

# Evaluation of perspectives about clinical trial design from patients with pain, depression and/or anxiety as a component of patient engagement: a systematic scoping review

McKenzie Ferguson, PharmD, BCPS

Southern Illinois University Edwardsville

Ewan McNicol, PharmD

Massachusetts College of Pharmacy and Health Sciences (MCPHS) University

Annie Kleykamp, PhD

Karin Sandoval, PhD, MPH

# Objective

Summarize patient perspectives, facilitators and barriers to study participation from studies of human participants of all ages with pain-related conditions, depression and/or anxiety.

# Methods

## Inclusions

- Patient-specific preferences related to clinical trial design for the treatment of any pain condition OR depression OR anxiety
- Patient-specific preferences related to participation in clinical trials (barriers, time, etc.)

## Exclusions

- Treatment preferences or goals of therapy, only
- Researcher preferences
- Mixed samples of patients and clinicians
- Studies reporting attrition without any other data or qualitative component

# Literature Search

PubMed/PSYCHInfo/CINAHL/Cochrane CENTRAL

patient  
participant



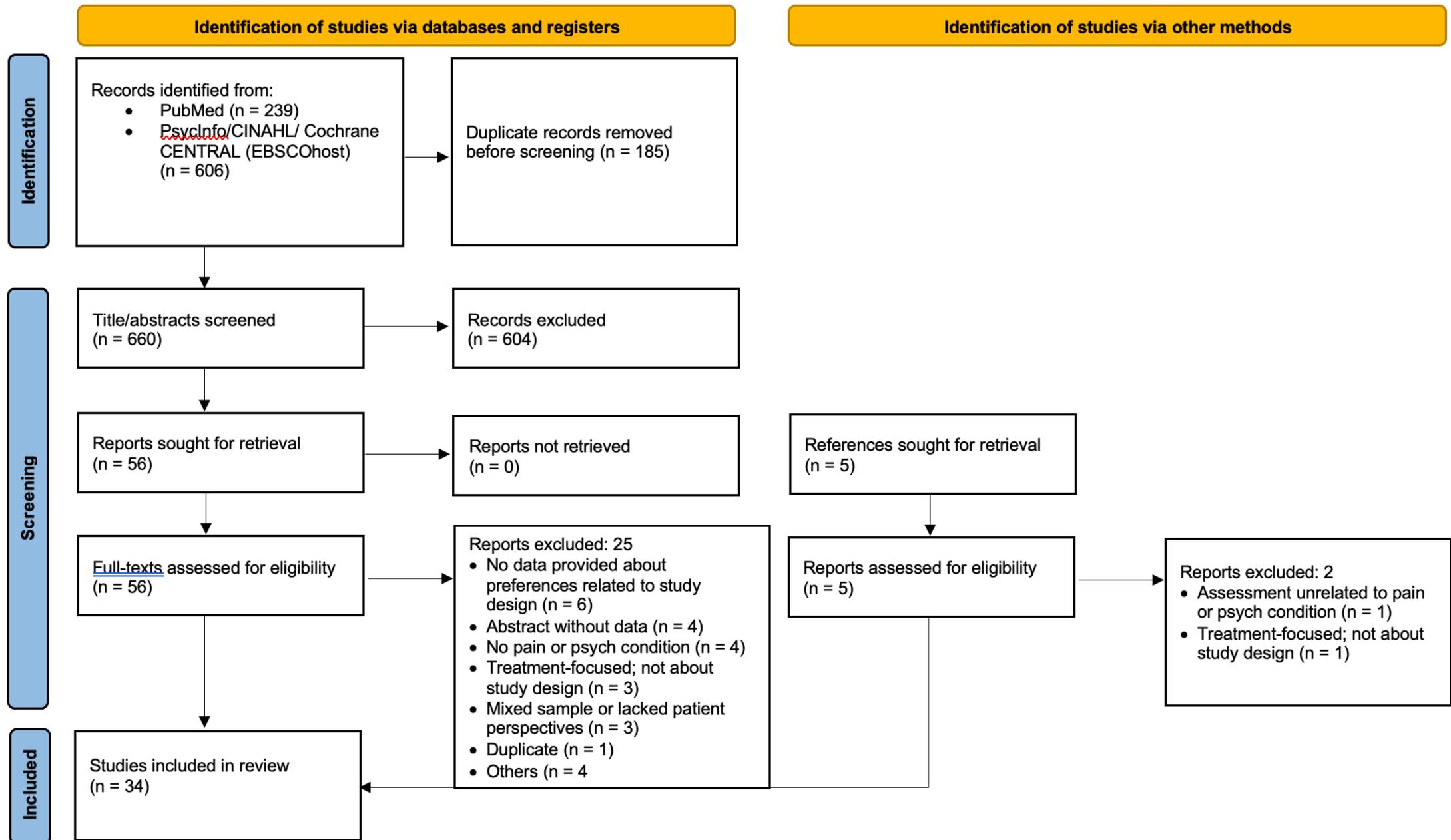
engagement  
preference  
acceptability  
beliefs  
attitude  
attitudes  
perspective  
perspectives  
engagement  
perspective\*  
attitude\*  
belief\*  
opinion\*  
feeling\*  
preference\*  
view\*



