APPENDIX

A systematic review of Patient-Reported Outcome (PRO) Measures for Use in Randomized Controlled Trials (RCT) of Patients with Systemic Lupus Erythematosus (SLE)

Search Methods
October 20, 2019

1. Search methods will include multiple methods to ensure a sensitive search of literature across geographical and discipline areas and to ensure that all applicable literature is found. These search methods include searching multiple databases, and citation searching of reference lists of included studies.

1.1. Two Databases

The goal of the initial database searches is to capture the breadth of multidisciplinary literature. The databases to be included in this review are:

- Ovid Medline: the United States National Library of Medicine’s (NLM) premier bibliographic database providing information from the following fields: medicine, nursing, dentistry, veterinary medicine, allied health and pre-clinical sciences
- Embase: a biomedical and pharmacological database containing bibliographic records with citations, abstracts and indexing derived from biomedical articles in peer reviewed journals, and is especially strong in its coverage of drug and pharmaceutical research. Better captures European literature.

1.2 Search Terms

- Search terms: 
  — Appendix I for Medline
Appendix II for Embase

1.3 Search Parameters/Limiters

- Limiters will be added once all search terms (OR/AND) combined.
  - Articles written in English language (secondary to the language limitations of reviewers) and human studies only (secondary to the objective of the review)
- Searches will not be limited by age group or year (year up to date of search)
  - Searches will not be limited by “review;” reviews will be filtered out during screening/selection process. Related reviews will be noted and references will be checked for applicable included articles

1.4 Running database searches

- The literature searches will be completed by librarian/information specialist (EVIDERA Team), who has extensive experience in database searching and systematic reviews.
- The primary search will be done for Medline database and the altered as necessary for other databases.
- Searches will be tailored to each database based on the above terms.
- Copies of each search structure per database will be retained.
- The librarian will remove duplicates within and between databases
- Key articles (Appendix III) will be provided to validate the search developed by the librarian and to supplement the library with important literature

1.5 Citation search

- Using screening/selection process (Appendix IV)
- Title search will be completed by primary reviewer (Member of EVIDERA)
- Both reviewers will use independent-agreement process to screen/select abstracts and then full articles.

1.6 Hand Search reference lists of relevant recent reviews
• Described in Appendix I-II
• Using screening/selection process (Appendix IV)
• Title/abstract/full-article screening will be completed by primary reviewer (LE) to make list of any new included articles
• 2nd reviewer will check to see if any new included articles meet inclusion criteria

Appendix 1: Search terms for Medline

<table>
<thead>
<tr>
<th>#</th>
<th>Query</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td>AB &quot;systemic lupus erythematosus&quot; OR MM &quot;Lupus Erythematosus, Systemic&quot; OR TI &quot;systemic lupus erythematosus&quot;</td>
<td>54,488</td>
</tr>
<tr>
<td>S2</td>
<td>PT &quot;randomized controlled trial&quot; OR &quot;Randomized Controlled Trials as Topic&quot; OR AB (rct OR random*) OR TI (rct OR random*)</td>
<td>1,075,153</td>
</tr>
<tr>
<td>S3</td>
<td>AB (SF-36 OR SF36 OR &quot;Short Form 36&quot; OR &quot;36 SF&quot;) OR TI (SF-36 OR SF36 OR &quot;Short Form 36&quot; OR &quot;36 SF&quot;)</td>
<td>21,385</td>
</tr>
<tr>
<td>S4</td>
<td>AB (Lupus-QOL OR &quot;Lupus Quality of Life&quot; OR LupusQOL) OR TI (Lupus-QOL OR &quot;Lupus Quality of Life&quot; OR LupusQOL)</td>
<td>38</td>
</tr>
<tr>
<td>S5</td>
<td>AB (FACIT-F OR (&quot;Functional Assessment of Chronic Illness Therapy&quot; AND Fatigue)) OR TI (FACIT-F OR (&quot;Functional Assessment of Chronic Illness Therapy&quot; AND Fatigue))</td>
<td>311</td>
</tr>
<tr>
<td>S6</td>
<td>(S1 AND S2) AND (S3 OR S4 OR S5)</td>
<td>35</td>
</tr>
<tr>
<td>S7</td>
<td>S6 AND DT 2015-2017 AND LA english AND PT &quot;journal article&quot;</td>
<td>8</td>
</tr>
<tr>
<td>S8</td>
<td>PT &quot;observational study&quot; OR MH &quot;Observational Studies as Topic&quot; OR AB observational OR TI observational</td>
<td>135,514</td>
</tr>
<tr>
<td>S9</td>
<td>(S1 AND S8) AND (S3 OR S4 OR S5)</td>
<td>10</td>
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</table>
Appendix II: Search terms for Embase

Embase Session Results (23 Jun 2017)

