



University of Colorado **Anschutz Medical Campus**

# Pragmatic Trials and Hybrid Implementation- Effectiveness Designs in Real-World Clinical Settings

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# Learning Objectives

01

Define pragmatic and hybrid trials and explain their use in dissemination and implementation research

02

Describe the use of the PRECIS-2 framework to design a pragmatic trial

03

Specify steps in planning pragmatic research including selection of appropriate study designs and data sources





# Bio

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  - Social health psychologist and Dissemination and implementation (D&I) scientist
  - Pragmatic trials of chronic disease management interventions in primary care
  - Associate Professor, Department of Family Medicine, University of Colorado School of Medicine
  - ACCORDS Education program lead and D&I program member
  - Director of D&I Research, Colorado Clinical & Translational Sciences Institute (CCTSI)
  - Conference chair, Colorado Pragmatic Research in Health Conference

# Pragmatic Trial

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- A trial conducted in typical “real world” settings with typical patients, using study design features readily achievable under typical practices conditions (i.e., “usual care”)
- Comparator arm(s) are real-world alternatives
- Results are intended to support decisions about intervention adoption by health care providers and patients
  - Maximize applicability across a range of common care settings



# Pragmatic vs Explanatory (Efficacy) Trials

- Explanatory

- Focused more on efficacy than effectiveness
- Focused more on internal validity than external validity
- Engagement with stakeholders often minimal as that is seen as a later step
- Outcomes prioritize efficacy and component analysis

- Pragmatic

- Focused more on effectiveness than efficacy
- Focused more on external validity than internal validity
- Stakeholder engagement is critical to ensure relevance to those who will later apply these approaches
- Outcomes include both effectiveness and process measures to more fully define impact

Huebschmann AG, Leavitt IM, Glasgow RE , Ann Rev Pub Health, 2018 (in press)  
Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The  
PRECIS-2 tool: designing trials that are fit for purpose. BMJ, 2015;  
[www.PRECIS-2.org](http://www.PRECIS-2.org);





# Characteristics of Pragmatic Research

- The research question of interest...
  - ...tests if an intervention is effective in routine practice or service settings, often compared to well-defined usual care or existing programs and/or other comparator interventions.
  - ...considers the setting in which the intervention will be used (and its existing personnel and infrastructure) and how the intervention will be implemented and sustained in real-world contexts





# Characteristics of Pragmatic Research

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- The settings studied are...
  - ...typical delivery settings (e.g., typical workplaces, schools, or communities rather than highly specialized types of these settings).
- Those delivering the intervention are...
  - ...those who typically exist in typical delivery settings
- The population of interest will include...
  - ....broad eligibility criteria to represent “typical real-world” recipients of this program
  - ...a recruitment path identified in typical ways for clinical/community settings (e.g., registry data, best practice alerts, other)



A group of medical professionals, including a woman and a man in white lab coats, are gathered around a large computer monitor. The man is pointing at the screen, which displays a complex medical visualization of a human torso with various colored overlays and data points. The background shows a clinical or research setting with other monitors and equipment.

# Dissemination and Implementation Research

- The systematic study of the adoption and use of evidence-based interventions
  - Interventions with proven efficacy and effectiveness



# Dissemination and Implementation Research

- Dissemination is an active approach of spreading evidence-based interventions to the target audience via determined channels using planned strategies
  - Dissemination research is the systematic study of processes and factors that lead to widespread use of an evidence-based intervention by the target population
  - Dissemination strategies describe mechanisms and approaches that are used to communicate and spread information about interventions to targeted users.

# Dissemination and Implementation Research

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- Implementation is the process of putting to use or integrating evidence-based interventions within a setting.
  - Implementation research seeks to understand the processes and factors are associated with successful integration of evidence-based interventions within a particular setting (e.g., worksite, school, clinic).
  - Implementation strategies are the systematic processes or methods, techniques, activities, and resources that support implementation of evidence-based interventions in practice.



# Planning Pragmatic Research

- **Pragmatic research features**
  - Characterizing the setting and resources required for real-world use
  - Designing the study protocol to mirror usual care workflows, systems, resources, and delivery settings
  - Ensuring outcomes to be assessed reflect outcomes that matter to those who will use the results of the research
  - Ensuring that data collection is low burden (e.g., secondary use of existing data)
  - Emphasis on external validity
- **I spy D&I...**
  - Evaluate and describe the context in which an intervention will be delivered (population, setting, resources, infrastructure, systems and workflows)
  - Engage stakeholders in the design, conduct, and/or dissemination of research including selection of outcomes, relevance of research questions, and alignment with existing systems, processes, and workflows
  - Consider strategies needed to communicate to real-world practice settings the value of participating in research and prepare practice personnel to deliver interventions according to protocol

