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  | MediumRCT/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 | MediumRCTs/ 2 Fair | ConsistentInconsistent | DirectDirect | PreciseImprecise | Greater improvement in functional capacityb with adalimumab For health-related quality of life, some results favored adalimumabc  | ModerateLow |
| **Etanercept vs. placebo**2 RCTs; N=265  | MediumRCTs/2 Fair | ConsistentUnknown, single studyd | DirectDirect | PrecisePrecise | Greater improvement in functional capacity with etanerceptGreater improvement in quality of life with etanercept | ModerateLow |
| **Golimumab vs. placebo**1 RCT; N=405  | LowRCT/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  | MediumRCTs/2 Fair | ConsistentUnknown, single studyd | DirectDirect | PreciseImprecise | Greater improvement in functional capacity with infliximabGreater improvement in quality of life with infliximab | ModerateLow |
| **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