

#### Project Plan – December 2021

#### **PARTICIPANTS**

#### **Core Oversight Team**

Bryant R. England, MD, PhD (Co-Principal Investigator)
Benjamin J. Smith, DMSc, PA-C (Co-principal Investigator)
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Jennifer L. Barton, MD, MCR (Content Expert)
Carol Oatis, PT, PhD (Content Expert)
Jonathan Treadwell (Literature Review Leader)
Gordon Guyatt, MD (GRADE Expert)

#### Literature Review Team

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### Content Expert (integrative rheumatology)

Neha Shah, MD

### **ACR Board Liaison**

Barbara Slusher

#### **Voting Panel**

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Karmela Kim Chan, MD
Carole V. Dodge, OTR, CHT
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Karen Smarr, PhD
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#### **Patient Panel**

TBD

#### ACR Staff

Cindy Force Regina Parker Amy Turner



### Project Plan – December 2021

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34 35 36 ORGANIZATIONAL LEADERSHIP AND SUPPORT

3 4	This project is led and funded by the American College of Rheumatology (ACR).
5	BACKGROUND
6	
7	Rheumatoid arthritis (RA) is a chronic, systemic, inflammatory condition that requires early diagnosis,
8	evaluation, and management. Persons with chronic diseases, like rheumatoid arthritis, seek many
9	available therapies to maintain function, reduce pain, and improve their quality of life. These therapies
10	include pharmacologic options for the which the American College of Rheumatology (ACR) has published
11	guidelines to aid patients and clinicians when making a shared decision regarding a treatment approach.
12	Together with pharmacologic treatment options, physical, psychosocial, mind-body, and nutritional
13	interventions are considered as potential adjunctive treatments for RA. Patients and clinicians often
14	seek evidence-based insight into these treatment options. Recognizing the need to support patients and
15	clinicians when considering treatments to complement their pharmacologic regimen, the ACR is
16	developing this guideline for physical, psychosocial, mind-body, and nutritional interventions for the
17	treatment of RA.
18	
19	OBJECTIVES
20	
21	The objective of this project is to develop a clinical practice guideline that includes evidence-based
22	consensus recommendations regarding the use of physical, psychosocial, mind-body, and nutritional
23	interventions for the treatment of rheumatoid arthritis.
24	Consideration was also been
25	Specifically, we aim to:
26	1. Develop recommendations for evidence-based use of effective physical, psychosocial, mind-body,
27 28	and nutritional interventions for the treatment of rheumatoid arthritis, including:  a. Dietary supplement and nutritional options
20 29	, ,,
30	<ul><li>b. Physical activity modalities and rehabilitative approaches</li><li>c. Mind-body activities</li></ul>
31	d. Bracing, splinting and orthotics

e. Psychosocial and vocational treatments

f. Adjunctive therapies (e.g., acupuncture, massage therapy)



### Project Plan – December 2021

37 38	METHODS
39	Identification of Studies
40	Literature search strategies, based on PICO questions (Population/patients, Intervention, Comparator,
41	and Outcomes; see Appendix A) will be developed by the principal investigators, systematic literature
42	review leader, and a research librarian, with input from the Core Team. Searches will be performed in
43	OVID Medline (1946 +), Embase (1974 +), and the Cochrane Central Register of Controlled Trials
44	(CENTRAL).
45	
46	The search strategies will be developed using the controlled vocabulary or thesauri language for each
47	database: Medical Subject Headings (MeSH) for OVID Medline; and Emtree terms for Embase. Text
48	words will also be used in OVID Medline and Embase.
49	
50	Search Limits
51	Only English language articles will be retrieved.
52	
53	Literature Search Update
54	Literature searches will be updated just before the voting panel meeting to ensure completeness.
55	
56	Inclusion/Exclusion Criteria
57	Appendix A includes the project's drafted PICO questions, which outline the defined patient population,
58	interventions, comparators, and outcomes. <i>Appendix B</i> includes the list of inclusion/exclusion criteria.
59	Management of Charles and Date
60	Management of Studies and Data
61	References and abstracts will be imported into bibliographic management software (EndNote) (1),
62	duplicates removed, and exported to Distiller SR, a web-based systematic review manager (2). Screening
63	forms will be created in Distiller SR. Search results will be divided among reviewers, and two reviewers
64 65	will screen each title/abstract, with disagreements at the title/abstract screening stage defaulting to
65 66	inclusion for full manuscript review. Following the same dual review process, disagreements at the full manuscript screening stage will be discussed and adjudicated by the literature review leadership, if
67	necessary.
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1. A search for randomized controlled trials and non-randomized controlled studies will be

performed to determine existing studies covering PICOs of interest.

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70 71 **Phases** 



### Project Plan – December 2021

- Additionally, recently published systematic reviews covering outcomes of interest will also be
   sought and used for reference cross-checking.
  - 3. Included studies will be assessed for risk of bias using modified versions of the Cochrane Risk of Bias tool [3] and the Newcastle-Ottawa Scale [4].
  - 4. Subsequently, identified studies will be assessed using the RevMan (5) and GRADE Pro tools (6).