# D&I Context Assessments



Readiness to change

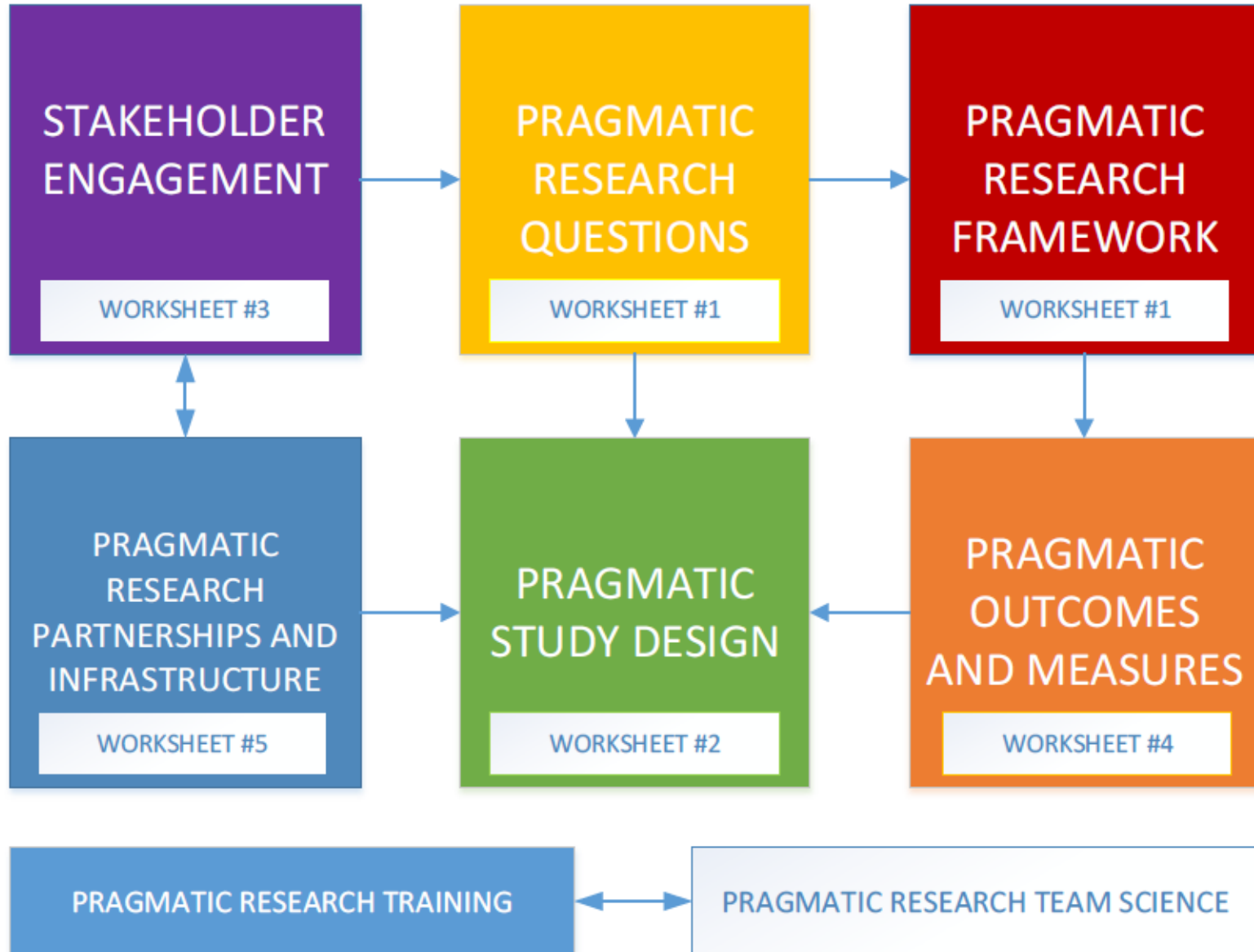


Implementation climate



Existing infrastructure and  
systems and processes of care





The COPRH Pragmatic Research Plan Workbook  
Designing Research for Real World Impact

<https://coprhcon.learningtimesevents.org/>

# Stakeholder Engagement

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A bi-directional, longitudinal relationship between stakeholders and researchers that informs decision-making about research prioritization, conduct, and dissemination.

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Involving multiple stakeholder types (e.g., patients, care partners, health care providers, advocacy groups, policy makers) in research helps to ensure the research is feasible, scientifically rigorous, and relevant.

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<https://dicemethods.org/WhatIsStakeholderEngagement>





# STAKEHOLDER ENGAGEMENT NAVIGATOR

DICEmethods.org | Dissemination, Implementation, Communication, and Engagement  
A guide for health researchers



Data Science to Patient Value (D2V)  
UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

Home > Stakeholder Engagement Selection Tool

EDUCATION HUB

FIND ENGAGEMENT STRATEGIES

## Stakeholder Engagement Selection Tool

Welcome! The purpose of this tool is to help your team select the most appropriate engagement method or tool for your particular project.

Before using the tool, consider the following:

- ☑ **Purpose:** What do you hope to achieve through stakeholder engagement?
- \$ **Budget:** What budget do you expect to have for your engagement activities?
- 📅 **Number of interactions:** Over what period of time do you expect to engage your stakeholders?
- 🕒 **Time per interaction:** How much time do you expect from your stakeholders in any given interaction?
- 👤 **Staffing/expertise:** What types of staffing and expertise are available to you?

START!



## STAKEHOLDER ENGAGEMENT NAVIGATOR

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A guide for health researchers

RE-LAUNCH  
TOOL

[Home](#) > [Stakeholder Engagement Selection Tool](#) > [Research Stage Selection](#) > [Engagement Purpose Selection](#) > [Refinements and Results Page](#)

Your chosen research stage(s): **Planning**

Your chosen purpose(s) of engagement: **Develop research questions relevant to stakeholders**

Use the sliders to further refine your search. You may use the sliders to set a range or to select one point.

**\$ Budget**

\$      \$\$\$      \$\$\$\$\$

**🕒 Time per interaction**

An hour or less      Half a day      A full day

**👤 Number of interactions**

1-2 times      Appx. 5 times      10+

After adjusting sliders, click on highlighted strategies below to discover more.

25/10 CROWDSOURCING

APPRECIATIVE INQUIRY

CITIZEN JURIES

COMMUNITY ENGAGEMENT STUDIO

CONCEPT MAPPING

CONVERSATION CAFE

DELIBERATIVE POLLING

DELPHI TECHNIQUE

DISCOVERY AND ACTION DIALOGUES

FOCUS GROUPS

HUMAN-CENTERED DESIGN

KEY INFORMANT INTERVIEWS

NOMINAL GROUP TECHNIQUE

ONLINE COLLABORATIVE PLATFORMS

ONLINE COMMUNITIES

TOWN HALL MEETING

USER EXPERIENCE FISHBOWL





# 7Ps stakeholder framework

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- Patients and the public
- Providers
- Policymakers
- Purchasers
- Payers
- Product makers
- Principal investigators

Concannon TW, Meissner P, Grunbaum JA, McElwee N, Guise JM, Santa J, Conway PH, Daudelin D, Morrato EH, Leslie LK. A new taxonomy for stakeholder engagement in patient-centered outcomes research. J Gen Intern Med. 2012 Aug;27(8):985-91.