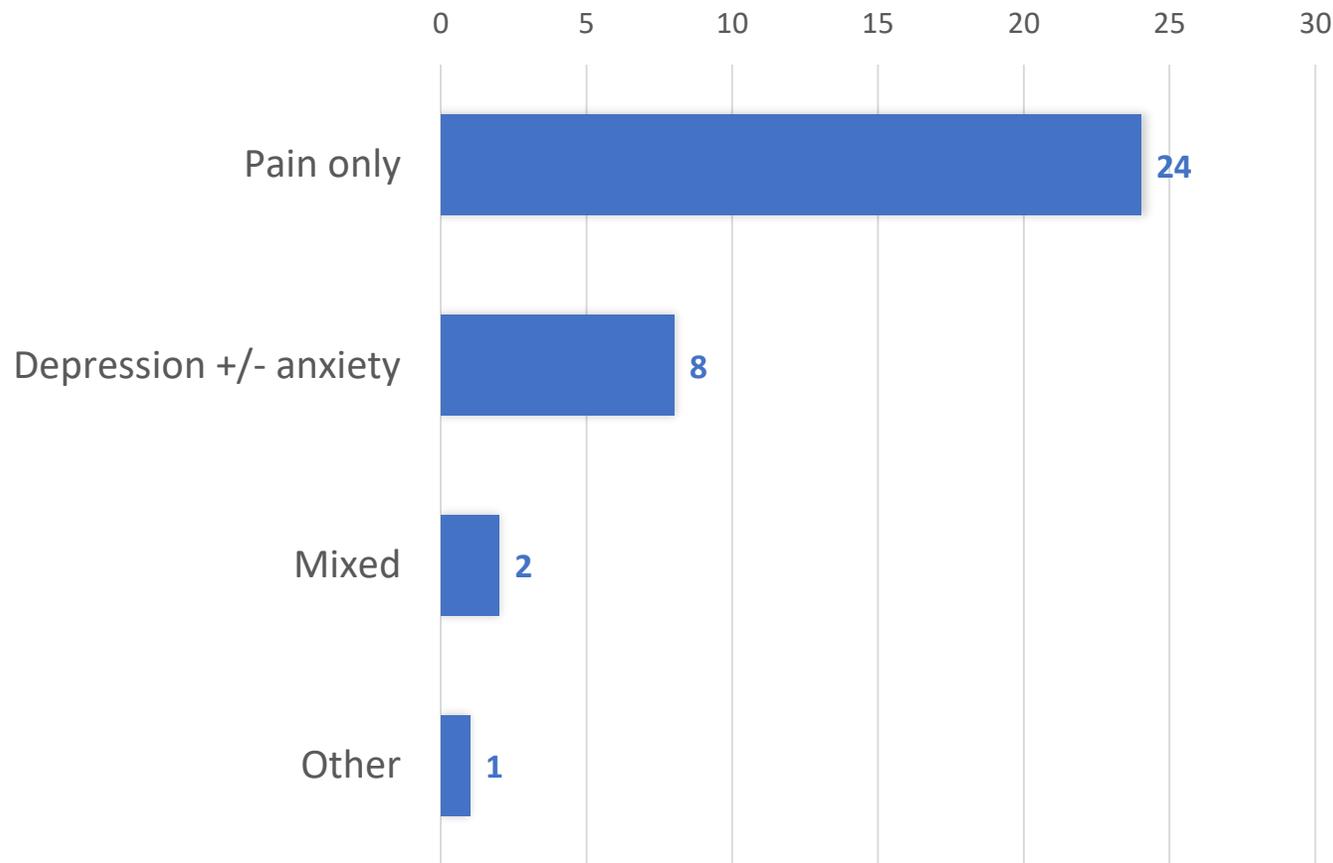
trial  
clinical trials  
trial design  
clinical trial design  
trial  
trial\*  
conjoint analysis



depression  
anxiety  
pain  
migraine  
arthritis  
chronic pain (MeSH)



# Findings – Study Features



Juvenile arthritis (3)

Osteoarthritis (3)

Pelvic pain (including endometriosis) (3)

Back and/or joint not otherwise specified (2)

Chronic pain not otherwise specified (2)

Headache (including migraine) (2)

Acute coronary syndrome; chest pain

Cancer

Duchenne muscular dystrophy (DMD)

