Table I-2. Strength of evidence for functional capacity and quality of life outcomes

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Number of Studies; # of Subjects** | **Risk of Bias**  **Design/ Quality** | **Consistency** | **Directness** | **Precision** | **Results** | **Strength of Evidence** | |
| **Oral DMARD vs. placebo** | | | | | | | |
| **Leflunomide vs. placebo**  1 RCT;  N=190 | Medium  RCT/Fair | Unknown, single study | Direct | Precise | Greater improvement in functional capacitya and quality of life with LEF than placebo | Low | |
| **Biologic DMARD vs. placebo** | | | | | | | |
| **Adalimumab vs. placebo**  2 RCTs;  N=415 | Medium  RCTs/ 2 Fair | Consistent  Inconsistent | Direct  Direct | Precise  Imprecise | Greater improvement in functional capacityb with adalimumab  For health-related quality of life, some results favored adalimumabc | Moderate  Low | |
| **Etanercept vs. placebo**  2 RCTs;  N=265 | Medium  RCTs/2 Fair | Consistent  Unknown, single studyd | Direct  Direct | Precise  Precise | Greater improvement in functional capacity with etanercept  Greater improvement in quality of life with etanercept | Moderate  Low | |
| **Golimumab vs. placebo**  1 RCT;  N=405 | Low  RCT/Good | Unknown, single study | Direct | Precise | Greater improvement in functional capacity and quality of life with golimumab | Low | |
| **Infliximab vs. placebo**  2 RCTs;  N=304 | Medium  RCTs/2 Fair | Consistent  Unknown, single studyd | Direct  Direct | Precise  Imprecise | Greater improvement in functional capacity with infliximab  Greater improvement in quality of life with infliximab | Moderate  Low | |
| **Oral DMARD vs. Oral DMARD** | | | | | | | |
| No studies | n/a | n/a | n/a | n/a | n/a | Insufficient | |
| **Biologic DMARDs vs. Biologic DMARDs** | | | | | | | |
| No studies | n/a | n/a | n/a | n/a | n/a | | Insufficient |
| **Biologic DMARDs vs. Oral DMARDs** | | | | | | | |
| No studies | n/a | n/a | n/a | n/a | n/a | | Insufficient |
| **Biologic DMARDs + Oral DMARDs vs. Biologic DMARDs** | | | | | | | |
| No studies | n/a | n/a | n/a | n/a | n/a | | Insufficient |
| **Biologic DMARDs + Oral DMARDs vs. Oral DMARDs** | | | | | | | |
| No studies | n/a | n/a | n/a | n/a | n/a | | Insufficient |

aDifference was statistically significantly different, but did not reach the threshold for a clinically important difference.

bDifference in one of two studies was statistically significantly different (difference in improvement in HAQ of 0.2, *P* = 0.01), but did not reach the threshold for a clinically important difference of ≥ 0.22. In the other study, the difference was both clinically and statistically significant.

cDifferences were statistically and clinically significant for the SF-36 PCS, but not for the MCS in both studies. Both studies reported results on the dermatology life quality index; one found a difference favoring adalimumab and the other found no statistically significant difference.

dOnly one of the two trials reported a quality of life outcome.

N = number; n/a = not applicable; RCT = randomized controlled trial