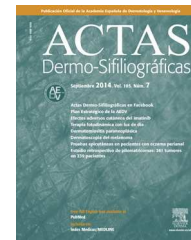




# ACTAS Dermo-Sifiliográficas

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## ORIGINAL ARTICLE

# Identifying Randomized Clinical Trials in Spanish-Language Dermatology Journals<sup>☆</sup>



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### KEYWORDS

Randomized clinical trial;  
Manual literature search;  
Dermatology journals

### Abstract

**Background:** The necessary foundation for good clinical practice lies in knowledge derived from clinical research. Evidence from randomized clinical trials (RCTs) is the pillar on which decisions about therapy are based.

**Objective:** To search exhaustively and rigorously to identify RCTs in dermatology journals published in Spanish.

**Methods:** We located dermatology journals through the following search engines and indexes: PubMed, LILACS, SciELO, Periódica, Latindex, Índice Médico Español, C-17, IBECS, EMBASE, and IMBIOMED. We also sought information through dermatology associations and dermatologists in countries where Spanish was the usual language of publication, and we searched the Internet (Google). Afterwards we searched the journals electronically and manually to identify RCTs in all available volumes and issues, checking from the year publication started through 2012.

**Results:** Of 28 journals identified, we included 21 in the search. We found a total of 144 RCTs published since 1969; 78 (54%) were in Latin American journals and 66 (46%) were in Spanish journals. The most frequent disease contexts for RCTs in Spanish journals were psoriasis, mycoses, and acne vulgaris. In Latin American journals, the most frequent disease contexts were common warts, mycoses, acne vulgaris, and skin ulcers on the lower limbs. Manual searches identified more RCTs than electronic searches.

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**PALABRAS CLAVE**

Ensayo clínico  
aleatorizado;  
Búsqueda manual;  
Revistas  
dermatológicas

*Conclusions:* Manual searches found a larger number of RCTs. Relatively fewer RCTs are published in Spanish and Latin American journals than in English-language journals. Internet facilitated access to full texts published by many journals; however, free open access to these texts is still unavailable and a large number of journal issues are still not posted online.  
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**Identificación de ensayos clínicos en revistas dermatológicas publicadas en español****Resumen**

*Introducción:* Para asegurar una práctica adecuada se hace necesario incorporar el conocimiento derivado de la investigación clínica, en la que los ensayos clínicos con asignación aleatoria (ECA) son el pilar fundamental para la decisión de una terapia.

*Objetivo:* Buscar e identificar de manera exhaustiva y rigurosa los ECA publicados en revistas dermatológicas en español.

*Métodos:* Se detectaron las revistas dermatológicas mediante búsquedas en PubMed, LILACS, SciELO, Periódica; Latindex; Índice Médico Español; el C-17; el IBECS, EMBASE e IMBIOMED; y/o por el contacto con las asociaciones de dermatología/especialistas de cada país y la búsqueda libre por Google. Posteriormente se realizó tanto una búsqueda manual como electrónica de los ECA en los volúmenes y números disponibles. La revisión de cada revista se realizó en cada volumen y número desde su publicación hasta el año 2012.

*Resultados:* De las 28 revistas encontradas se incluyeron 21. Desde 1969 se identificaron 144 ECA, 54% (78) en las revistas latinoamericanas y 46% (66) en las españolas. Entre las enfermedades estudiadas predomina la psoriasis, las micosis y el acné vulgar entre las revistas españolas, mientras que entre las latinoamericanas prevalecen las verrugas vulgares, las micosis, el acné vulgar y las úlceras de los miembros inferiores. La búsqueda manual identificó más ECA de los detectados por búsqueda electrónica.

*Conclusiones:* La búsqueda manual permitió una alta detección de ECA. El número de ECA identificados en revistas dermatológicas iberolatinoamericanas es bajo comparado con las revistas publicadas en inglés. Internet facilitó el acceso al texto completo de muchas revistas, pero se carece aún de un acceso libre al texto completo y de un volumen importante de números publicados por esta vía.