End of life

Gout

Rheumatoid arthritis

Sickle cell

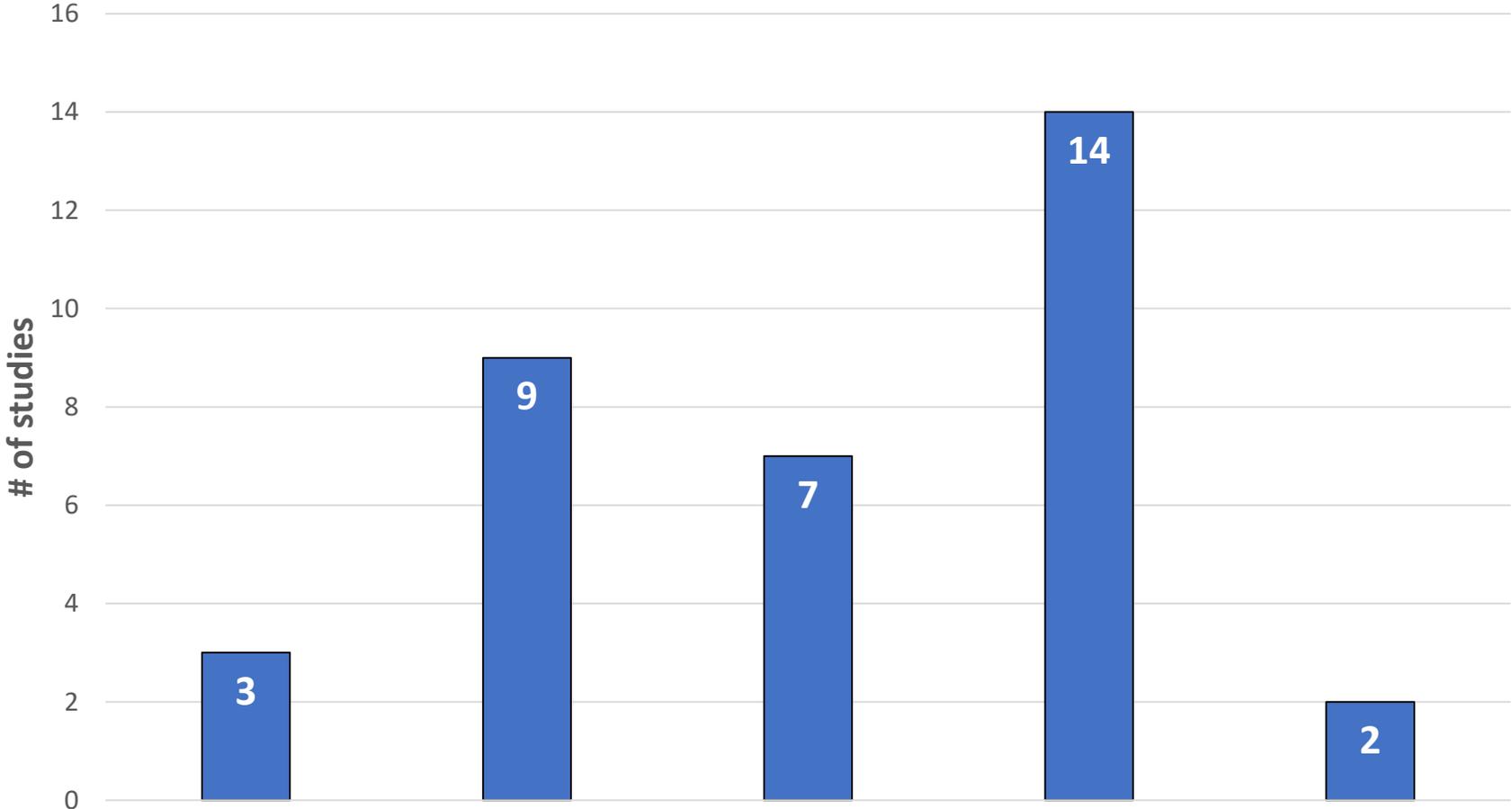
Spinal stenosis

Rheumatoid arthritis; fibromyalgia

Back and/or joint not otherwise specified; musculoskeletal not otherwise specified; osteoarthritis; fibromyalgia; neuropathic pain not otherwise specified; chronic pain not otherwise specified; CRPS; "multiple" (not otherwise defined)

Osteoarthritis; rheumatoid arthritis; headache (including migraine); cancer; neck or shoulder pain not otherwise specified; back and/or joint not otherwise specified; fibromyalgia; neuropathic pain not otherwise specified; "other"

