to receive treatment-as-usual (TAU), it is imperative to describe thoroughly what that constitutes. If the control group or intervention group is to receive a combination of interventions, these should be thoroughly described.^{16,17}

Recently, attempts have been made to modify the CONSORT guidelines.¹⁸ However, these are not widely used, even though it has been claimed that implementing these might improve the reporting quality of trials in this area.¹⁹ The guidelines need to be continuously updated as our understanding of the issues surrounding eMedia interventions is constantly improving.^{15,20}

By taking an overview of the interventions in a specific area it may be possible to highlight areas that need further development in this new and exciting development in mental health care.

Aims

The aim of this survey was to provide a broad overview of the type of eMedia interventions for all randomized trials relevant to people with schizophrenia. We also wanted to examine whether these interventions are described in details using a criterion (for example, existing CONSORT eHealth checklist). We did not aim to review the effects of these interventions.

Methods

Search methods

Searched source

On January 6, 2015, we searched the Cochrane Schizophrenia Group's Study-Based Register of Trials and updated this search on October 5, 2015. The Cochrane Schizophrenia Group's Register of Trials is kept on Microsoft access-based computer program called MeerKat (version 1.6) and is compiled by systematic searches of major national and international resources (including monthly updates of AMED, BIOSIS, CINAHL, EMBASE, MEDLINE, PsycINFO, PubMed and registries of clinical trials) and their monthly updates, hand-searches, gray literature and conference proceedings (for detailed description of the register see Group's Module). There is no language, date, document type or publication status limitations for the inclusion of records into this register.

Search strategy

We used the following search strategy, which has been developed based on literature review and consulting with the authors of the review:

(*Computer* OR *Internet* OR *Electronic* OR *Media* OR *Phone*) in Intervention Field of STUDY (418 results).

In such a study-based register, searching the major concept retrieves all the synonym keywords and relevant studies because all the studies have already been organized based on their interventions and linked to the relevant topics (Table S1 describes detailed keywords).

Table 1 Overall classification of media to deliver interventions for mental health

Human media	Therapy delivered by human therapists
Print media	Books, journals, magazines, newspapers, workbook, textbooks
Non-print media	1. Projected media: they require a light source for projection (eg, film projector slides) 2. Non-projected media: they do not require light source. They include 3-dimensional objects, 2-dimensional objects, prints, charts, models, etc.
Electronic media	Audio media, visual media and audiovisual This can be further divided into: 1. Analog 2. Digital media

Inclusion criteria

We included published randomized or quasi-RCTs using any eMedia relevant to people with schizophrenia or schizophrenia-like illnesses with at least one outcome relevant to that same group of people. We also included studies that used social media or the Internet for patient or caregiver education. There was no requirement for papers to report any particular outcome measure or length of follow-up.

By eMedia, we meant media that use electronics or electromechanical energy for end users (audience) to access content (for example, interventions delivered through [but not limited to] mobile phones, tablets, computers, TV or radio). Initially, we wanted to classify interventions according to the type of media and type of e-platform being used, based on information technology (IT) system. IT experts advised that the interventions could be classified based on the extension and file type. However, it might be too complicated for health professionals (Table 2). On detailed examination of studies, however, we found that only limited information was available in the majority of studies on these aspects of intervention, and it was impossible to classify on this basis. In any event, this was also not clinically relevant and we, therefore, decided to classify studies according to the type of intervention.

Initial search returned 296 abstracts. Of these, 96 were considered irrelevant. All the abstracts were carefully inspected. Full paper was obtained for clarification if warranted. Given the lack of consensus criteria for eMedia, we adopted a broad definition whereby a paper was included if the intervention was deemed to be delivered by an electronic medium by the trialist. We also included papers in which the trialists did not explicitly mention the intervention, but there was evidence that some electronic medium was employed. Multiple reports of single trials were grouped to avoid double counting. Two authors (FN and SX) held numerous discussions to clarify selection, issues around media categories, suitability and classification of studies into groups. The selected trials were then grouped by type of intervention, and the data on the description of the intervention and size of the trial were independently extracted (FN, SX and TM). SF was consulted when there was a disagreement and to clarify issues. We worked with a team of IT specialists to clarify issues around the classification of eMedia types. One author (SX) has qualifications in IT and medicine. Data were entered into an electronic database. In addition, we also inspected published meta-analyses and relevant Cochrane reviews. After excluding duplicates, and studies

Table 2 Types of digital media

Extensions	Types
3g2	Cell phones video
3gp	Cell phones video
aac	Audio
asf	Video
avi	Video
azw	Interactive video book
divx	Video
docx	Video book
drc	Open source
dsi	Nintendo audio media file
epub	Interactive video book
exe	Interactive book and some other executable
fla	Interactive flash
flv	Flash video
jpg	Artwork file
m2v	Video
m4v	Video
mkv	Matroska video
mobi	Interactive book
mov	Video
mp2	Video
mp3	Audio
mp4	Video/artwork-embedded file
mp4v	Video
mpe	Video
mpeg	Video
mpg	Video
mpv	Video
ogg	Open source
ogv	Open source
pdb	Interactive book
pdf	Interactive video book
Plk	Interactive book
prc	Interactive book
qt	Quicktime
rm	Real media
rmvb	Real media
svi	Samsung format
swf	Interactive flash
umd	Universal media disc
vob	dvd format
webm	html5 video
wma	Audio
wmv	Video

not concerning a therapeutic intervention or assessment, we finally selected 61 studies.