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**Introduction**

An individual clinician's experience is an important source of knowledge in dermatology. However, when such knowledge becomes the sole basis for clinical decision-making, therapeutic effects are often overestimated. Compounding this problem is the physician's tendency to rely on knowledge acquired during residency training or to find it difficult to incorporate current evidence into routine practice, especially if new information calls beliefs and previous experience into question.<sup>1-3</sup> Clinical trials follow an experimental design in which a researcher manipulates exposure to 1 or more treatments in order to compare effects.<sup>4,5</sup> The main purpose of this type of study is to assess the efficacy and safety of an intervention that seeks to prevent or cure a health condition or to speed recovery.<sup>4,5</sup>

Given the importance of randomized clinical trials (RCTs), it might be supposed that they would be easily available to both treating physicians and researchers. Problems arise, however, when health care professionals seek to locate and use information from RCTs. Among the difficulties that have been reported are 1) the novelty of the terminology itself, 2) the underuse of descriptors when trials are indexed in

databases, and 3) the high percentage of journals that do not post articles online.<sup>6-8</sup> Problems that further interfere with physicians' use of RCTs are lack of time for reading these articles and the lack of access to the publishing journals.<sup>9,10</sup>

To help identify RCTs published in the Spanish language in several medical specialties, the Cochrane Collaboration undertook a project to search for them manually. Searching in databases alone reportedly fails to find a significant number of RCTs in the specialties of ophthalmology, public health, anesthesiology and critical care, and general and internal medicine.<sup>8,11-14</sup> In addition, online MEDLINE searches can fail to return up to 25% of RCTs available, mainly when the authors have not included the search terms *randomized controlled trial* or *controlled clinical trial* in the titles.<sup>15</sup>

We present the results for dermatology journals included in the Cochrane Collaboration's project on hand searching for RCTs in Spanish, as these findings complement the important earlier work of González-Castro et al.<sup>7,16</sup> in identifying trials reported in *Actas Dermo-Sifiliográficas* between 1948 and 2000 and *Medicina Cutánea Ibero-Latino-Americana* between 1970 and 2000.

## Aim of This Study

We sought to exhaustively and rigorously search for RCTs in dermatology journals published in the Spanish language.

## Material and Methods

### Identification of Journals

We identified journals within the framework of a project led by the Iberoamerican Cochrane Centre (IbCC) in Barcelona, Spain, to find biomedical journals in countries where Spanish is spoken. An IbCC-trained researcher, who was responsible for managing and coordinating the study, carried out the journal search and sent the results to the IbCC collaborators in each country. The collaborators were charged with confirming that the journal information was complete and accurate. Any other sources that might help us find these journals, such as national library catalogs and collections, were also searched.

Appropriate databases (IBECs [the Spanish health sciences index], EMBASE [Excerpta Médica dataBASE], and IMBIOMED) and the web pages of dermatology associations in Latin American countries where Spanish is spoken were included in the search. We also made direct contact with journals' editorial boards and specialists in dermatology, and as a last resort we searched for candidate journals in Google.

Journals were eligible if they published original research articles and made full texts available to researchers in print or online. Journals were excluded if they focused on pediatric dermatology, covered areas already included in the project under another specialty (for example, infectious diseases), or published only reviews or case reports in dermatology. If a journal's full texts could not be obtained by any means, it was likewise excluded.

Each journal was searched in reverse chronological order from 2012 to the first issue published (provided full texts were still available). If no RCTs were found for 5 consecutive years, the manual search was halted, unless we had ready access to issues, in which case we extended the search.

Additionally, we checked whether these journals instructed authors to follow the CONSORT (Consolidated Standards of Reporting Trials) guidelines and whether they were indexed in MEDLINE or EMBASE.

### Hand Search Method

We asked 40 undergraduate and postgraduate students in the health sciences to carry out the systematic hand searches. Each student did a test search of a journal for a period the IbCC had already assessed. The searchers' training was based on the IbCC's hand RCT search protocol for Spanish articles (available from <http://www.cochrane.es/~cochrane/?q=es/node/140>). That protocol was based on the Cochrane Collaboration's *Training Manual for Hand-searchers*.