#### **GRADE Methodology**

GRADE methodology will be used in this project to grade available evidence and facilitate development of recommendations. The certainty of the evidence (also known as 'quality' of evidence) will be graded as high, moderate, low or very low. The recommendations will have a strength, strong or conditional, and a direction, as in favor or against the intervention. The strength of recommendations will not depend solely on the certainty in the evidence, but also on patient preferences and values, and the weight between benefits and harms. A series of articles that describe the GRADE methodology can be found on the GRADE working group's website: <a href="https://www.gradeworkinggroup.org">www.gradeworkinggroup.org</a>.

### Data Analysis and Synthesis

The literature review team will analyze and synthesize data from included studies that address the PICO questions. An evidence profile, including a GRADE Summary of Findings table, will be prepared for each PICO question using Review Manager (RevMan) (5) and GRADEprofiler (GRADEpro) software (6). The Summary of Findings table contains the benefits and harms for each outcome across studies, the assumed and corresponding risk for comparators and interventions (95% CI), the absolute risk and relative effect (95% CI), the number of participants/number of studies, and the certainty in the evidence for each critical and important outcome (i.e., high, moderate, low or very low).

The evidence profile documents the overall certainty in the evidence for each critical and important outcome across studies and summarizes the rationale of the GRADE criteria for downgrading (risk of bias, inconsistency, indirectness, imprecision, and publication bias), or upgrading the certainty in a body of evidence (large magnitude of effect, dose-response gradient, and all plausible confounding that would reduce a demonstrated effect).

#### **Development of Recommendation Statements**



### Project Plan – December 2021

PICO questions will be revised into drafted recommendation statements. Using the GRADE Evidence Profiles and Summaries of Findings tables, the voting panel, consisting of seven rheumatologists, two physical therapists, two occupational therapists, one psychologist, one nurse, one exercise scientist, one nutritionist, and two patient representatives, will consider the drafted recommendation statements in two stages. The first assessment will be done individually, and the results will be anonymous; this vote will only be used to determine where consensus might or might not already exist and develop the voting panel meeting agenda. At the voting panel meeting, chaired by the principal investigators, the panelists will discuss the evidence in the context of their clinical experience and expertise, as well as patient values and preferences, to arrive at consensus on the final recommendations. The voting panel meeting discussions will be supported by the literature review leader, the GRADE expert, and selected members of the literature review team, who will attend the meeting to provide details about the evidence, as requested. Voting panel discussions and decisions will also be informed by a separately convened patient panel, which will meet in the days before the voting panel meeting, to provide unique patient perspectives on the drafted recommendations based on their experiences and the available literature.

#### PLANNED APPENDICES (AT MINIMUM)

- A. Final literature search strategies
- 123 B. Inclusion/Exclusion Criteria
  - C. GRADE evidence profiles and summary of findings tables for each PICO question

#### **AUTHORSHIP**

Authorship of the guideline will include principal investigators Bryant R. England, MD, PhD, and Benjamin J. Smith, DMSc, PA-C; literature review leader Jonathan Treadwell; content experts Jennifer Barton, MD; Carol Oatis, PT, PhD; and Nancy Baker, ScD, MPH, OTR/L; and Gordon Guyatt, MD, GRADE expert. Members of the voting panel and literature review team will also be authors. The PIs will determine final authorship, dependent on the efforts made by individuals throughout the guideline development process, using international authorship standards as guidance.

#### **DISCLOSURES/CONFLICTS OF INTEREST**

The ACR's disclosure and COI policies for guideline development will be followed for this project. These can be found in the ACR Guideline Manual on <a href="mailto:this page of the ACR web site">this page of the ACR web site</a>, under Policies & Procedures. See Appendix C for participant disclosures.



141	REFERENCES	
142		
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145	3.	Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of 239 Interventions
146		Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available:
147		http://handbook.cochrane.org
148	4.	Wells GA, Shea B, O'Connell D, Welch V, Losos M, Tugwell P. The Newcastle-Ottawa Scale (NOS)
149		for assessing the quality of nonrandomised studies in meta-analyses. 2010. Available:
150		http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp
151	5.	Review Manager [software]. <a href="https://training.cochrane.org/online-learning/core-software-">https://training.cochrane.org/online-learning/core-software-</a>
152		cochrane-reviews/revman
153	6.	GRADEprofiler [software]. https://gradepro.org/