Results

The 61 studies involved 5,352 people with schizophrenia (mean =123, median =87, range =20–507). Studies of this type are of increasing in frequency (Figure 1).

These trials used a variety of eMedia (eg, mobile/static telephone – calls/messaging/applications [apps], computer

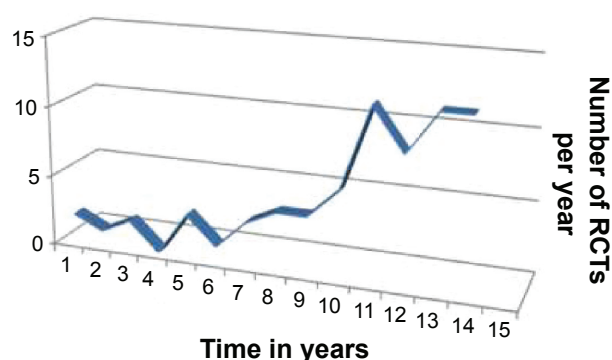


Figure 1 Number of RCTs over the years (2001–2014).

Abbreviation: RCTs, randomized control trials.

software, web pages) and reported outcomes such as adherence, assessment of symptoms, patient education, symptom improvements and compliance (Table 3).

We classified the interventions according to the target areas into the following types:

- Education and information
- Assessment, screening and monitoring
- Improved communications
- Relapse management/engagement
- Specialized interventions

Eleven trials reported testing of eMedia-delivered education/information or training (mean = 124, median = 91, range = 25–311); four on assessment, screening or symptom monitoring (mean = 100, median = 90, range = 24–225), another four on communication improvement (mean = 221, median = 165, range = 50–507) and six on relapse management and engagement (mean = 135, median = 124, range = 47–254). However, the largest number of trials (37) focused on testing of provision of specialized interventions. These included cognitive remediation (CR) (34 RCTs, N = 1,833), problem solving (one RCT, N = 20) and a novel cognitive behaviour therapy [CBT]-based Avatar therapy (one RCT, N = 26).

TAU was the most common control group. Only a small number of studies compared the intervention with an active control (eg, an educational training video compared with a non-educational control video) or with a real-life intervention (eg, VR job skills training compared with the therapist-delivered group). Only two studies compared the same intervention delivered through a different eMedia (eg, SMS-delivered problem solving compared with telephone-delivered problem solving). None of the trials surveyed in this study mentioned the use of CONSORT-eHEALTH checklist. These papers did not describe the interventions in details using an existing criterion. Although a significant minority of studies reported feasibility of the interventions (n = 12), none reported end user experience. None of the trials reported participants' level of digital literacy.²⁰

Discussion

Nearly half (n = 35) of the studies reported the use of computer programs for CR. Trials of eMedia-delivered interventions are increasing in frequency. Studies that may have seemed unusual a decade ago are now much more common.

Most studies are small (please note the lower end of the range of numbers in “Results” section). We recognize that many were undertaken by researchers working on very low budgets, and power calculations may have been uninformative when there is little to base them on. Now this does not apply. There are studies albeit small. More informative power calculations are possible, and we suggest that these should be for outcomes that end users designate as important. Even if studies of the exact eMedia do not exist, those proposing to undertake such trials should be able to extrapolate from other good evidence – even if the original intervention was not delivered by eMedia.

To our knowledge, this is the first literature survey reporting an overview of eMedia-delivered interventions for schizophrenia. Previous literature reviews have focused mainly on the outcome of interventions.^{3–6,13,21} The eMedia interventions, like any other health care intervention, should be clearly described so that results can be replicated.¹⁵

Types of eMedia

There was a wide variation in the eMedia used. It varied from television (TV), radio, telephone and desktop computer to game console, smartphones and handheld device. It is not possible to classify eMedia due to the variety of file formats. On the basis of this survey, currently there are two types of media used:

- Interactive media (eg, mobile phone apps or websites)
- Didactic media (TV, video, etc.)

The survey also highlighted the following types of interventions that are delivered by eMedia;

Type 1: Intervention delivered by a human therapist through a mobile app or a computer program (eg, telephone-delivered problem solving by a therapist, Avatar therapy).