Once training and the pilot search had been completed, the searcher was assigned volumes in which to find RCTs by 1) reading the tables of contents, 2) locating key terms for RCT-associated concepts in Spanish (*aleatorizado, prospectivo,*

*comparación, etc.*) in titles and abstracts, and 3) reading the patients and methods sections of the full texts. Afterwards, the searcher filled in the form for recording the results of hand searches of journals or updates.

### Electronic Search Method

So that we could compare electronic and hand-searching results, we conducted RCT searches in MEDLINE (through PubMed), EMBASE, LILACS (Latin American index of scientific and technical literature) and IBECs. Validated combinations of descriptors were used in multiterm combinations, along with free-text terms.<sup>1,2</sup> (See Appendix 1, online supplementary material.) These searches were updated in November 2014 to check for RCTs published between 2012 and 2014.

### RCT Inclusion Criteria

We followed the Cochrane Collaboration criteria for defining RCTs. Thus, we included 1) trials comparing treatments in humans; 2) trials designed to gather data prospectively; 3) clinical comparisons of 2 or more interventions (1 of which could be a control treatment) of any type (medications, operations, diagnostic or educational procedures, rehabilitation therapies, management systems, or other); and 4) trials using random, or quasi-random, assignment of treatments, and/or use of double blinding. The randomization units could be individuals, clusters (hospitals, communities), or parts of the body (such as split faces or different limbs).

### Classification of Information and Identification of RCTs

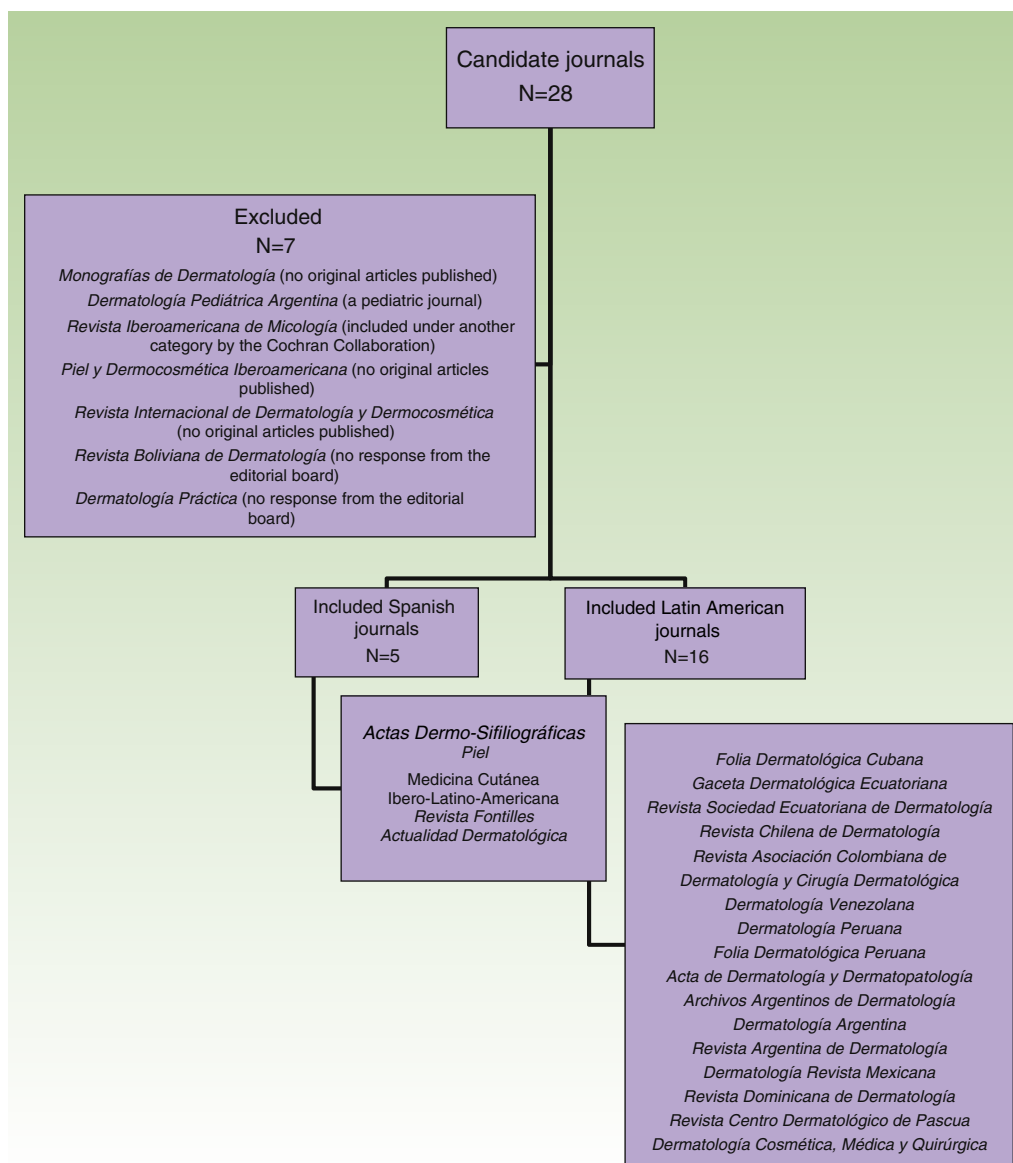
Each searcher recorded the number of RCTs found while reading the assigned issues. Later, 2 evaluators who had formal training in clinical epidemiology (G. S. and H. P.) read the full texts in order to confirm that each RCT met the selection criteria.