# Study Methods



## Sample Size

Study Method	N	Range	Mean
Focus Groups	3	14-50	32
Individual interviews	9	5-258	72
Mixed	7	13-25	22
Survey	14	51-959	347

# Findings – Study Features

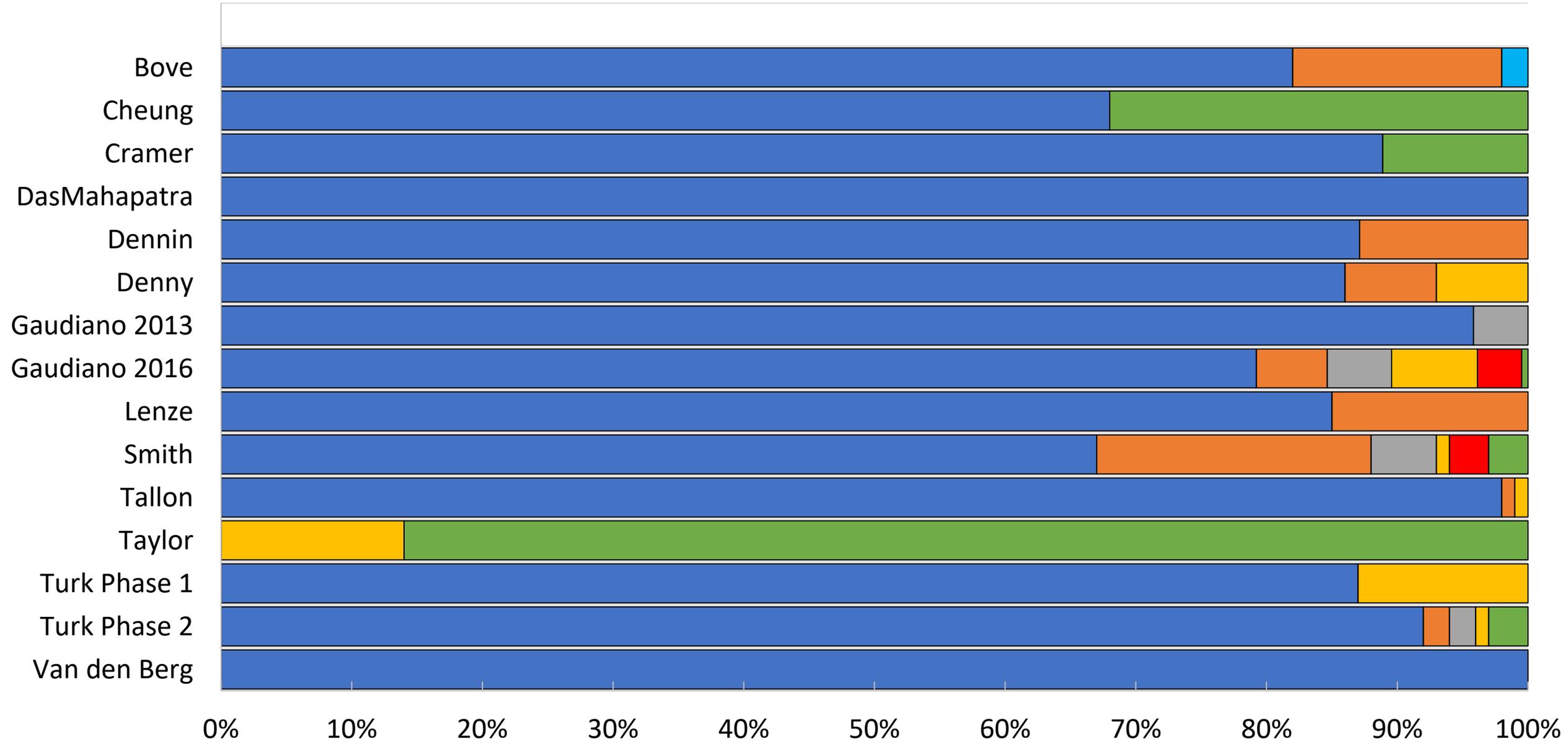
- 23/35 (66%) assessed perspectives as the primary objective
- 12/35 (34%) were pilot/feasibility studies (3 depression)
- 21/35 (60%) study *sites* were located in metropolitan areas
- Only one study described where the *sample* was from (rural/urban)
- 21/35 (60%) were conducted outside the U.S. (only)