# Pragmatic Research Questions

- The research question of interest...
  - ...tests if an intervention is effective in routine practice or service settings, often compared to well-defined usual care or existing programs and/or other comparator interventions.
  - ...considers the setting in which the intervention will be used (and its existing personnel and infrastructure) and how the intervention will be implemented and sustained in real-world contexts.

Table 1  
Types of hybrid designs and the associated research aims.

Study Design	Hybrid Type 1	Hybrid Type 2	Hybrid Type 3
Research Aims	<i>Primary Aim:</i> Determine effectiveness of an intervention <i>Secondary Aim:</i> Better understand context for implementation	<i>Primary Aim:</i> Determine effectiveness of an intervention  <i>Co-Primary* Aim:</i> Determine feasibility and/or (potential) impact of an implementation strategy *or Secondary Aim	<i>Primary Aim:</i> Determine impact of an implementation strategy <i>Secondary Aim:</i> Assess clinical outcomes associated with implementation

# Hybrid Implementation- Effectiveness Trials

- Landes SJ, McBain SA, Curran GM. Reprint of: an introduction to effectiveness-implementation hybrid designs. *Psychiatry research*. 2020 Jan 1;283:112630.





## Types of D&I Aims

- Engage stakeholders in the design, conduct, and/or dissemination of research
- Evaluate and describe the context in which an intervention will be delivered (population, setting, resources, infrastructure, systems and workflows)
- Evaluate dissemination and implementation of an intervention, such as adoption, feasibility, fidelity and adaptations
- Design and test implementation strategies
- Design and test dissemination strategies

# PRECIS-2

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## The PRECIS-2 tool: designing trials that are fit for purpose

Kirsty Loudon,<sup>1</sup> Shaun Treweek,<sup>1</sup> Frank Sullivan,<sup>2</sup> Peter Donnan,<sup>3</sup> Kevin E Thorpe,<sup>4</sup>  
Merrick Zwarenstein<sup>5</sup>



### Pragmatic-Explanatory Continuum

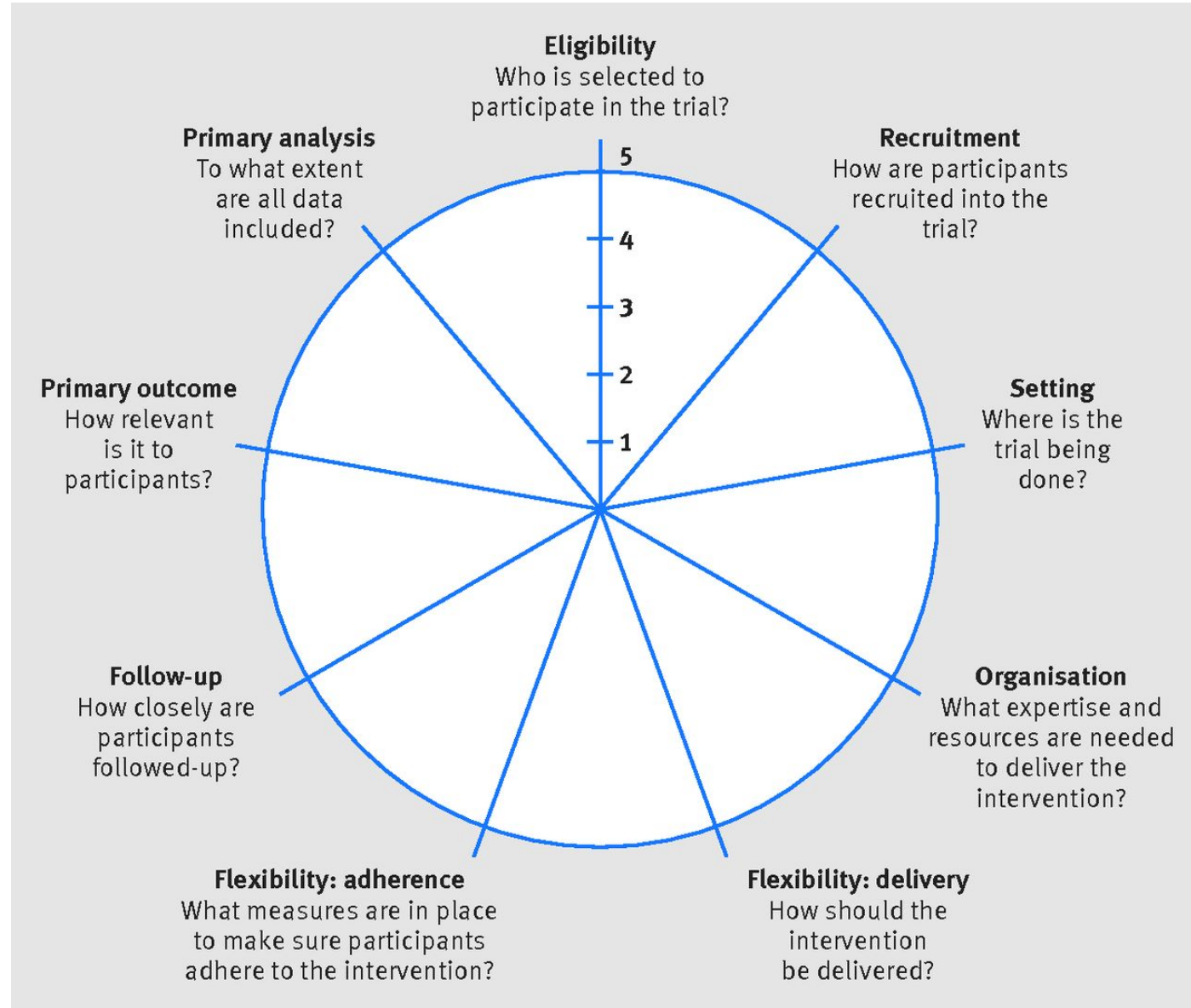
Intent or attitude  
Series of dimensions



### PRECIS-2

9-domain framework for evaluating how  
pragmatic an intervention is relative to usual  
care  
Useful for planning and reporting