### Planned Analysis

Descriptive statistics were compiled. Continuous variables were summarized in appropriate measures. Qualitative variables were reported as absolute and relative frequencies and percentages. Data were stored in a spreadsheet (Excel, version 2010, Microsoft Office, Redmond, WA, USA). SPSS software (IBM, version 19 (Armonk, NY, USA) was used to analyze the data.

## Results

The only dermatology journal we found to be indexed in both MEDLINE and EMBASE at this time is *Actas Dermo-Sifiliográficas*. The journals indexed only in EMBASE are *Dermatología Revista Mexicana*, *Revista Argentina de Dermatología*, *Medicina Cutánea Ibero-Latino-Americana*, and *Piel*.



**Figure 1** Flow chart of the dermatology journal search process and the selection of included and excluded journals.

### Included and Excluded Journals

Of the 28 candidate journals, 21 were included. All 28 journals and the reasons for exclusions are shown in Fig. 1.

*Actas Dermo-Sifiliográficas* is the only journal included in this study that specifies and promotes the use of the CONSORT guidelines.<sup>17</sup>

### RCTs Identified

A total of 144 RCTs published since 1969 were found in the 21 included journals (Table 1). Seventy-eight (54%) of the RCTs were published in the 16 Latin American journals searched, and 66 (46%) were found in the 5 Spanish journals (Table 1, which also shows the number of RCTs

found in each journal). A large number of the RCTs found in *Actas Dermo-Sifiliográficas* and *Medicina Cutánea Ibero-Latino-Americana* were previously gathered and described in 2 earlier publications.<sup>7,16</sup>

Analysis by 5-year intervals shows that many of the RCTs (89 in total) were published in the last 20 years (from 1993 to 2012). The 25 preceding years (from 1992 to 1968) saw 55 RCTs published (Fig. 2).

The most frequently studied skin diseases in the Spanish trials were psoriasis (11 RCTs), mycoses (9), and acne vulgaris (8). The most frequent disease contexts in the Latin American trials were common warts (9 RCTs), mycoses (8), acne vulgaris (7), and lower-limb ulcers (6). Details of the RCTs found are listed in Appendix 2 of the online supplementary material.