# Findings – Study Features

- 23/35 (65%) utilized active recruitment
  - 5/35 (14%) used both active and passive techniques for recruitment (mixed)
- 17/35 (49%) noted that some or all participants had current/past participation in clinical research studies
- Age group of perspectives
  - 26/35 (74%) adults
  - 2/35 (6%) pediatric
  - 5/35 (14%) mixed
  - 2/35 (6%) not stated
- Within studies that quantified sex, most study samples were predominantly female 26/28 (93%)

# Race Distributions

White/Caucasian Black/African-American Hispanic/Latino Asian Multiple Others Not Provided

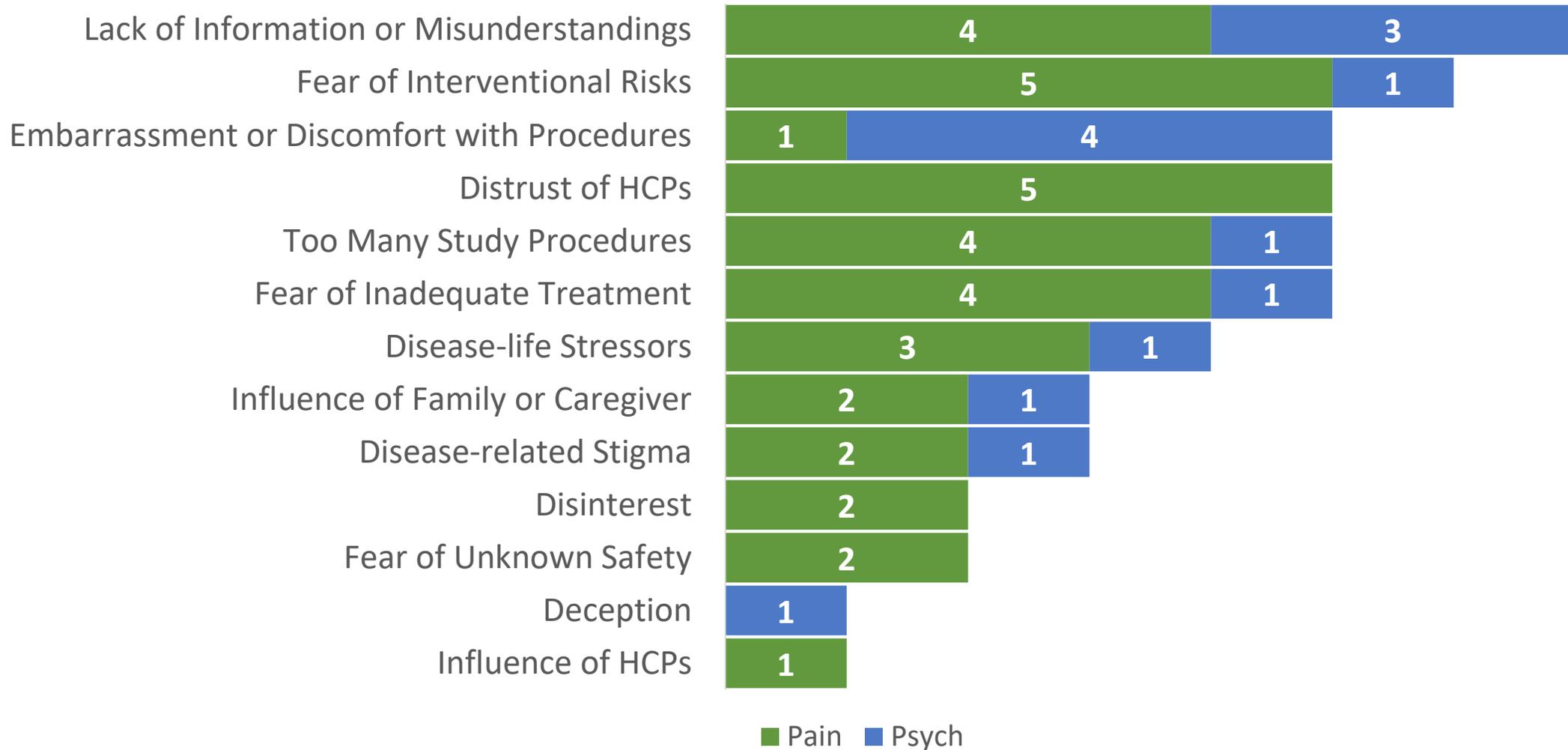


# Findings – Study Features

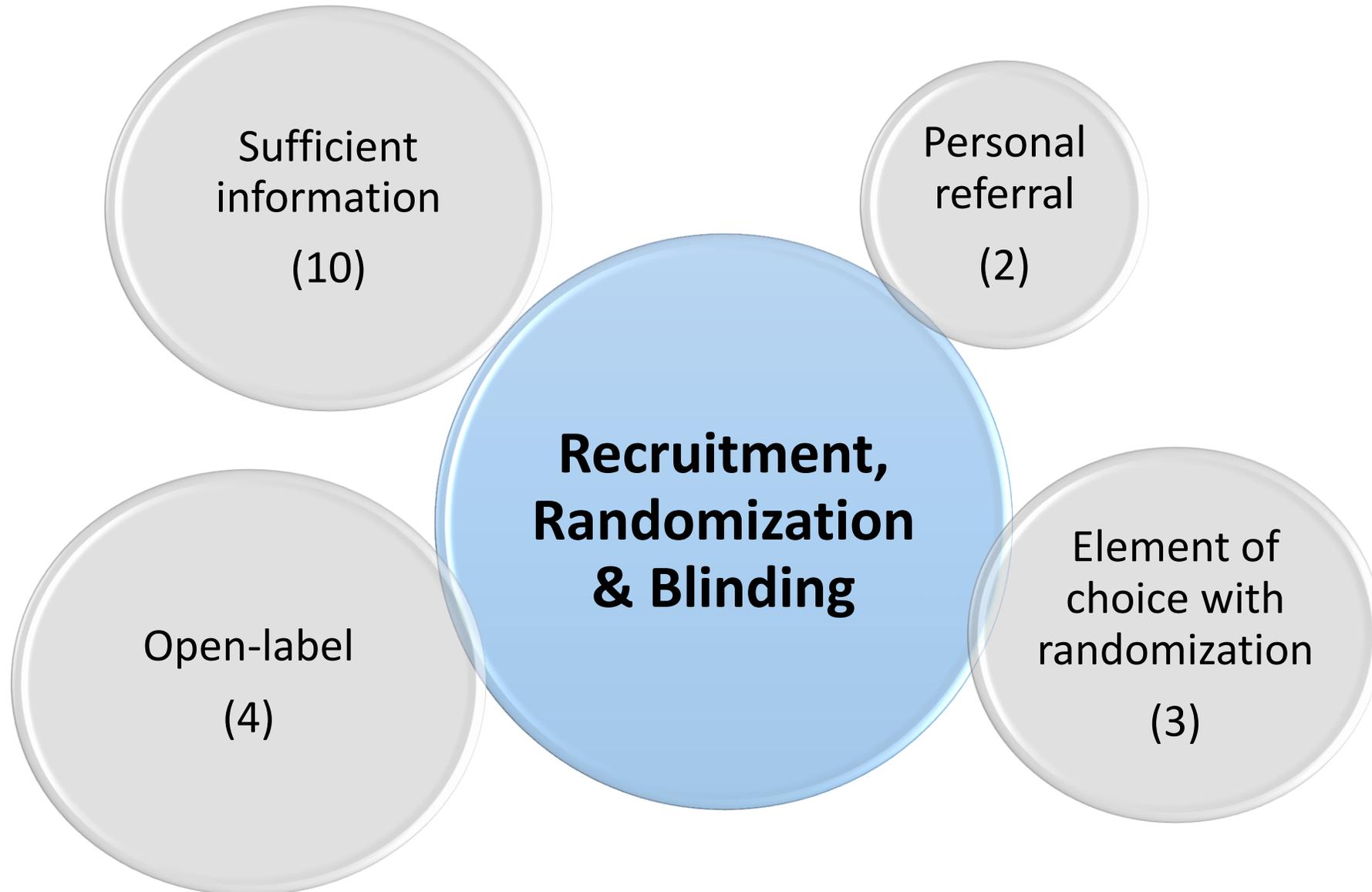
# Reporting	
12/35 (34%)	Educated $\geq$ high school (9/12)
10/35 (29%)	Lived with spouse, caregiver, or parent
10/35 (29%)	Employment inconsistently reported; 4 of these captured disability in this reporting
12/35 (34%)	Disease severity inconsistently reported