Type 2: Intervention based on a manualized, well-established therapy delivered through eMedia (eg, MoodGym).

Type 3: Intervention that did not exist before and is not underpinned by an existing theoretical framework.

Standardizing, regulating, guiding regarding the intervention

There is an interest in standardizing interventions in this area and have been attempts to establish criteria to self-certify mobile

Table 3 Summary of randomised trials of eMedia interventions for schizophrenia

Broad category	Sub-category	Studies (N)	Total participants	Intervention			Outcomes	Potential comparison(s)
				1	2	3		
Education information	Psychoeducation ³²⁻³⁶	2	311	Computer program	Educational material (paper)	TAU	Quality of life and functioning	Computer program (non educational)
					Education by nurse	I+2	Psychological well being	Education by a person
		2	55	Website*	TAU		Improved knowledge and well being	Website (non educational)
					Paper based consent		Informed consent	Education by a person
					Control video		Education by a person	Education by a person
	Parenting training ²⁷	1	78	Video tape*	Control video		Informed consent	Control video
					Listserv	Online healthy lifestyle course	Parenting skills	Listserv (non educational)
		1	60	Virtual Reality (VR) program for role-plays*	Standard SST groups	Social skills	Educational material on paper	
							VR program (non educational)	Education by a person
							VR program (non educational)	Education by a person
Assessment, screening, symptom monitoring	Vocational training ³⁹⁻⁴¹	2	39	Virtual Reality Job Interview Training*	TAU	Therapist-delivered group	Job interview skills	VR program (non educational)
								Education by a person
		1	200	Computer game	TAU		Psychosis, functioning	Educational material on paper
							Computer program (non educational)	Education by a person
							Education by a person	Education by a person
	Peer support ⁴²	1	300	Listserv	Bulletin board	TAU	Psychotic symptoms, distress	Educational material on paper
								Education by a person
		2	335	Web based interview	Face to face interview		Assessment of symptoms	Listserv (non educational)
					Face to face visits		Suicidal ideation	Education by a person
								Educational material on paper
Communication improvement	Improve communication ^{47,48}	1	24	Smartphone app	Short message service (SMS)	Symptom monitoring	Video/website (non interventional)	
					Educational video	Patient empowerment	Real life intervention	
		2	50	Website*	TAU			
					TAU			
Structured patient-clinician communication ^{49,50}	2	250	Computer assisted clinician-patient communication*	TAU	Quality of life	Computer program (non interventional I)		

(Continued)

(Continued)

Table 3 (Continued)

Broad category	Sub-category	Studies (N)	Total participants	Intervention			Outcomes	Potential comparison(s)
				1	2	3		
Relapse management & engagement	Follow up & engagement ⁵¹	1	113	Telephone delivered	TAU		Engagement, compliance	Telephone calls (befriending)
	Relapse prevention ⁵²	1	146	Information technology-aided program of relapse prevention (Itareps)	TAU		Hospitalization, relapse	Face to face visits
	Dispensing ⁵³	1	47	Electronic Pill dispenser (DoPill)	TAU		Adherence with medication	Face to face visits
	Monitoring ^{54,55}	2	142	Med-eMonitor (MM)*	In person monitoring (PharmCAT)	TAU	Adherence with medication	In person monitoring
Specialized interventions	Appointment reminders ⁵⁶	1	254	@Home Medication Monitoring system (Telemonitor)	Self-report	pill counts	Adherence with medication	In person monitoring
	Cognitive remediation therapy ⁵⁷⁻⁶⁰	34	1,833	Short message service (SMS)*	TAU		Follow up appointment	Telephone calls
				Computer program*	Various		Psychotic symptoms, functioning, quality of life	
	Problem solving ⁷¹	1	20	SMS*	Telephone calls	Both	Symptoms and medication adherence	
	Avatar therapy (iCBT) ⁷²	1	26	Computer program		TAU	Hallucinations	

Note: *Included in a Cochrane review.
Abbreviation: TAU, Treatment As Usual.

app development.²² This followed concerns about the lack of standardization and risk assessment of medical apps.^{23,24}

The health regulatory agencies have not paid sufficient attention to eMedia-delivered interventions, and therefore limited information and guidance are available for clinicians or end users. The US Food and Drug Administration (FDA) released guidance recently, focusing primarily on apps that transform the mobile platform into a regulated medical device.²⁵ The remaining eMedia will be subject to “enforcement discretion”, that is, no regulation.²⁶ The Therapeutic Goods Administration for health care practitioners in Australia provides limited guidance.²⁷ Similarly, the British Medicines and Healthcare Products Regulatory Agency does not offer concrete advice for clinicians or end users. However, the Business Standards Institution has developed “PAS 277 *Health and wellness apps – Quality criteria across the life cycle – Code of practice*”²⁸ in conjunction with Innovate UK (www.innovateuk.gov.uk). The purpose of these guidelines is to develop a set of principles that health app developers should follow to ensure that their products and services can be trusted by health care professionals and the public. This is an important starting point. However, with the slow recognition, acceptance and standardization of health apps and the fast pace of development, it seems unlikely that standards and regulation will keep up with technological advancement.²⁹ No trial reported ease (or difficulty) of access and use of the eMedia under test.