The MEDLINE search identified 3997 entries, 669 of which were in *Actas Dermo-Sifilográficas*. Two of these entries

**Table 1** Included Dermatology Journals.

No.	Journal Name	Period Searched	First Year of Publication	Periods Not Searched <sup>a</sup>	No. of RCTs Found
<b>Latin America</b>					
1	<i>Dermatología Revista Mexicana</i>	1981–2012	1956	1969–1980, 1984, 1987	21
2	<i>Dermatología Venezolana</i>	1984–2012	1957	1969–1983	13
3	<i>Dermatología Peruana</i>	1996–2012	1996	–	9
4	<i>Revista Asociación Colombiana de Dermatología</i>	1991–2012	1991	–	8
5	<i>Revista Chilena de Dermatología</i>	1985–2012	1985	–	8
6	<i>Dermatología Cosmética, Médica y Quirúrgica</i>	2003–2012	2003	–	4
7	<i>Revista del Centro Dermatológico Pascua</i>	1999–2012	1999	–	4
8	<i>Revista Argentina de Dermatología</i>	1981–2012	1908	1969–1980	4
9	<i>Folia Dermatológica Peruana</i>	1986–2012	1986	–	2
10	<i>Dermatología Argentina</i>	1995–2012	1995	–	2
11	<i>Folia Dermatológica Cubana</i>	2007–2012	2007	–	2
12	<i>Archivos Argentinos de Dermatología</i>	1983–2012	1951	1969–1982	1
13	<i>Actas de Dermatología y Dermatopatología</i>	2001–2009	2001 (publication ceased in 2009)	–	0
14	<i>Revista Dominicana de Dermatología</i>	2010–2012	1971	1971–2009	0
15	<i>Revista Sociedad Ecuatoriana de Dermatología</i>	2003–2010	1991	1991–2002, 2005, 2008, 2009, 2011, 2012	0
16	<i>Gaceta Dermatológica Ecuatoriana</i>	1998	1998	1997–2012	0
<b>Total RCTs in Latin American journals</b>					<b>78</b>
<b>Spain</b>					
17	<i>Actas Dermo-Sifiliográficas</i>	1969–2012	1909	–	30
18	<i>Medicina Cutánea Ibero-Latino-Americana</i>	1969–2012	1966	–	25
19	<i>Piel</i>	1986–2012	1986	–	10
20	<i>Actualidad Dermatológica</i>	1974–2008	1962	1969–1973,	1
21	<i>Revista Fontilles</i>	2008–2012	1932	1969–2002	0
<b>Total RCTs in Spanish journals</b>					<b>66</b>

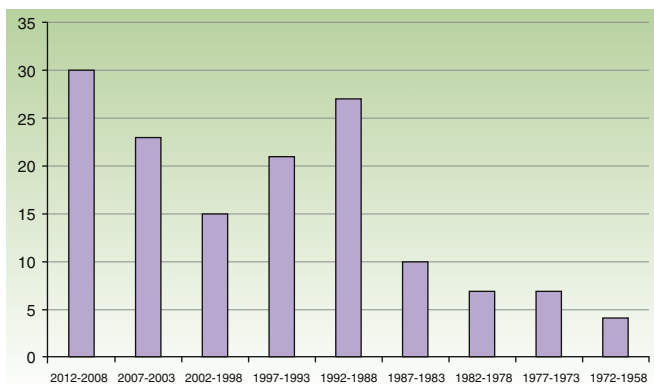
Abbreviation: RCT, randomized clinical trial.

<sup>a</sup> These years could not be searched because neither print nor digital content was available.

were initially considered candidates for inclusion, but were not in fact RCTs, and 4 were. These 4 articles included the word *randomized* in their indexed title. All these RCTs had also been found by hand searching (Fig. 3).

The EMBASE search initially yielded 9584 entries (Fig. 3); 16 of these were for RCTs. Of these, 6 had been previously

identified by hand searching and 2 were newly identified ones from the *Dermatología Revista Mexicana*. These 2 articles had not been found during earlier hand searching because neither print nor digital versions of the table of contents could be found for issue 6 of volume 56 or issue 2 of volume 48 (Fig. 3).