## Project Plan – December 2021

<ul> <li>PHYSICAL, PSYCHOSOCIAL, MIND-BODY, AND NUTRITIONAL THERAPIES</li> <li>Nutritional</li> <li>Should patients with RA use a formally defined diet?</li> <li>P - Patients with RA</li> <li>Formally defined diet/diet pattern (anti-inflammatory, Mediterranean, ketogenic, paleo, gluten-free, vegetarian, vegan, intermittent fasting, elemental, elimination, raw foods, whole food plant based)</li> <li>C - Current or alternative diet</li> <li>O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (mortality, CVD, joint replacement)</li> <li>Potential effect modifiers/subgroup analyses: None</li> <li>Should patients with RA use a commercially available dietary supplement?</li> <li>P - Patients with RA</li> <li>I - Dietary supplement (vitamin D, probiotics, fish oil/omega-3 fatty acids, antioxidants [selenium, zinc, vitamin A, vitamin C, vitamin E], turmeric, glucosamine, γ-linolenic acid, borage seed oil, evening primrose oil, black currant seed oil, selenium, Boswellia, ginger, probiotics)</li> <li>C - No specific dietary supplement or other dietary supplement</li> <li>O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (mortality, CVD, joint replacement)</li> <li>Potential effect modifiers/subgroup analyses: None</li> <li>3. Should patients with RA who are overweight or obese</li> <li>I - Weight loss intervention (lifestyle modifications (diet/exercise), weight-loss surgery alone, weight-loss surgery combined with lifestyle modifications, support groups, health coaching, branded dietary weight loss programs)</li> </ul>	154	APPENDIX A – PICO Questions
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<ul> <li>I - Dietary supplement (vitamin D, probiotics, fish oil/omega-3 fatty acids, antioxidants [selenium, zinc, vitamin A, vitamin C, vitamin E], turmeric, glucosamine, γ-linolenic acid, borage seed oil, evening primrose oil, black currant seed oil, selenium, Boswellia, ginger, probiotics)</li> <li>C - No specific dietary supplement or other dietary supplement</li> <li>O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (mortality, CVD, joint replacement)</li> <li>Potential effect modifiers/subgroup analyses: None</li> <li>3. Should patients with RA who are overweight or obese receive a weight loss intervention?</li> <li>P - Patients with RA who are overweight or obese</li> <li>U Weight loss intervention (lifestyle modifications (diet/exercise), weight-loss surgery alone, weight-loss surgery combined with lifestyle modifications, support groups, health coaching, branded dietary weight</li> </ul>		·
<ul> <li>vitamin A, vitamin C, vitamin E], turmeric, glucosamine, γ-linolenic acid, borage seed oil, evening</li> <li>primrose oil, black currant seed oil, selenium, Boswellia, ginger, probiotics)</li> <li>C - No specific dietary supplement or other dietary supplement</li> <li>O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (mortality, CVD, joint replacement)</li> <li>Potential effect modifiers/subgroup analyses: None</li> <li>3. Should patients with RA who are overweight or obese receive a weight loss intervention?</li> <li>P - Patients with RA who are overweight or obese</li> <li>I - Weight loss intervention (lifestyle modifications (diet/exercise), weight-loss surgery alone, weight-loss surgery combined with lifestyle modifications, support groups, health coaching, branded dietary weight</li> </ul>		
<ul> <li>primrose oil, black currant seed oil, selenium, Boswellia, ginger, probiotics)</li> <li>C - No specific dietary supplement or other dietary supplement</li> <li>O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (mortality, CVD, joint replacement)</li> <li>Potential effect modifiers/subgroup analyses: None</li> <li>3. Should patients with RA who are overweight or obese receive a weight loss intervention?</li> <li>P - Patients with RA who are overweight or obese</li> <li>I - Weight loss intervention (lifestyle modifications (diet/exercise), weight-loss surgery alone, weight-loss surgery combined with lifestyle modifications, support groups, health coaching, branded dietary weight</li> </ul>		
<ul> <li>C - No specific dietary supplement or other dietary supplement</li> <li>O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance</li> <li>measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (mortality, CVD, joint replacement)</li> <li>Potential effect modifiers/subgroup analyses: None</li> <li>3. Should patients with RA who are overweight or obese receive a weight loss intervention?</li> <li>P - Patients with RA who are overweight or obese</li> <li>I - Weight loss intervention (lifestyle modifications (diet/exercise), weight-loss surgery alone, weight-loss surgery combined with lifestyle modifications, support groups, health coaching, branded dietary weight</li> </ul>		the state of the s
<ul> <li>O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (mortality, CVD, joint replacement)</li> <li>Potential effect modifiers/subgroup analyses: None</li> <li>3. Should patients with RA who are overweight or obese receive a weight loss intervention?</li> <li>P - Patients with RA who are overweight or obese</li> <li>U- Weight loss intervention (lifestyle modifications (diet/exercise), weight-loss surgery alone, weight-loss surgery combined with lifestyle modifications, support groups, health coaching, branded dietary weight</li> </ul>		
<ul> <li>measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (mortality, CVD, joint replacement)</li> <li>Potential effect modifiers/subgroup analyses: None</li> <li>3. Should patients with RA who are overweight or obese receive a weight loss intervention?</li> <li>P - Patients with RA who are overweight or obese</li> <li>U- Weight loss intervention (lifestyle modifications (diet/exercise), weight-loss surgery alone, weight-loss surgery combined with lifestyle modifications, support groups, health coaching, branded dietary weight</li> </ul>		· · · · · · · · · · · · · · · · · · ·
<ul> <li>joint replacement)</li> <li>Potential effect modifiers/subgroup analyses: None</li> <li>3. Should patients with RA who are overweight or obese receive a weight loss intervention?</li> <li>P - Patients with RA who are overweight or obese</li> <li>U- Weight loss intervention (lifestyle modifications (diet/exercise), weight-loss surgery alone, weight-loss surgery combined with lifestyle modifications, support groups, health coaching, branded dietary weight</li> </ul>		
<ul> <li>Potential effect modifiers/subgroup analyses: None</li> <li>3. Should patients with RA who are overweight or obese receive a weight loss intervention?</li> <li>P - Patients with RA who are overweight or obese</li> <li>U - Weight loss intervention (lifestyle modifications (diet/exercise), weight-loss surgery alone, weight-loss surgery combined with lifestyle modifications, support groups, health coaching, branded dietary weight</li> </ul>		
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<ul> <li>P - Patients with RA who are overweight or obese</li> <li>I - Weight loss intervention (lifestyle modifications (diet/exercise), weight-loss surgery alone, weight-loss surgery combined with lifestyle modifications, support groups, health coaching, branded dietary weight</li> </ul>		2. Chauld nationts with DA who are examinisht or characterists a weight loss intervention?
<ul> <li>180 I - Weight loss intervention (lifestyle modifications (diet/exercise), weight-loss surgery alone, weight-loss</li> <li>181 surgery combined with lifestyle modifications, support groups, health coaching, branded dietary weight</li> </ul>		· · · · · · · · · · · · · · · · · · ·
surgery combined with lifestyle modifications, support groups, health coaching, branded dietary weight		<b>G</b>
183 C - No weight loss intervention		
184 O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance		
measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (mortality, CVD,		

joint replacement)