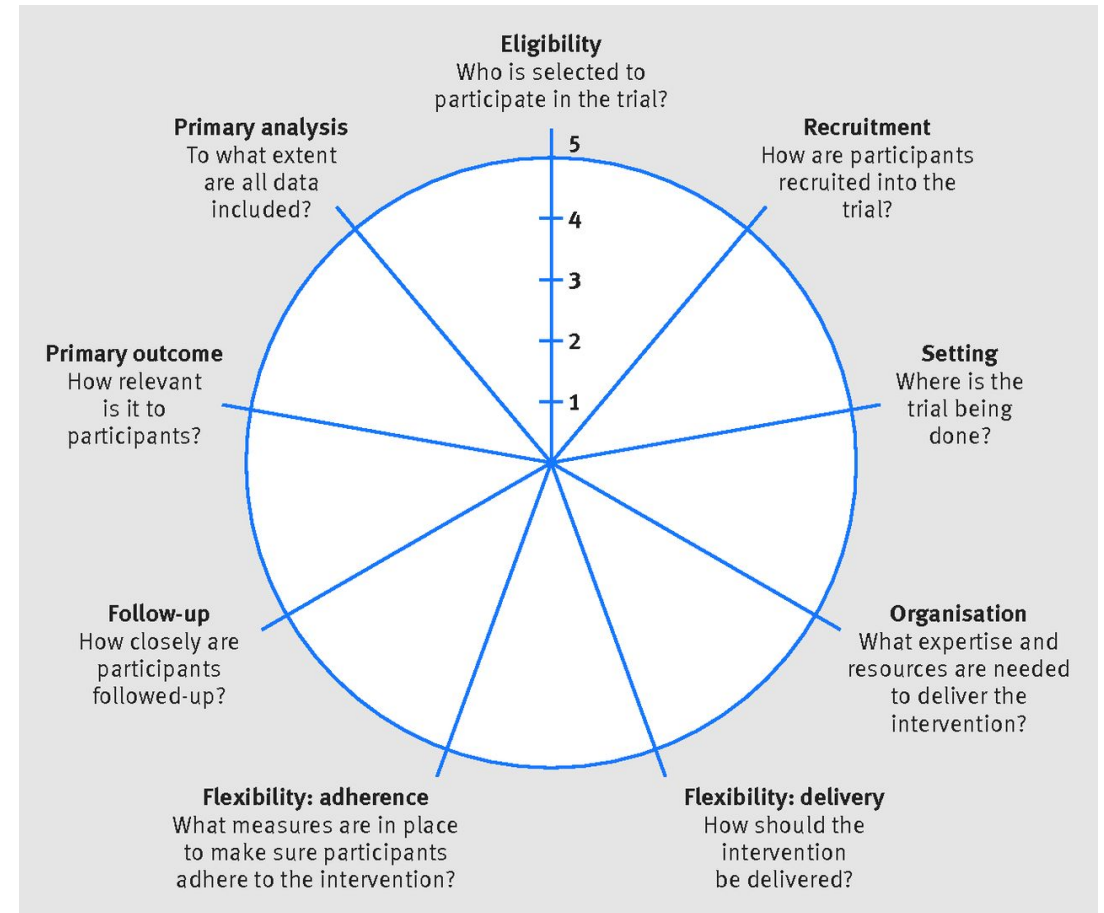
# How Pragmatic is your Study? The PRECIS-2 Tool





# PRECIS-2 domains

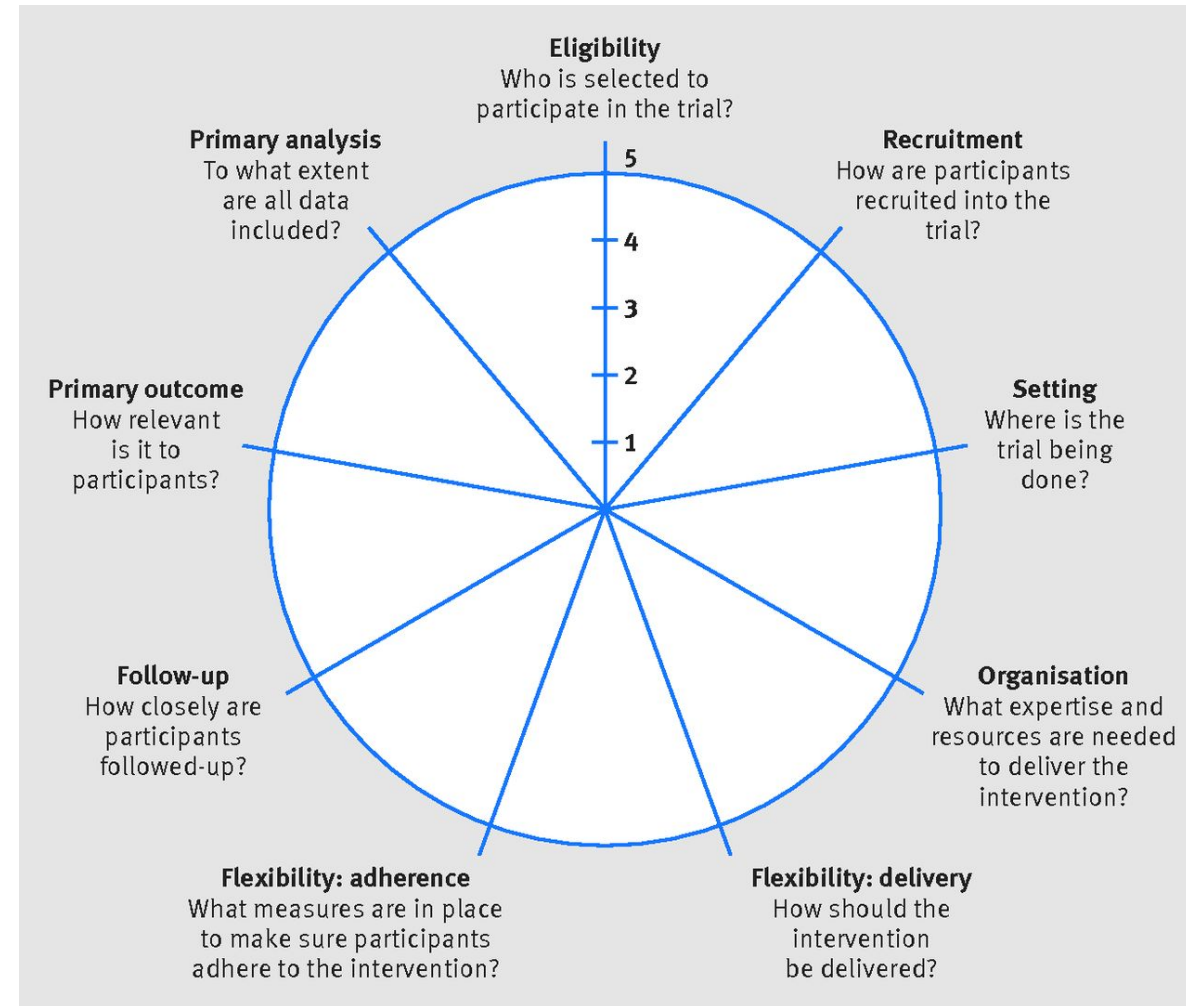
- **Eligibility:** the extent to which participants in the trial are similar to those who would potentially receive the intervention in usual care settings
  - Highly pragmatic (rating of 5): selection criteria are highly inclusive
  - In-between (rating of 3): selection criteria limit study population to some extent, but most “typical” patients are included.
  - Highly explanatory (rating of 1): step-wise selection criteria, restricted to participants highly responsive to experimental intervention



Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ*. 2015; 350:h2147.

# PRECIS-2 domains

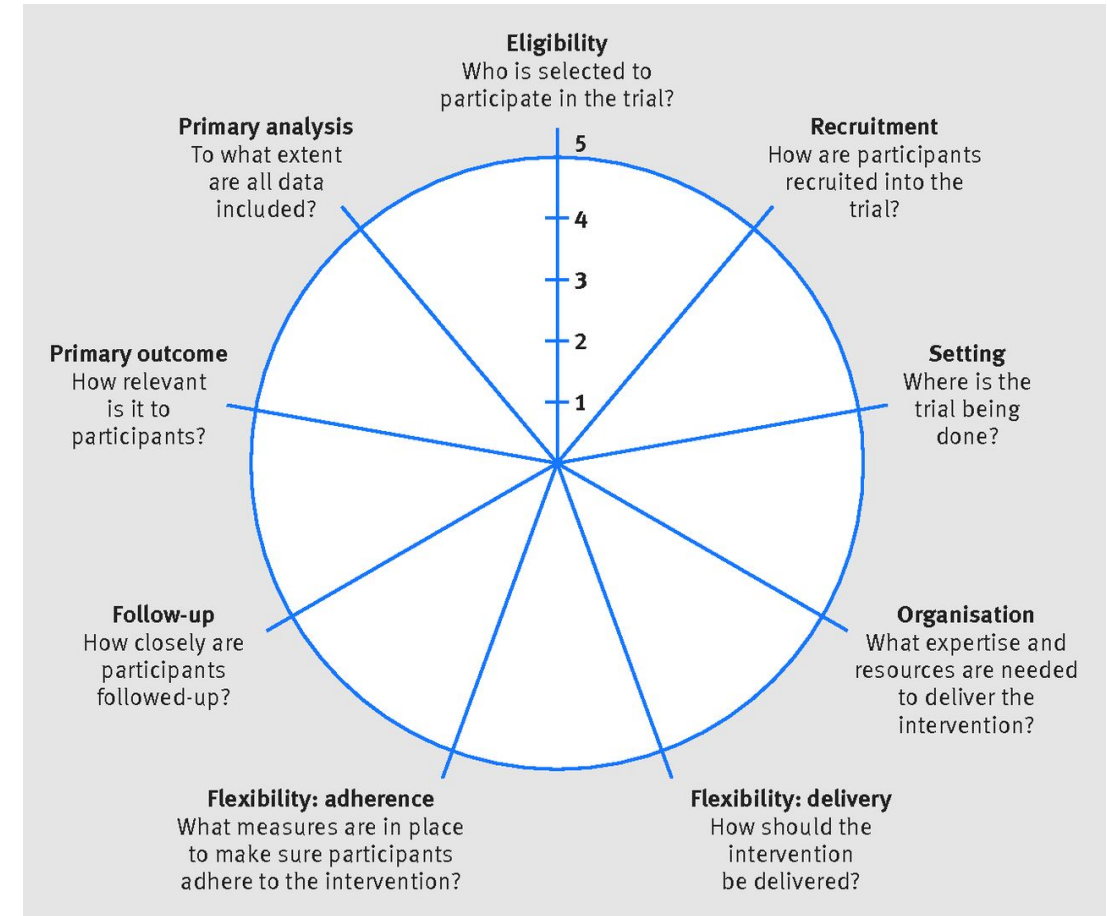
- **Settings:** how different are settings of the trial from usual care?
  - Highly pragmatic (rating of 5): setting is nearly identical to location where results are intended to be applied (usual care)
  - In-between (rating of 3): setting is partially representative of usual care sites; at least 2 sites are involved
  - Highly explanatory (rating of 1): study is not at all representative of usual care – highly specialized center or tertiary-care center, only one center involved



Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ*. 2015; 350:h2147.