# Barriers to Participation

# Studies

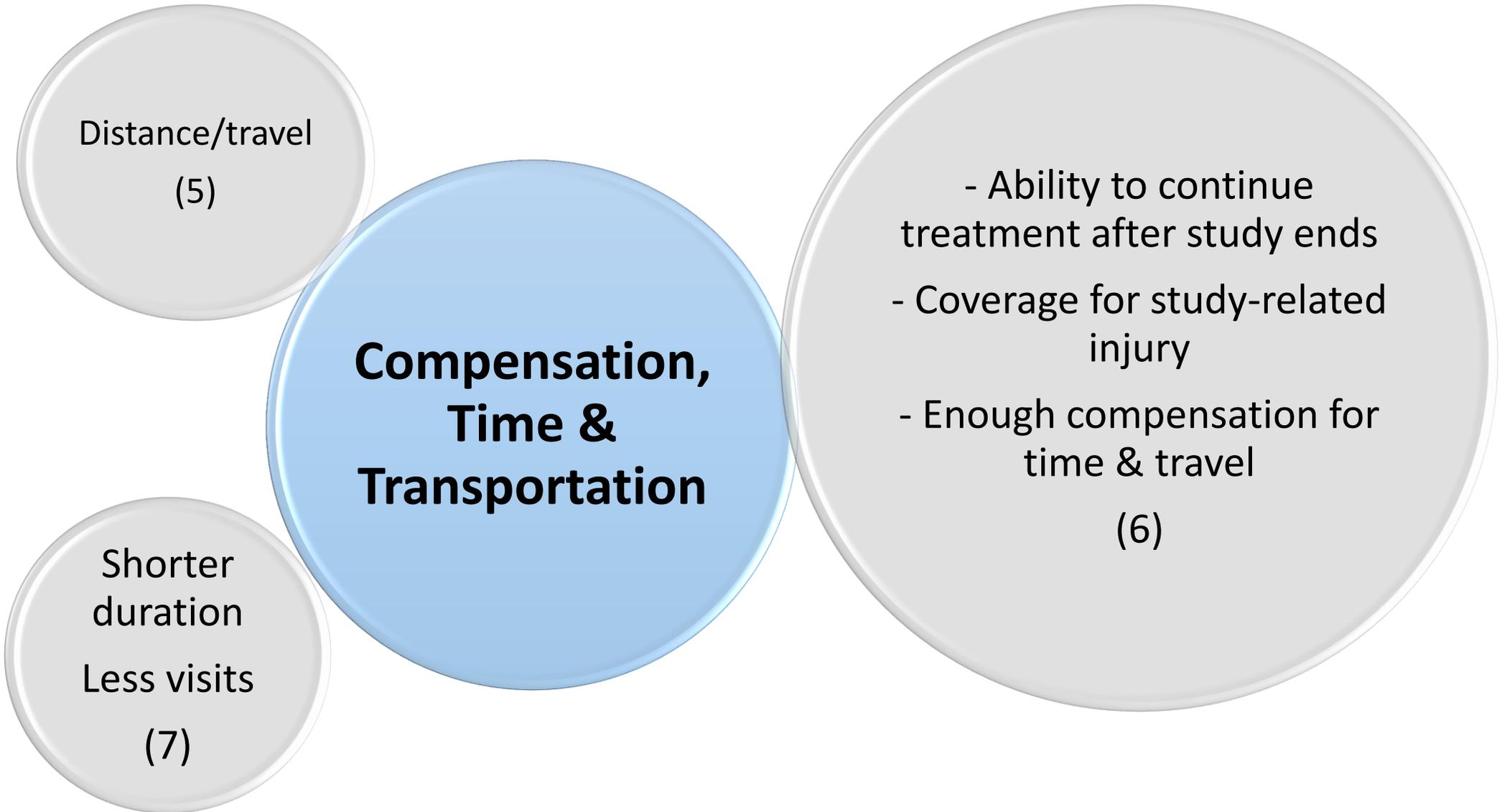


# Participant Preferences

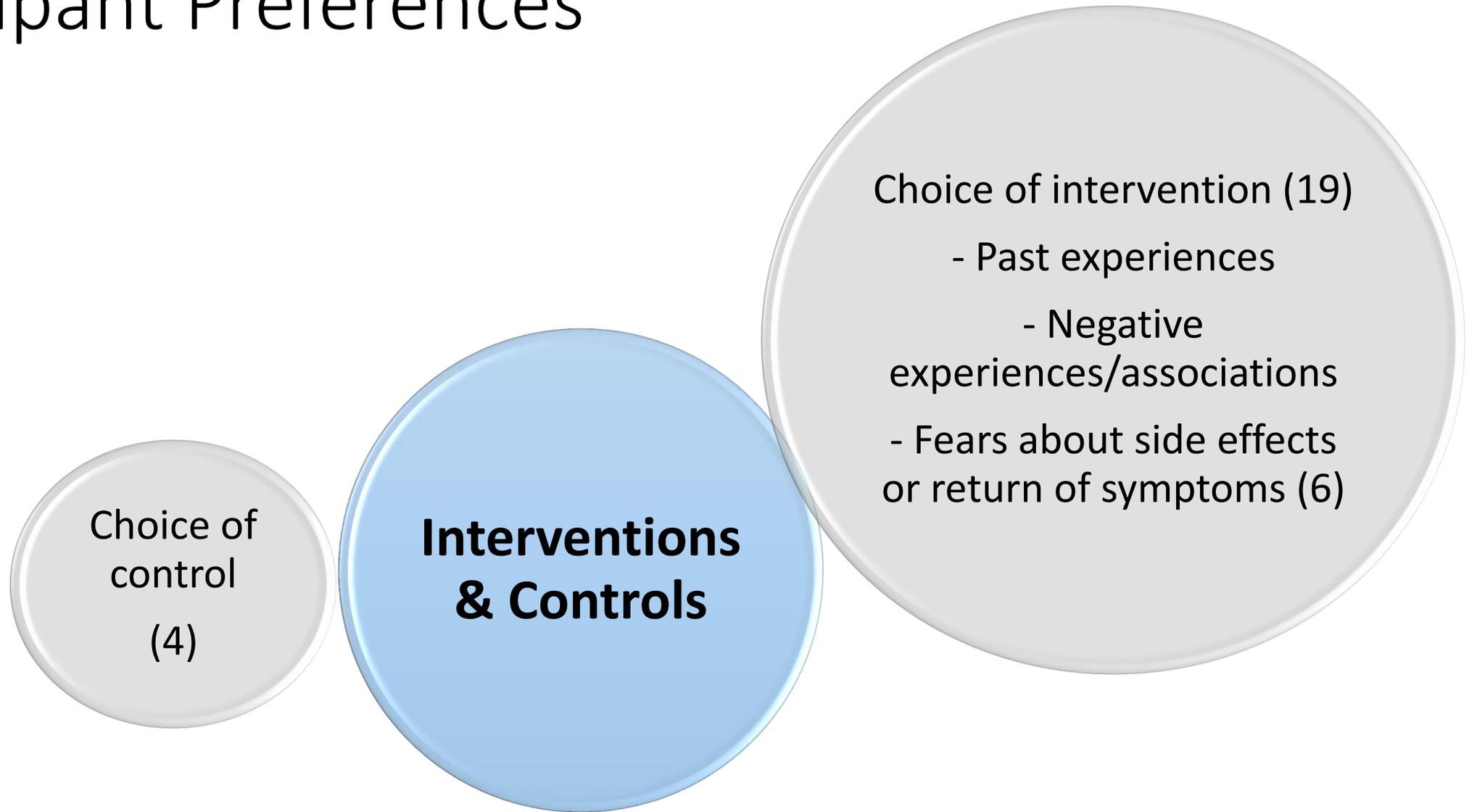


(# of studies)

# Participant Preferences

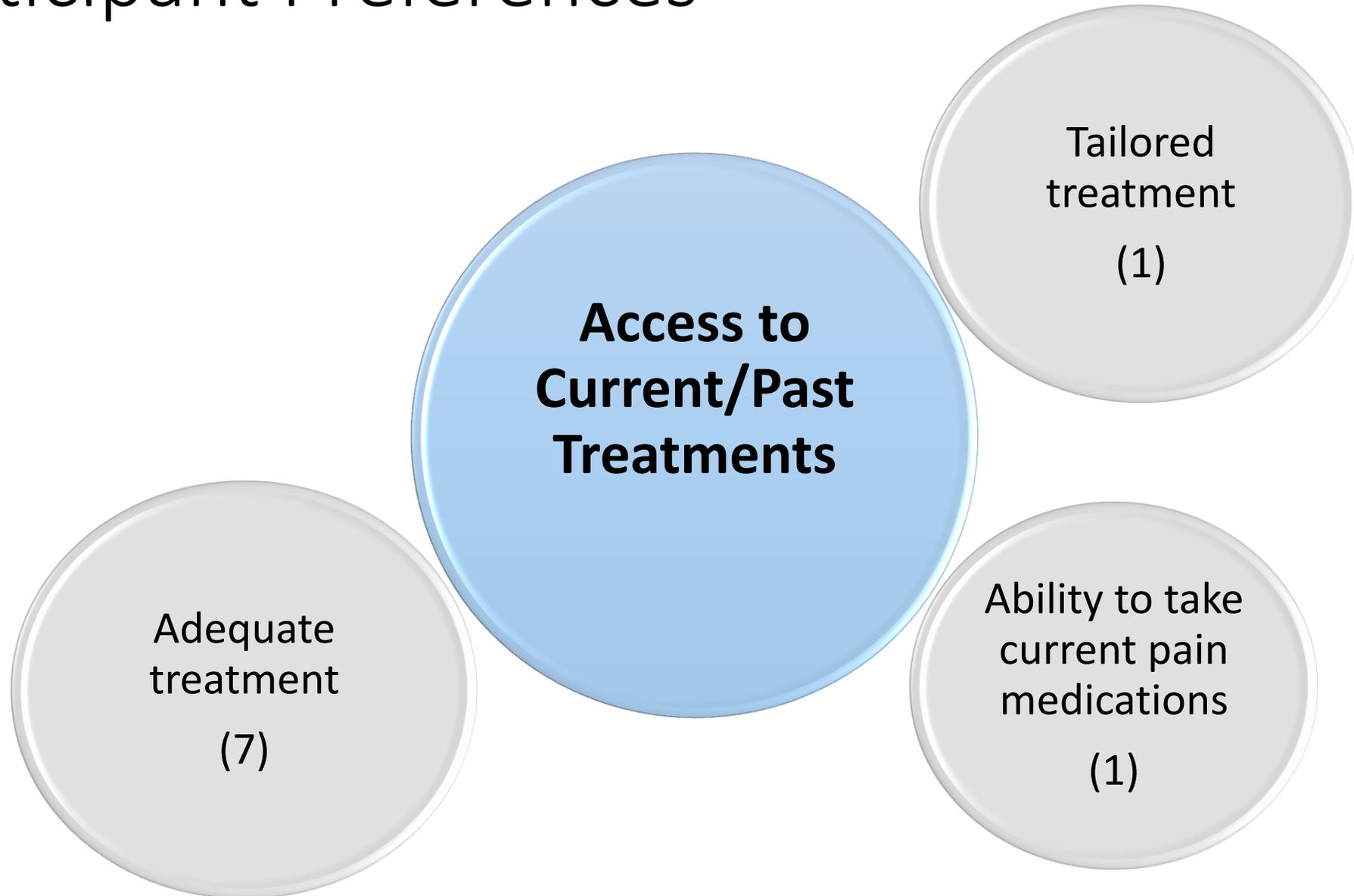


# Participant Preferences



(# of studies)

# Participant Preferences



(# of studies)

# Participant Preferences

Functional and  
symptom-based  
outcomes

(11)

Less invasive  
measures

(5)