### *Project Plan – December 2021*

187 188	Potential effect modifiers/subgroup analyses: None
189	Physical Activity
190 191	4. Should patients with RA consistently engage in an aerobic exercise program?
192	P - Patients with RA
193	I – Consistent engagement in an Aerobic exercise program
194	C - No aerobic exercise program or other exercise programs
195	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
196	measures), pain, fatigue, quality-of-life, treatment-related harms, self-efficacy, work status, sleep status,
197	mental health status, long term outcomes (mortality, CVD, joint replacement)
198	Potential effect modifiers/subgroup analyses: functional ability and comorbidities (i.e., knee OA),
199	controlled or uncontrolled RA.
200	
201	5. Should patients with RA engage in an aquatic exercise program?
202	P - Patients with RA
203	I - Aquatic exercise program
204	C - No aquatic exercise program or other exercise programs
205	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
206	measures), pain, fatigue, quality-of-life, treatment-related harms, self-efficacy, work status, sleep status,
207	mental health status, long term outcomes (mortality, CVD, joint replacement)
208	Potential effect modifiers/subgroup analyses: well-controlled vs. uncontrolled RA
209	
210	6. Should patients with RA consistently engage in a resistance training exercise program?
211	P - Patients with RA
212	I - Consistent engagement in a Resistance training exercise program
213	C - No resistance training exercise program or other exercise programs
214 215	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance measures), pain, fatigue, quality-of-life, treatment-related harms, self-efficacy, work status, sleep status,
215	mental health status, long term outcomes (mortality, CVD, joint replacement)
217	Potential effect modifiers/subgroup analyses: functional ability, comorbidities (i.e., knee OA), well-
218	controlled vs. uncontrolled RA
219	Controlled vs. differenced ItA
220	7. Should patients with RA engage in a mind-body exercise program?
221	P – Patients with RA

I – Mind-body exercise program (Yoga, Tai Chi, qigong, Pilates)



### Project Plan – December 2021

223	C – No mind-body exercise program or other exercise programs
224	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
225	measures), pain, fatigue, quality-of-life, treatment-related harms, self-efficacy, work status, sleep status,
226	mental health status, long term outcomes (mortality, CVD, joint replacement)
227	Potential effect modifiers/subgroup analyses: well-controlled vs. uncontrolled RA
228	
229	8. Should patients with RA and hand involvement perform resistive hand exercises?
230	P - Patients with RA and hand involvement
231	I – Resistive hand exercises
232	C - No resistive hand exercises
233	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
234	measures), pain, fatigue, quality-of-life, treatment-related harms, self-efficacy, work status, sleep status,
235	mental health status, long term outcomes (joint replacement)
236	Potential effect modifiers/subgroup analyses: well-controlled vs. uncontrolled RA
237	Bracing/splinting/orthoses
238	9. Should patients with RA and hand/wrist impairment/deformity use
239	splinting/orthoses/compression?
240	P - Patients with RA and hand/wrist impairment/deformity
241	I – Wrist, hand and/or finger splinting/orthoses/compression
242	C - No splinting/orthoses
243	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
244	measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (joint
245	replacement)
246	Potential effect modifiers/subgroup analyses: none
247	
248	10. Should patients with RA and foot/ankle involvement use bracing/orthoses/taping?
249	P - Patients with RA and foot/ankle involvement
250	I – Bracing/orthoses
251	C - No bracing/orthoses/taping
252	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
253	measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (joint
254	replacement)
255	Potential effect modifiers/subgroup analyses: bracing vs. orthoses



### Project Plan – December 2021

11. Should patients with RA and knee involvement use bracing/orthoses?

258 259	P - Patients with RA and knee involvement  I – Bracing/orthoses
260	C - No bracing/orthoses
261	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
262	measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (joint
263	replacement)
264	Potential effect modifiers/subgroup analyses: bracing vs. orthoses
265	Rehabilitation
266	12. Should patients with RA use joint protection techniques?
267	P - Patients with RA
268	I - Joint protection
269	C - No joint protection
270	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
271	measures), pain, fatigue, quality-of-life, treatment-related harms, self-efficacy, work status, sleep status,
272	mental health status, long term outcomes (joint replacement)
273	Potential effect modifiers/subgroup analyses: well-controlled vs. uncontrolled RA
274	
275	13. Should patients with RA use activity pacing/energy conservation/activity modification/fatigue
276	management techniques?
277	P - Patients with RA
278	I – Activity pacing/energy conservation/activity modification/fatigue management techniques
279	C - No Activity pacing
280	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
281	measures), pain, fatigue, quality-of-life, treatment-related harms, self-efficacy, work status, sleep status,
282 283	mental health status, long term outcomes (joint replacement)
284	Potential effect modifiers/subgroup analyses: well-controlled vs. uncontrolled RA
285	14. Should patients with RA use assistive devices?
286	P - Patients with RA
287	I – Assistive devices (crutches, canes, walkers, wheelchairs, tricycles, scooters)
288	C - No assistive devices
	o ito addicate actions