<table>
<thead>
<tr>
<th>No.</th>
<th>Query</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>'systemic lupus erythematosus'/exp/mj AND 'systemic lupus erythematosus':ab,ti</td>
<td>37436</td>
</tr>
<tr>
<td>#2</td>
<td>randomized controlled trial'/exp OR 'randomized controlled trial (topic)'/exp OR rct:ab,ti OR random*:ab,ti</td>
<td>1354497</td>
</tr>
<tr>
<td>#3</td>
<td>'sf-36':ab,ti OR 'sf36':ab,ti OR 'short form 36':ab,ti OR '36 sf':ab,ti OR 'short form 36'/exp</td>
<td>40482</td>
</tr>
<tr>
<td>#4</td>
<td>'lupus-qol':ab,ti OR 'lupus quality of life':ab,ti OR lupusqol:ab,ti</td>
<td>95</td>
</tr>
<tr>
<td>#5</td>
<td>'facit-f':ab,ti OR ('functional assessment of chronic illness therapy':ab,ti AND 'fatigue':ab,ti)</td>
<td>735</td>
</tr>
<tr>
<td>#6</td>
<td>#1 AND #2 AND (#3 OR #4 OR #5)</td>
<td>65</td>
</tr>
<tr>
<td>#7</td>
<td>#6 AND (article)/lim OR [article in press]/lim AND [2015-2017]/py AND [english]/lim</td>
<td>9</td>
</tr>
<tr>
<td>#8</td>
<td>'observational study'/exp OR observational:ab,ti</td>
<td>206795</td>
</tr>
<tr>
<td>#9</td>
<td>#1 AND #8 AND (#3 OR #4 OR #5)</td>
<td>18</td>
</tr>
<tr>
<td>#10</td>
<td>#9 AND ([article]/lim OR [article in press]/lim) AND [2015-2017]/py AND [english]/lim</td>
<td>2</td>
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</tbody>
</table>
### Appendix III: Key articles used to validate the search and to supplement the library important literature

Key articles used to initially validate key search terms at title, keyword and abstract levels. These articles should be captured in data-base search. See reference list for full citation.


Touma Z, Gladman DD, Ibañez D, Urowitz MB. Is there an advantage over SF-36 with a quality of life measure that is specific to systemic lupus erythematosus? J Rheumatol 2011; 38:1898–905.


Clowse MEB, Wallace DJ, Furie RA et al: Efficacy and Safety of Epratuzumab in Moderately to Severely Active Systemic Lupus Erythematosus Results From Two Phase III Randomized, Double-Blind, Placebo-Controlled Trials Arth Rheum 2017; 69:362-75.


Nantes S, Strand V, Su J, Touma Z: Comparison of the sensitivity to change of the 36-item Short Form Health Survey and the LupusQoL using various definitions of minimal clinically important differences in patients with active systemic lupus erythematosus. Arth Care Research 2017; DOI 10.1002/acr.23240 [repeat]


Wolfe F, Michaud K, Li T, Katz RT. EQ-5D and SF-36 quality of life measures in systemic lupus erythematosus: comparisons with rheumatoid arthritis,


Appendix IV: Criteria for screening and selection process

<table>
<thead>
<tr>
<th>Title and abstract level</th>
<th>Include</th>
<th>Exclude</th>
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<tbody>
<tr>
<td>Population: Should</td>
<td>Should include Individuals experiencing SLE</td>
<td>Population: Not SLE</td>
</tr>
<tr>
<td>Outcome: Should</td>
<td>Should include description of concept related to health-related quality of life – SF-36, LupusQoL or FACIT-F</td>
<td>Outcome: Not focused on health-related quality of life – SF-36, LupusQoL or FACIT-F</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Full Article Level</th>
<th>Include</th>
<th>Exclude</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population: Adult SLE</td>
<td>Adult SLE diagnosis for the participants. If mixed diagnostic population, results will be excluded</td>
<td>Any exclusion from title level</td>
</tr>
<tr>
<td>Outcome: quality of life</td>
<td>quality of life particularly on SF-36, LupusQoL or FACIT-F</td>
<td>1. Article not in English</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Full-text not available (i.e. abstract for conference) or not able to find full-text using multiple sources.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Not peer-reviewed published evidence (e.g., grey literature, magazine article, thesis dissertation)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. Does not have quantitative data.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6. Population: Does not include adult SLE diagnosis for participants.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8. Outcome: Does not report quality of life – particularly on SF-36, LupusQoL or FACIT-F</td>
</tr>
</tbody>
</table>

Lupus Sci Med
doi: 10.1136/lupus-2019-000373
References


10. Yellen SB, Cella DF, Webster K, Blendowski C, Kaplan E. Measuring fatigue and other anemia-related symptoms with the Functional Assessment of Cancer Therapy