**Outcomes &  
Data Collection**

Manageable questionnaires &  
frequency of administration

Convenient scheduling

Assessments at home, online or  
tele-mental health

Phone contact vs in-person

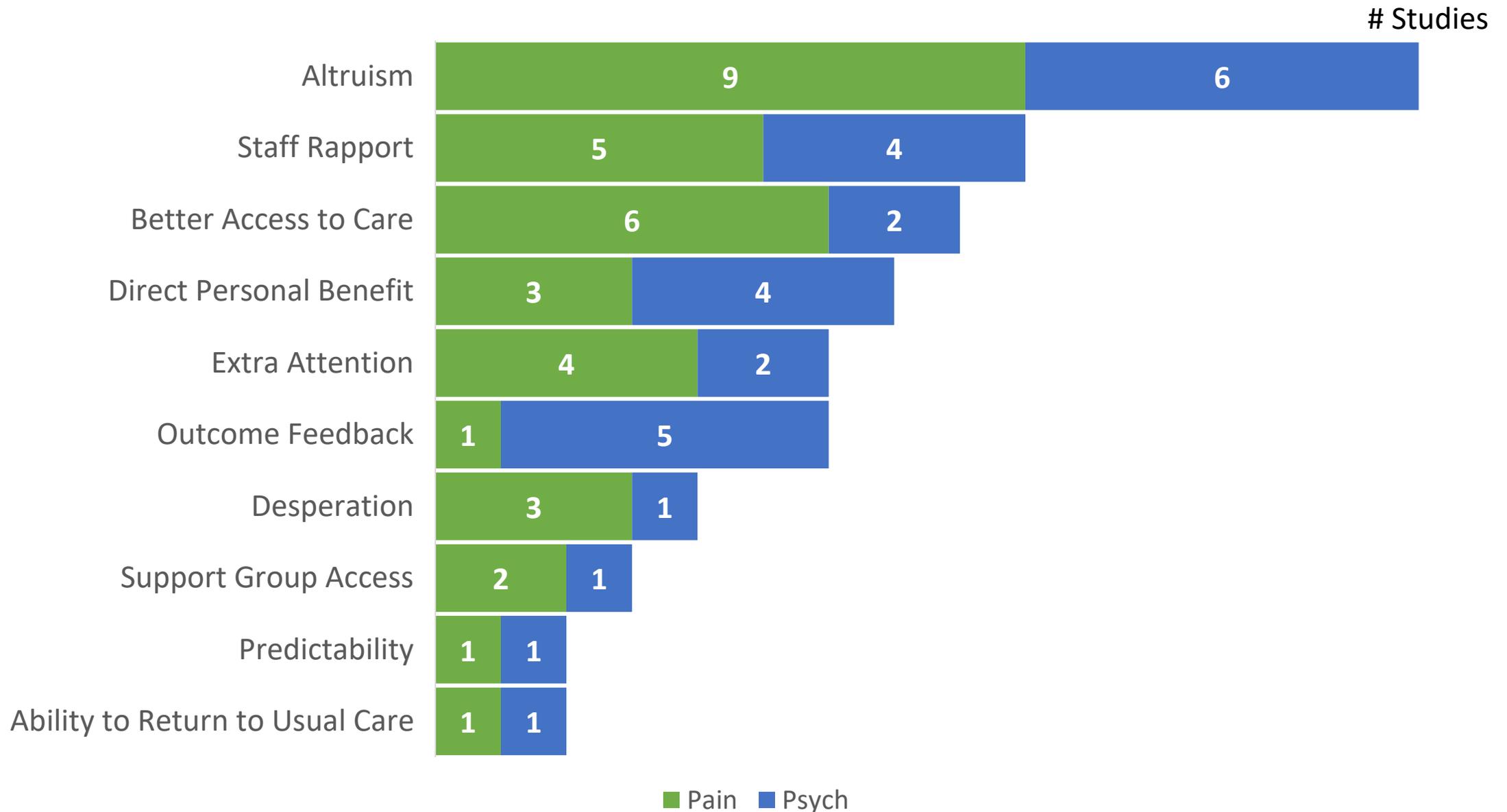
Tablet-based

Consistency with RAs

(# of studies)

RAs-research assistants

# Motivating Factors for Participation



# Reporting & Recruitment Considerations

- Advocate for studies to report reasons (with demographics) for declination
- Collect demographics related to site of residence (urban/rural, etc.)
- Recruitment strategies
  - Direct recruitment may benefit engagement

# Design Considerations

- Research team
  - Empathy/rapport
  - Training
  - Address fears & expectations
- Appropriate incentives for compensation of time and travel
- Flexibility with data collection methods

# Other Considerations

- For some, participation may not be related to study-specific factors
  - Stigma
  - Negative expectations of treatment
  - Burden of illness
- Value of qualitative component within RCTs to assess engagement with clinical trial participation and reasons for declination (O’Cathain 2013)

# Included Studies

Ackerman IN, et al. Factors limiting participation in arthritis self-management programmes: an exploration of barriers and patient preferences within a randomized controlled trial. *Rheumatology (Oxford)*. 2013 Mar;52(3):472-9. PMID: 23148089.

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<https://search.ebscohost.com/login.aspx?direct=true&db=psyh&AN=2020-04049-039&site=ehost-live&scope=site>

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Leinisch-Dahlke E, et al. Patient preference in clinical trials for headache medication: the patient's view. *Cephalalgia.* 2004 May;24(5):347-55. PMID: 15096223.

Lenguerrand E, et al. Effect of Group-Based Outpatient Physical Therapy on Function After Total Knee Replacement: Results From a Multicenter Randomized Controlled Trial. *Arthritis Care Res (Hoboken).* 2020 Jun;72(6):768-777. PMID: 31033232.

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Sherratt FC, et al. Protective parents and permissive children: what qualitative interviews with parents and children can tell us about the feasibility of juvenile idiopathic arthritis trials. *Pediatr Rheumatol Online J*. 2018 Dec 4;16(1):76. PMID: 30514320.

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