### Project Plan – December 2021

289	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
290	measures), pain, fatigue, quality-of-life, treatment-related harms, self-efficacy, work status, sleep status,
291	mental health status, long term outcomes (joint replacement)
292	Potential effect modifiers/subgroup analyses: None
293	
294	15. Should patients with RA use adaptive equipment?
295	P - Patients with RA
296	I – Adaptive equipment (Eating devices (built up handled cutlery, plates, cups), bathing devices (long
297	handled sponges, wash mitt) dressing (long handled shoehorn, dressing stick, reacher, sock aide, button
298	hook), grooming (tube dispenser/squeezer, adapted flosser, adapted nail clipper, long handled
299	comb/brush), large button telephones, built up handles, knob turners, pill cutters, large size pill
300	organizer, universal cuff, leg lifter, cellphone holder)
301	C - No adaptive devices
302	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
303	measures), pain, fatigue, quality-of-life, treatment-related harms, self-efficacy, work status, sleep status,
304	mental health status, long term outcomes (joint replacement)
305	Potential effect modifiers/subgroup analyses: None
306	
307	16. Should patients with RA use environmental adaptations?
308	P - Patients with RA
309	I – Environmental adaptation (Toileting: Raised toilet seat, commode, toilet safety rail; Showering: tub
310	seat, handheld shower, walk in bath; Grab bars; Ramps; Stairglide; Home modification)
311	C - No Environmental adaptations
312	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
313	measures), pain, fatigue, quality-of-life, treatment-related harms, self-efficacy, work status, sleep status,
314	mental health status, long term outcomes (joint replacement)
315	Potential effect modifiers/subgroup analyses: None
316	
317	17. Should patients with RA participate in comprehensive occupational therapy?
318	P - Patients with RA
319	I - Comprehensive occupational therapy
320	C - No comprehensive occupational therapy
321	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
322	measures), pain, fatigue, quality-of-life, treatment-related harms, self-efficacy, work status, sleep status,
323	mental health status, long term outcomes (joint replacement)
324	Potential effect modifiers/subgroup analyses: None



326 327 328 329 330 331 332	Comprehensive OT: Evaluated by Occupational Therapist for functional status with the goal of increasing function/participation. Receives patient-centered individualized treatment. Components of OT services vary and may include: arthritis education, ADL training, joint protection, ergonomic training (joint protection techniques), fatigue management, exercise (particularly for the hand and arm), splinting/orthotics, provision of assistive/adaptive devices, work and leisure counselling/rehabilitation, sexual advice, relaxation, and pain and stress management training.
333	18. Should patients with RA participate in a comprehensive physical therapy program?
334	P - Patients with RA
335	I - Comprehensive physical therapy program
336	C - No comprehensive physical therapy
337 338	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance measures), pain, fatigue, quality-of-life, treatment-related harms, self-efficacy, work status, sleep status,
339	mental health status, long term outcomes (joint replacement)
340	Potential effect modifiers/subgroup analyses: None
341	
342	Comprehensive PT: Evaluated and treated by a physical therapist. Some of the literature uses "physical
343	therapy" as synonymous with exercise and should not be included in the PT PICOs. Components of PT
344 345	services will vary and hopefully can be identified by reviewers. Should include exercise. May also include functional training and physical activity, energy conservation, workplace accommodations, mobility and
346	gait training, manual therapy, self-management education, pain-management including thermal
347	therapy, electrotherapy, application of orthoses, instruction in assistive devices
348	Psychosocial and vocational
349	19. Should patients with RA use a standardized, evidence-based self-management program?
350	P - Patients with RA
351	I – Any of the available standardized self-management programs (e.g., Arthritis Self-Management
352	Program, Chronic Disease Self-Management Program, Better Choices Better Health; Tomando Control
353	de su Salud; RA Self-Management Intervention, OPERAS [an On-demand Program to EmpoweR Active
354	Self-management, peer mentoring/support groups])
355	C - No standardized self-management program
356	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
357	measures), pain, fatigue, quality-of-life, treatment-related harms, self-efficacy, work status, sleep status,
358	mental health status, long term outcomes (joint replacement)
359	Potential effect modifiers/subgroup analyses: disease duration