# PRECIS-2 domains

- **Organizational infrastructure:** the difference between the resources, provider expertise, and the organization of care delivery employed in the intervention arm of the trial as compared to those available in usual care
  - Highly pragmatic (rating of 5):
    - No extra non-reimbursable time for staff required or additional staff resources required beyond what would be expected in usual care – but may consider emerging models of usual care such as patient-centered medical homes
    - Staff require no or minimal additional training beyond what is expected in usual care
  - In-between (rating of 3):
    - Intervention requires some extra staff time, infrastructure, and training – any reimbursements for the extra staff time could raise this rating to be more pragmatic than if that was not present
  - Highly explanatory (rating of 1):
    - Intervention requires many extra hours of staff time and additional infrastructure
    - Requires highly specialized staff and/or significant extra training

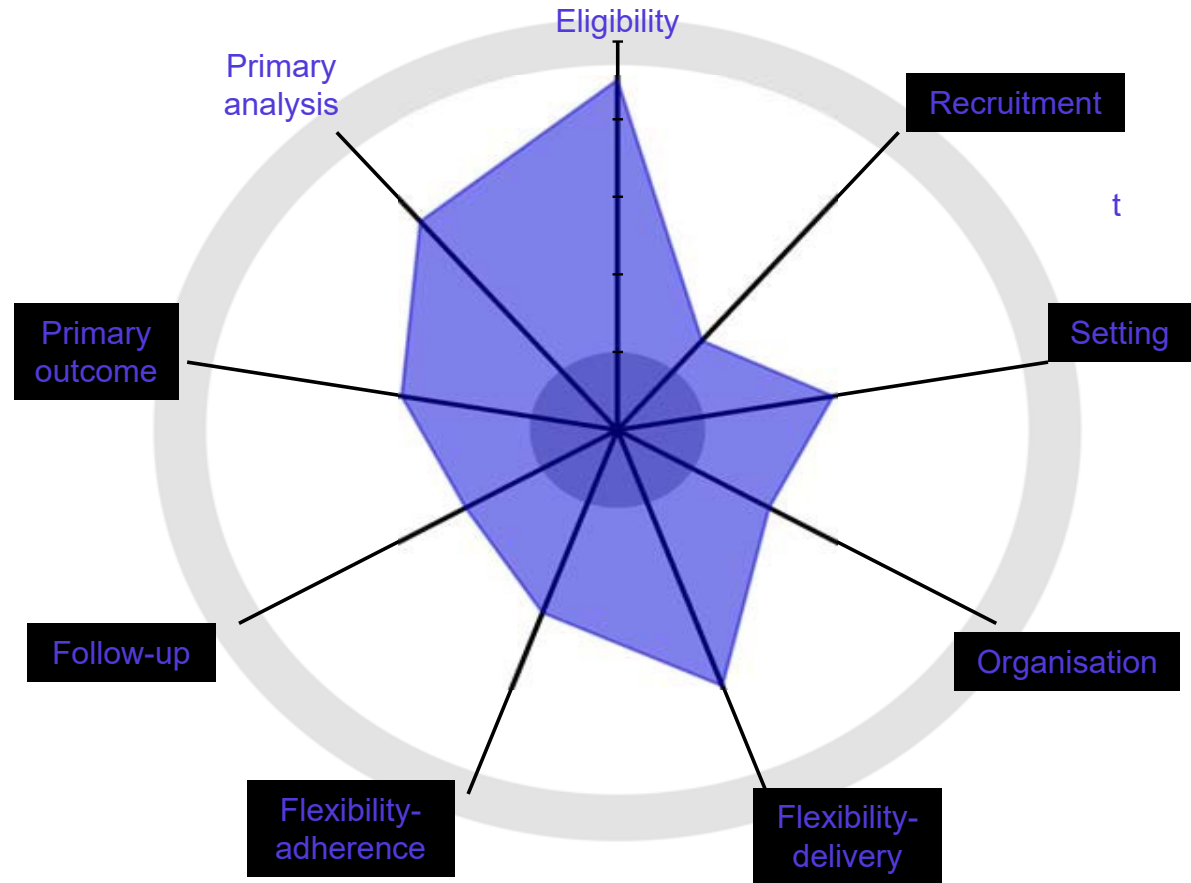


Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ*. 2015; 350:h2147.



**Panel A:** Explanatory trial of cognitive behavioral therapy to prevent chronic pain:  
limited attention to external validity

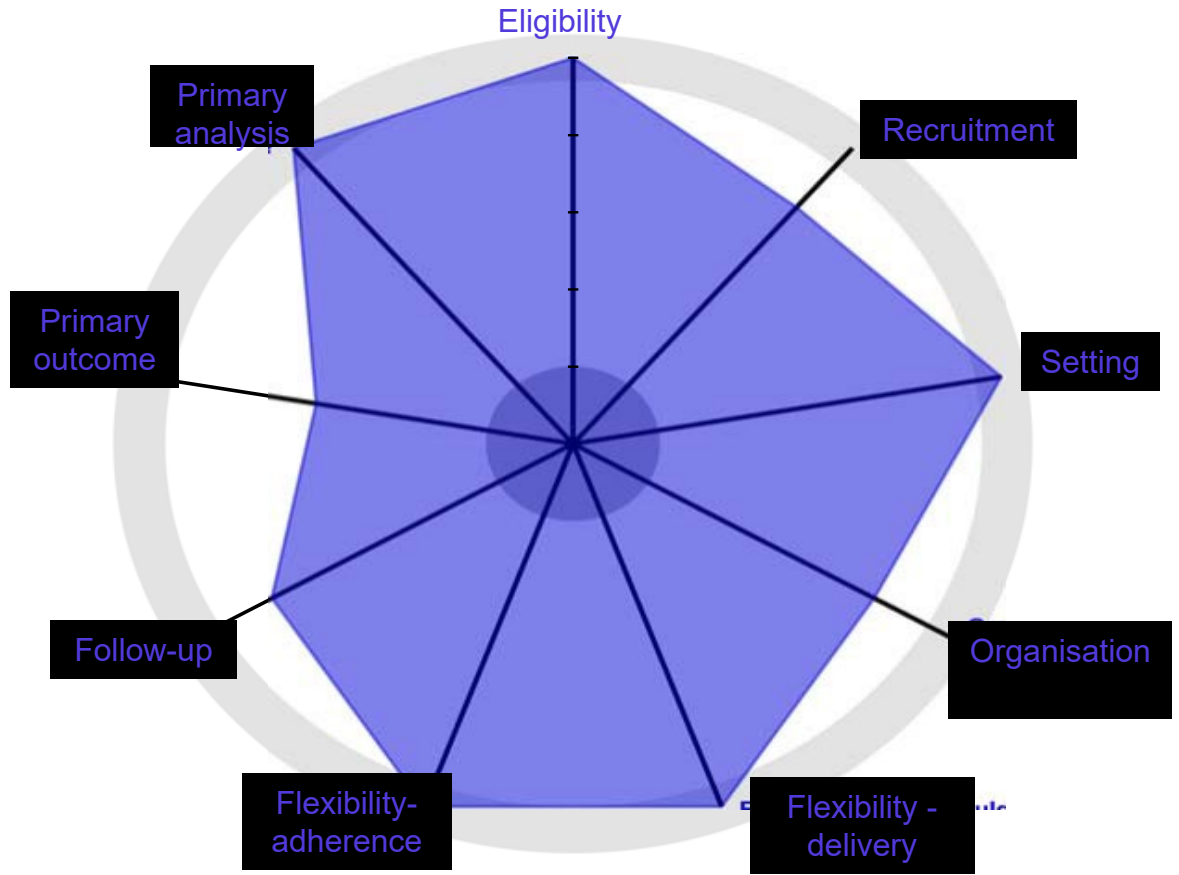
- High score for **Eligibility** but low scores for **Recruitment** and **Settings**: the results are likely to be relevant to patients in the TYPES OF SETTINGS studied, but these patients will not necessarily represent patients in the general population
- Low score for **Organization** means that the resources used for this trial are not common in real-world settings