None of the studies in this survey followed a set of guidelines for quality control.²⁷ Having read these studies in detail, we remain unclear about the fidelity of most interventions. A small number of studies describe the evidence relating to the manualized intervention, which is, in their trial, delivered through an eMedia (for example, CR trials). A few studies gave details of the eMedia developers, and an even smaller number gave details of the intervention in the public arena (for example, <https://www.itareps.com>). While some of these interventions might be ready to be used in clinical practice (eg, ClinTouch), others may well be impractical (eg, Avatar therapy) due to cost, training or ease/difficulty of use.

These relatively new interventions present trialists with a dilemma of what to use as a comparison. TAU can be problematic,³⁰ and most studies using a TAU comparison failed to describe adequately what exactly was “usual”. A small number of trials employed innovative control groups such as an active control using a similar eMedia, a real-life intervention or a different eMedia used to deliver the same intervention.

Reporting and outcomes

Use of technical (IT) jargon may not make sense to many health professionals. This could easily be overcome

by providing details of the intervention in an online supplement or website. Some guidance is available in reporting mPSI.¹⁵

Outcomes were not clearly of importance to end users. Scale-derived measures (for example, scores on Positive and Negative Syndrome Scale) are important mostly to researchers and are not usual in routine care. While researchers are an important constituency for the trial to serve, they are not the only one. End users might be more interested in an outcome like user experience. It is important that eMedia trials do not lose the opportunity to undertake trials that are likely to make any effective procedure applicable to wide use.²⁹

None of the studies reported on direct or indirect adverse effects or on the cost-effectiveness of these interventions (or just the cost of the intervention). Effective encouragement of taking medications may lead to adverse events. There is evidence that psychosocial interventions also cause adverse outcomes.³¹ Delivery through eMedia complicates and possibly increases risks. Furthermore, there may be risks particular to eMedia such as reduction in social activities or even addiction to eMedia.²³

There seems to be an underlying assumption in developing eMedia-delivered interventions that they are cost-effective compared with human media-delivered treatments. No study reported cost per unit of intervention or cost-effectiveness. The assumption of eMedia being more cost-effective remains an assumption.

Criteria

There is an urgent need to set criteria for standardization of development, evaluation and reporting of eMedia interventions. It is imperative that uniform processes are followed and that criteria for trial reporting are developed in consultation with experts in care, evaluation and IT. Recognizing that such suggestions must evolve with technology, we suggest that the CONSORT statement needs to be constantly updated.

Conclusion

This survey reports numerous areas of weakness in current description of eMedia-delivered interventions for schizophrenia. Most notable issues are descriptions of development and initial testing and reporting of interventions, their theoretical underpinning and their side effects. There is also a need to improve reporting end user experience and adapting interventions to their digital or e-literacy skills. None of the trials reported use of CONSORT eHealth. Updating these guidelines, especially for psychosocial interventions, might be the way forward.

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Disclosure

The authors report no conflicts of interest in this work.

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Supplementary material

Table S1 Detailed keywords

Concept	Keywords	Concept	Keywords
Internet	3rd Generation	Electronic	iPad-Assisted
	Chat		Keyboarding Skills
	Electronic Mail		Software Program
	Email		Telehealth
	E-Mail		Telepsychiatry
	Facebook		Telepsychotherapy
	Internet		Virtual
	Internet-Based		CD
	Internet App		CD ROM
	Internet Application		CD ROM Learning
	Mailing List		CDROM
	Newsgroup		DVD
	Online		Electronic
	Second Life		Fax
	Third Generation		Floppy
	Tweeting	Media	Patient-Facing Kiosks
	Twitter		Films
	Web		Hypermedia
	Weblog		Media
	Website		Movies
	WWW		Multimedia
Computer	Avatar Therapy	Phone	News
	Computer		Radio
	Computer Controlled		Television
	Computer Education		TV
	Computer Game		Video
	Computer Package		Mobile Phone
	Computer Skills		Phone
	Computer-Assisted		Phone Application
	Computer-Based		Phone Call
	Computerised		Short Message
	Computerized		Short Message Prompt
	Computer-Mediated		Short Message Reminder
	Digital Communication Device		SMS Prompt
	Electronic Health		SMS Reminder
	Electronic Learning		Telephone
	Informatics		Text Messaging
	Information Technology		

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