## Project Plan – December 2021

360 361 362 363 364 365 366 367 368 369 370	<ul> <li>20. Should patients with RA use mind-body approaches?</li> <li>P - Patients with RA</li> <li>I - Mind-body approaches (cognitive behavioral therapy, biofeedback, goal setting, meditation, mindfulness, breathing exercises, progressive muscle; guided imagery (GI); relaxation guided imagery (RGI)</li> <li>C - No mind-body approaches or alternative mind-body approaches</li> <li>O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance measures), pain, fatigue, quality-of-life, treatment-related harms, self-efficacy, work status, sleep status mental health status, long term outcomes (joint replacement)</li> <li>Potential effect modifiers/subgroup analyses: type of mind-body intervention</li> </ul>
370	Fotential effect mounters/subgroup analyses. type of mind-body intervention
372 373	21. Should patients with RA, who are currently employed or want to become employed, use vocational rehabilitation?
374 375	P - Patients with RA, who are currently employed or want to become employed I - Work interventions
376	C - No work interventions
377 378 379 380 381 382	O - Work-related outcomes (presenteeism, absenteeism, work satisfaction, work underemployment, work disability [e.g., Workplace Activity Limitations Scale (WALS), Work Instability Scale (WIS), Work Limitations Questionnaire (WLQ) Work Productivity and Activity Impairment Questionnaire (WPAI), Rheumatoid Arthritis Specific Work Productivity Survey (WPS-RA)], quality-of-life Potential effect modifiers/subgroup analyses: None
383	22. Should patients with RA, who are currently employed or want to become employed, receive work
384 385 386 387 388 389 390 391	site evaluations and modifications?  P - Patients with RA, who are currently employed or want to become employed  I - Work site evaluations and modifications  C - No work site evaluations  O - Work-related outcomes (presenteeism, absenteeism, work disability [e.g., Workplace Activity Limitations Scale (WALS), Work Instability Scale (WIS), Work Limitations Questionnaire (WLQ) Work Productivity and Activity Impairment Questionnaire (WPAI), Rheumatoid Arthritis Specific Work Productivity Survey (WPS-RA)]), quality-of-life
392	Potential effect modifiers/subgroup analyses: none



### Project Plan – December 2021

394	23. Should patients with RA use acupuncture?
395	P - Patients with RA
396	I - Acupuncture
397	C - No acupuncture
398	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
399	measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (joint
400	replacement)
401	Potential effect modifiers/subgroup analyses: None
402	
403	24. Should patients with RA receive massage therapy?
404	P - Patients with RA
405	I – Massage therapy
406	C - No massage therapy
407	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
408	measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (joint
409	replacement)
410	Potential effect modifiers/subgroup analyses: None
411	
412	25. Should patients with RA receive thermal modalities?
413	P - Patients with RA
414	I – Thermal modalities (cryotherapy, heat, therapeutic ultrasound, infrared sauna)
415	C - No thermal modalities
416	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
417	measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (joint
418	replacement)
419	Potential effect modifiers/subgroup analyses: Type of thermal modality (i.e., heat vs cold)
420	
421	26. Should patients with RA receive electrotherapy?
422	P - Patients with RA
423	I – Electrotherapy (TENS, NEMS, vagal nerve stimulation)
424	C - No electrotherapy
425	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
426	measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (joint
427	replacement)
428	Potential effect modifiers/subgroup analyses: None
429	



431	P - Patients with RA
432	I – Chiropractic therapy / manipulation
433	C - No chiropractic therapy
434	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
435	measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (joint
436	replacement)
437	Potential effect modifiers/subgroup analyses: None
438	Other
439	28. Should patients with RA who are current smokers engage in a smoking cessation program?
440	P - Patients with RA who are current smokers
441	I - Smoking cessation program (counseling, nicotine replacement therapy, quit lines, apps)
442	C - No smoking cessation program
443	O - Disease activity, radiographic progression, functional status (HAQ, PROMIS, ADLs, performance
444	measures), pain, fatigue, quality-of-life, treatment-related harms, long term outcomes (mortality, CVD
445	Potential effect modifiers/subgroup analyses: None



446	<u>AP</u>	PENDIX B – INCLUSION/EXCLUSION CRITERIA
447		
448	Th	e purpose of this clinical practice guideline is to provide evidence-based
449	red	commendations regarding the physical, psychosocial, mind-body, and nutritional
450	int	erventions for the treatment of RA.
451	Ве	low are the inclusion and exclusion criteria reviewers will consider when reviewing
452	titl	les/abstracts and full manuscripts.
453	1.	Study must have had a full journal publication; studies published only as meeting
454		abstracts will be excluded.
455		
456	2.	Study must be an English language publication.
457		
458	3.	Study must include a population, intervention, comparison, and outcome specified in
459		the protocol.
460		
461	4.	Population studied must include adults with rheumatoid arthritis. If patients with
462		other conditions were included in the study, either they must have represented less
463		than 20% of the enrolled population, or data must be able to be extracted for only the
464		subset of patients with rheumatoid arthritis.
465		
466	5.	The following study designs may be included:
467		a. Randomized controlled trial
468		b. Controlled clinical trial
469		c. Prospective controlled cohort study
470		d. Retrospective controlled cohort study
471		e. Systematic review
472		i. Systematic reviews will be included only to scan reference lists to capture
473		relevant individual studies that may have been missed by the literature
474		search.
475		
476	6.	Studies of the following designs should be excluded:
477		a. Pre-post studies



478	b.	Single-arm studies/Case series
479	C.	Case report (N=3 or less)
480	d.	Narrative review
481	e.	Editorials or commentaries
482	f.	Surveys
483	g.	Cross-sectional studies
484	h.	Qualitative studies
485	i.	Expert opinion
486	j.	Foreign language studies
487	k.	Studies of risk factors or drug adherence
488	I.	Non-interventional studies
489	m.	Cost-effectiveness studies
490	n.	Abstracts
491	0.	Follow-up less than 12 weeks
492	p.	N<10 at follow-up
493	q.	Animal study
494		