Macfarlane GJ et al., The Maintaining Musculoskeletal Health (MamMOTH) Study, BMC Musculoskeletal Disorders, 2016.

**Panel B:** Pragmatic trial of computer-supported tailored asthma education mailers:  
major attention to external validity

- High scores for **Eligibility**, **Recruitment** methods, and **Setting** suggests excellent generalizability to other patients and settings
- High score for **Organization** means most settings could deliver this program
- High scores for **Flexibility** means that real-world implementation is likely to find the same results as in the study
- Middle score for **primary outcome** (hospital admissions for asthma) suggests this may not be the most meaningful outcome to patients



Osman LM, et al: Grampian Asthma Study of Integrated Care (GRASSIC). BMJ, 1994.

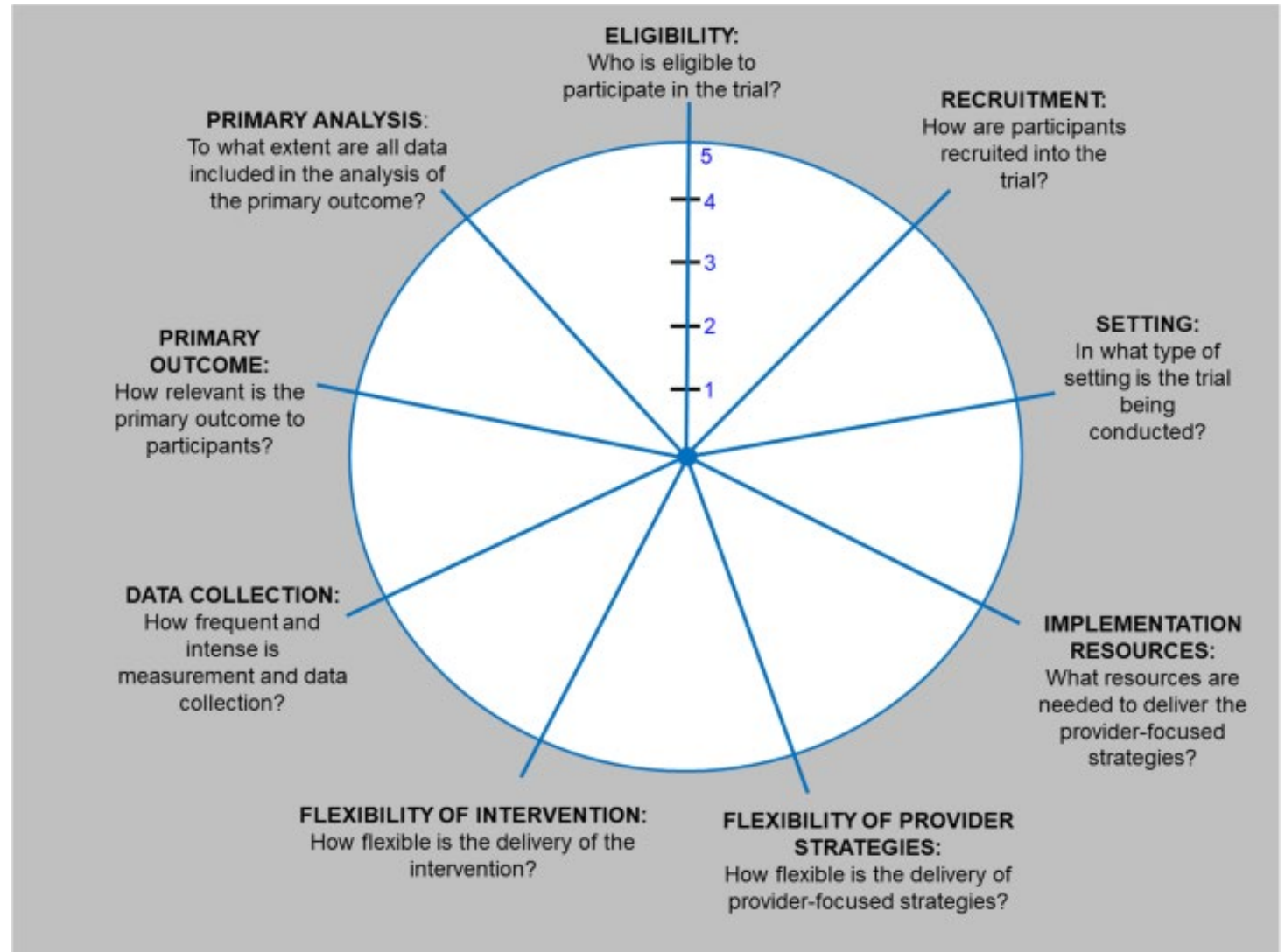
# Steps to applying PRECIS-2 to trial design

- **Step 1.** Consider your **intent for the trial** you are designing – more explanatory or more pragmatic? *Be deliberate in selection of the design, based on the research question.*
- **Step 2.** Assess your **trial design choices** for each of the 9 domains. *Bear in mind your intent.*
- **Step 3. Score** choices and mark on the wheel from 1 (very explanatory) to 5 (very pragmatic)
- **Step 4. Review** scores with collaborators and stakeholders and revise design choices as necessary. *Check that design choices are consistent with your intent (Step 1).*
- **Repeat. Iterate** until the design matches the intent

# PRECIS-2-PS (Provider Strategies)

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- Norton WE, Loudon K, Chambers DA, Zwarenstein M. Designing provider-focused implementation trials with purpose and intent: introducing the PRECIS-2-PS tool. Implementation Science. 2021 Dec;16(1):1-1.