**Figure 2** Number of randomized clinical trials published in 5-year periods.

The search of indexes on the Spanish language Virtual Health Library (BVS) initially returned 5140 entries (Fig. 3). After filtering for dermatology, 30 candidates were identified; 2 of these were not RCTs. Thus, the digital searches found only 28 (19.5%) of the 144 RCTs that had already been found by hand searching (Fig. 3).

We were unable to hand search all of the following journals because of missing volumes or issues: *Dermatología Revista Mexicana*, *Dermatología Venezolana*, *Revista Argentina de Dermatología*, *Archivos Argentinos de Dermatología*, the 2 Ecuadoran journals, the single journal published in the Dominican Republic, and *Revista Fontilles* (Table 1).

## Discussion

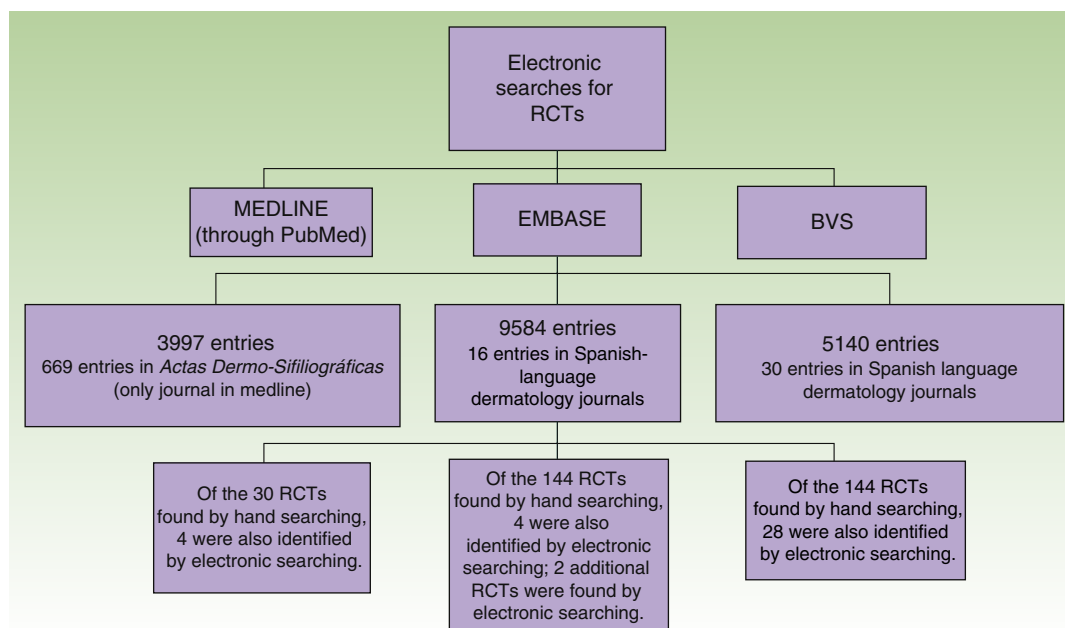
RCTs are the principal units of analysis for systematic reviews, clinical practice guidelines, and other documents

that synthesize knowledge. Regulatory agencies also require them before medicines can be approved for use in humans.

Hand searching identified about 80% more RCTs than database searching. This finding is consistent with previous reports for our own field, in which journals like *Archives of Dermatology*<sup>18</sup> and *Actas Dermo-Sifiliográficas*<sup>7,19</sup> were searched. It is also consistent with reports for other medical specialties.<sup>8</sup> These results underline the importance of manually checking dermatology journals, as many of the RCTs we found could not have been otherwise identified, possibly because MEDLINE and EMBASE are not sensitive to search terms in Spanish.<sup>11,19-22</sup> Alternatively, the reason may be that *Actas Dermo-Sifiliográficas* is the only Spanish language dermatology journal indexed in MEDLINE or that EMBASE does not index all of the other Spanish journals. Compounding the problem is the inherent difficulty of electronic searching in any language other than English. Searches in other languages have returned 37% fewer entries than searches in English.<sup>15</sup>