Project Plan – December 2021

#### **APPENDIX C: DISCLOSURES**

# Participant Disclosures - 2022 American College of Rheumatology (ACR) Guideline for Physical, Psychosocial, Mind-body, and Nutritional Interventions for RA: An Integrative Approach to Treatment

In order for the College to most effectively further its mission and to otherwise maintain its excellent reputation in the medical community and with the public, it is important that confidence in the College's integrity be maintained. The cornerstone of the ACR's Disclosure Policy is disclosure of actual and potential conflicts so that they can be evaluated by the College in order to avoid undue influence of potential conflicts. The purpose of the ACR's Disclosure Policy is identification of relationships which may pose actual or potential conflicts. These actual or potential conflicts can then be evaluated by the College so that adjustments can be made that will avoid any undue influence. This policy is based on the principle that, in many cases, full disclosure of the actual or potentially conflicting relationship will of itself suffice to protect the integrity of the College and its interests.

Participants	Role	Primary Employer	Interest Held By	Interest Type	Entity/Licensee	Additional Information	Value
Bryant England	Core Team - Co-PI	University of Nebraska	Self	Grant / Contract	Boehringer Ingelheim		\$287,000.00
			Self	Independent Contractor - Speaking engagement	Boehringer Ingelheim		
			Self	Intellectual Property - Other Intellectual Property			
			Self	Independent Contractor - Editorial Board Member	Arthritis Care Research		
Ben Smith	Core Team - Co-PI	Florida State University	Self	Employment	Florida State University		
			Self	Independent Contractor - Voting Panel Member, RA, gout, and vaccine guidelines	American College of Rheumatology		
			Self	Independent Contractor - Task Force Chair	American Academy of Physician Assistants		
			Self	Fiduciary Officer	nccPA Health Foundation		



			Self	Fiduciary Officer	National Commission on Certification of Physician Assistants		
			University	Grant / Contract	Health Resources and Services Administration		\$3,750,000.00
Nancy Baker	Core Team - Content Expert	Tufts University	Self	Grant / Contract	OERC		\$25,000.00
			Self	Grant / Contract	Tufts University		\$10,000.00
			Self	Independent Contractor - Secretary of AOTF Board	AOTF		
			Self	Grant / Contract	Tufts University		\$8,000.00
			Self	Independent Contractor - Consultant	American College of Rheumatology		\$1,000.00
			Self	Employment	Tufts University		
			Self	Grant / Contract	Tufts University		\$35,000.00
			Self	Independent Contractor - Consultant	USBJI		\$2,000.00
			Self	Grant / Contract	Encompass HealthSystems		\$8,850.00
Jennifer Barton	Core Team - Content Expert	U.S. Department of Veterans Affairs	Self	Grant / Contract	U.S. Department of Veterans Affairs		\$1,197,000.00
			Self	Independent Contractor - Editorial Board Member	Arthritis Care & Research	Editorial board member	
			Self	Employment	U.S. Department of Veterans Affairs		
Carol Oatis	Core Team - Content Expert	Arcadia University	Self	Independent Contractor - Consultant	Northwestern University		\$28,000.00
			Self	Intellectual Property - Other Intellectual Property		Royalties	



			Self	Independent Contractor - Consultant	Brown University		\$700.00
Jonathan Treadwell	Core Team - Literature Review Leader	ECRI Institute				Nothing to disclose	
Gordon Guyatt	Core Team - GRADE Expert	McMaster University				Nothing to disclose	
Barbara Slusher	ACR Board of Directors Liaison	MD Anderson Cancer Center				Nothing to disclose	
Rawan Alheresh	Lit Review Team	MGH Institute of Health Professions	Self	Employment	MGH Institute of Health Professions		
			Self	Grant / Contract	MGH Institute of Health Professions		\$90,000.00
Kamil Barbour	Lit Review Team	US Centers for Disease Control and Prevention				Nothing to disclose	
Thomas Bye	Lit Review Team	University of Delaware				Nothing to disclose	
Dana Guglielmo	Lit Review Team		Self	Employment	Centers for Disease Control and Prevention		
			Self	Independent Contractor - Volunteer - Operations Coordinator	Centers for Disease Control and Prevention		
Rebecca Haberman	Lit Review Team	NYU Langone Health				Nothing to disclose	
Tate Johnson	Lit Review Team	University of Nebraska Medical Center				Nothing to disclose	
Anatole Kleiner	Lit Review Team	University of Rochester Medical Center				Nothing to disclose	
Chris Lane	Lit Review Team	University of North Carolina at Chapel Hill				Nothing to disclose	



Linda Li	Lit Review Team	Arthritis Research Canada				Nothing to disclose	
Hiral Master	Lit Review Team	Vanderbilt University Medical Center, VICTR				Nothing to disclose	
Theresa Wampler Muskardin	Lit Review Team	NYU Langone Health	Self	Grant / Contract	NYU Colton Center for Autoimmunity	Co-PI: Wieqiang Chen, PhD. Rheumatoid arthritis synovium-on-a- chip (pannus-on-a-chip) development.	\$100,000.00
			Self	Employment	NYU Langone Medical Center		
			Self	Employment	NYU Grossman School of Medicine		
			Self	Independent Contractor - Committee member	Childhood Arthritis Rheumatology Research Alliance		
			Self	Grant / Contract	Doris Duke Charitable Foundation	Funding for technician support and core lab services.	\$122,734.00
			Self	Grant / Contract	Childhood Arthritis Rheumatology Research Alliance	10% of salary support (up to NIH cap) per year	\$60,000.00
Daniel Pinto	Lit Review Team	Marquette University	Self	Employment	Marquette University	Full time faculty	
				Independent Contractor - Project Lead	Patient Centered Outcomes Research Institute (PCORI)	20% effort	
				Independent Contractor - Consultant	Agency for Healthcare Research and Quality		\$19,000.00
				Independent Contractor - Site Primary Investigator	National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)	10% effort for project	



				Independent Contractor - Consultant	Viatris	Honorarium for the talk	\$1,300.00
Janet Poole	Lit Review Team	University of New Mexico	Self	Fiduciary Officer	Scleroderma Foundation		
			Self	Fiduciary Officer	American Occupation al Therapy Foundation		
Kimberly Steinbarger	Lit Review Team	Husson University	Self	Employment	Husson University	My place of full-time employment	
			Self	Intellectual Property - Other Intellectual Property		Self and Drexel University, where I will receive my doctorate in 2020	
Daniel Sztubinski	Lit Review Team	ECRI Institute				Nothing to disclose	
Louise Thoma	Lit Review Team	University of North Carolina at Chapel Hill	Self	Independent Contractor - Consultant	Brown University		\$5,408.00
Vlad Tsaltskan	Lit Review Team	University of California, San Diego	Self	Employment	School of Medicine, University of California, San Diego		
Marat Turgunbaev	Lit Review Team	American College of Rheumatology				Nothing to disclose	
Courtney Wells	Lit Review Team	University of Wisconsin, River Falls	Self	Employment	University of Wisconsin-River Falls		
Allen Anandarajah	Voting Panel	University of Rochester School of Medicine and Dentistry				Nothing to disclose	



Kristine Carandang	Voting Panel	Sel	elf	Employment	Global Healthy Living Foundation	Patient Expert for EA- PPRN-00047: Diversifying, Expanding and Tracking Patient Engagement In Arthritis Research; PCORI COVID-19- Related Enhancement for Existing Engagement Award. Commitment of 24 hours @\$200.00 per hour. Project completed.
		Sel	elf	Independent Contractor - Live Yes! Connect Facilitator	Arthritis Foundation	No compensation.
		Sel	elf	Employment	University of California, San Diego	
		Sel	elf	Employment	Children's Hospital of Philadelphia	Fee of \$40.39 per hour for 96 hours; Consulted on qualitative methods, including qualitative study design, facilitation guide creation, interviewing, analysis, and dissemination. Project completed.



			Self	Grant / Contract	Childhood Arthritis and Rheumatology Research Alliance	Principal Investigator. Original contract date June 1, 2019-May 31, 2020. No-cost extension from June 1, 2020-May 31, 2021. Grant completed.	\$25,000.00
			Self	Grant / Contract	Patient-Centered Outcomes Research Institute	Position: Co-Lead; Hourly Rate: \$45/Hour; Time Commitment: 25% FTE Income disbursed through University of Wisconsin-River Falls (Independent Consultant)	\$243,450.00
			Self	Independent Contractor - End Point Review Committee	Childhood Arthritis and Rheumatology Research Alliance		
Karmela Kim Chan	Voting Panel	Hospital for Special Surgery				Nothing to disclose	
Carole V. Dodge	Voting Panel	University of Michigan Hospital and Health System				Nothing to disclose	
Anita Bemis Dougherty	Voting Panel	American Physical Therapy Association (APTA)	Self	Employment	American Physical Therapy Association		
Sotiria Everett (Tzakas)	Voting Panel	Stony Brook University				Nothing to disclose	
Nadine Fisher	Voting Panel	University of Buffalo	Self	Employment	University at Buffalo		



Liana Fraenkel	Voting Panel	Yale	Self	Independent Contractor - Consultant	MyMee	(Total compensation to date (6/9/2021)	\$1,875.00
			Self	Grant / Contract	American College of Rheumatology Rheumatology Research Foundation		\$400,000.00
Susan Goodman	Voting Panel	Hospital for Special Surgery	Self	Grant / Contract	Novartis		\$601,771.00
			Self	Independent Contractor - Data And Safety Monitoring	UCB Biosciences Inc.		\$5,000.00
Victoria Menzies	Voting Panel	University of Florida	Self	Independent Contractor - Consultant	Biological Research for Nursing		
			Self	Employment	University of Florida		
Larry Moreland	Voting Panel	University of Colorado Anschutz Medical Campus				Nothing to disclose	
Iris Navarro- Millan	Voting Panel	Weill Cornell Medicine				Nothing to disclose	
Namrata Singh	Voting Panel		Self	Grant / Contract	American Heart Association		\$200,000.00
			Self	Grant / Contract	Rheumatology Research Foundation		\$375,000.00
Karen Smarr	Voting Panel	University of Missouri	Self	Independent Contractor - Editorial Board Member	Arthritis Care and Research journal Editorial Board	Volunteer role. Dates are based on by best recollection, unable to locate letter from Marian Hannan, PhD who was the editor of AC&R when agreed to serve on editorial board.	
Dan White	Voting Panel	University of Delaware				Nothing to disclose	



Neha Shah	Consultant	Stanford Medicine	Spouse/ Partner	Stock Option	Impossible Foods	
			Self	Stock Option	Upside Foods	