*Dermatología Revista Mexicana* and *Dermatología Venezolana* were the Latin American journals that published the largest number of RCTs. In Spain, *Actas Dermo-Sifiliográficas* published the most. We offer no explanation for these observations, but we think it may be that more funding is available for conducting RCTs in the countries where these journals are published. It is also possible that these journals have less stringent policies governing the RCTs they publish than other Latin American journals do.

Our findings showed an increase in the number of RCTs published in Spanish in recent decades. The reason for the increase may lie in the importance currently placed on evidence-based medicine, an approach that obliges researchers to value this type of study above others because it provides more and stronger evidence.



**Figure 3** Flow chart of the digital search process for each database searched and the selection of randomized clinical trials (RCTs). BVS refers to the Biblioteca Virtual de la Salud (Virtual Health Library).

We found 78 Spanish-language RCTs in Latin American journals and 66 in Spanish ones published over the course of 44 years. On average, RCTs were published at a rate of 1 to 2 per year, a statistic that is in sharp contrast with the rate of RCT publication in English. Up to 11 RCTs per year are published by *Archives of Dermatology* alone, for example.<sup>18</sup>

The CONSORT reporting guidelines were established in 1996 to standardize the way clinical trials are reported in different journals.<sup>17</sup> These standards indirectly encourage greater methodological rigor by obliging the researcher to describe the design explicitly and fully. Only 1 journal in this study, namely *Actas Dermo-Sifilográficas*, requires authors to follow the CONSORT guidelines. There seems to be a need, therefore, not only to promote the design of RCTs but also to encourage journals to require CONSORT-guided reporting, just as the important English-language dermatology journals do.

That both Spanish and Latin American researchers showed interest in psoriasis, mycoses, and acne was noteworthy. The attention is probably attributable to the greater impact of these diseases among patients, given that clinical importance would drive an effort to identify effective therapies; alternatively, the pharmaceutical industry may be more interested in funding RCTs in these areas.<sup>23,24</sup>

This study identified Spanish-language dermatology journals. Their full texts proved impossible to find in only a few cases once we applied various means to locate them. This experience underlines the importance of posting full texts online because this strategy not only facilitates the identification of RCTs for systematic reviews but also contributes to making knowledge available worldwide and enhancing the visibility of Spanish-language publications.

One of the strengths of this study is the large number of journals, volumes, and issues we searched exhaustively and systematically. A total of 28 dermatology journals were initially identified. Electronic searching found nearly all the RCTs that had been identified manually. Two references were found by database searching but not by hand searching, since print copies of the issues in question were unavailable. A limitation of our study is our lack of access to all of the articles published from the start of publication (Table 1). However, those early issues probably did not contain RCTs, since this design was little used before the 1970s. Another limitation is that we excluded relevant RCTs that were published in journals that focus on other specialties or in dermatology journals published in other languages. Furthermore, we did not evaluate the quality of the RCTs for this report, although we have recently been working on that task and plan to publish the results shortly.

In conclusion, manual searches identified a large number of RCTs in dermatology journals in Spain and Latin America. However, these journals publish far fewer RCTs than English-language dermatology journals do. Finally, ready access to these RCTs and a large number of other articles of interest is still lacking.

## Ethical Disclosures

**Protection of human and animal subjects.** The authors declare that no experiments were performed on humans or animals for this investigation.

**Data confidentiality.** The authors declare that no private patient data are disclosed in this article.

**Right to privacy and informed consent.** The authors declare that no private patient data are disclosed in this article.

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## Conflicts of Interest

The authors declare that they have no conflicts of interest.

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## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at [doi:10.1016/j.adengl.2015.04.010](https://doi.org/10.1016/j.adengl.2015.04.010).

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