# Study Designs

Considerations	Design Types
Randomization is possible...	Participant-level RCT (intent-to-treat)
...but there is likelihood of contamination within clusters	Cluster randomized trial (ITT)
...and sites are unlikely to accept randomization to control or implementation resources are limited	Stepped wedge design (ITT)
The intervention has multiple components that need to be optimized in terms of combination, dose, sequence, timing...	Randomized factorial design (ITT)
...and there may be participant- or setting-level criteria (such as non-response to first-line treatment) that dictate which sequence or combination is optimal	Sequential multiple assignment randomized trial (ITT) Adaptive trial (ITT)
Randomization is not ethical or feasible...	Observational, quasi-experimental, or natural experiment design

# Pragmatic Research Outcomes

## Stakeholder-centered outcomes

- Information needed to inform decisions about what health services to adopt, use, or pay for
- Long-term and short-term

## Framework-aligned constructs and outcomes

- Key domains from a conceptual model or theoretical framework

Study Topic Area:		Study Setting:	
Dimensions/Items		Included? (Yes, No, Yes-Inappropriate Use, N/A)	
<b>Reach</b>			
Exclusion Criteria (% excluded or characteristics)			
Percent individuals who participate, based on valid denominator (not of volunteers who indicate interest)			
Characteristics of participants compared to non-participants or to target population			
Use of qualitative methods to understand reach and/or recruitment			
<b>Effectiveness</b>			
Measure of primary outcome with or w/o comparison to a public health goal (e.g. HP 2020 goals, exercise 30 min/day; eat 5 Fruits & Veggies)			
Measure of broader outcomes (e.g., other outcomes, measure of QoL or potential negative outcome) or use of multiple criteria			
Measure of robustness across subgroups (e.g. moderation analyses)			
Measure of short-term attrition (%) and differential rates by patient characteristics or treatment condition			
Use of qualitative methods/data to understand outcomes			
<b>Adoption – Setting Level</b>			
Setting Exclusions (% or reasons)			
Percent of settings approached that participate (valid denominator)			
Characteristics of settings participating (both comparison and intervention) compared to either: non participants or some relevant resource data			

<https://re-aim.org/resources-and-tools/measures-and-checklists/>

# Data Sources for Pragmatic Research

## Use of secondary data sources

- Electronic health records
- Publicly available registries and data sets

## Pragmatic measures characteristics

- Brevity
- Criterion validity (does it predict what it is supposed to)
- Reliability (especially test-retest)
- Sensitivity to change (e.g., ability to detect intervention effects)
- Actionable and understood by users
- Quickly and easily scored
- Broad availability (e.g., validated in multiple languages and applicable across populations)
- Availability of norms

Glasgow RE, Riley WT. Pragmatic measures: what they are and why we need them. Am J Prev Med. 2013;45:237–43.

# Case Example



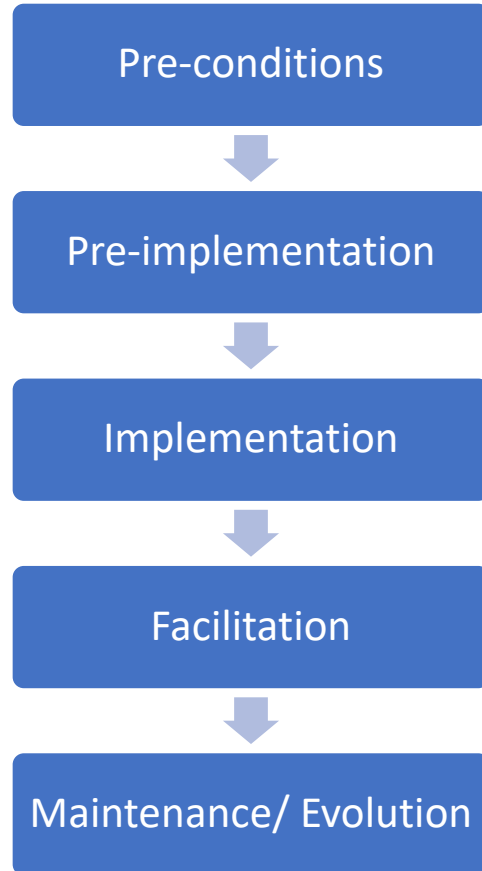
- Cluster randomized pragmatic trial (Hybrid type 2)
- Comparative effectiveness of patient-driven vs standardized diabetes shared medical appointments (SMAs)
  - SMA models use the same curriculum
  - Both are 6 sessions, about 2 hours each session
  - Models differ in terms of who delivers the curriculum (health educator vs multidisciplinary care team including behavioral health and a peer mentor) and tailoring module order and emphasis on topics to cohort needs and preferences
- Funded by PCORI Improving Healthcare Systems Award
- Patient and practice stakeholders engaged in research prioritization, design, conduct, and dissemination

Kwan BM, Dickinson LM..., Waxmonsky JA. The Invested in Diabetes Study Protocol: a cluster randomized pragmatic trial comparing standardized and patient-driven diabetes shared medical appointments. *Trials*. 2020 Jan 10;21(1):65



# Implementation and Adaptation

Enhanced Replicating Effective Programs



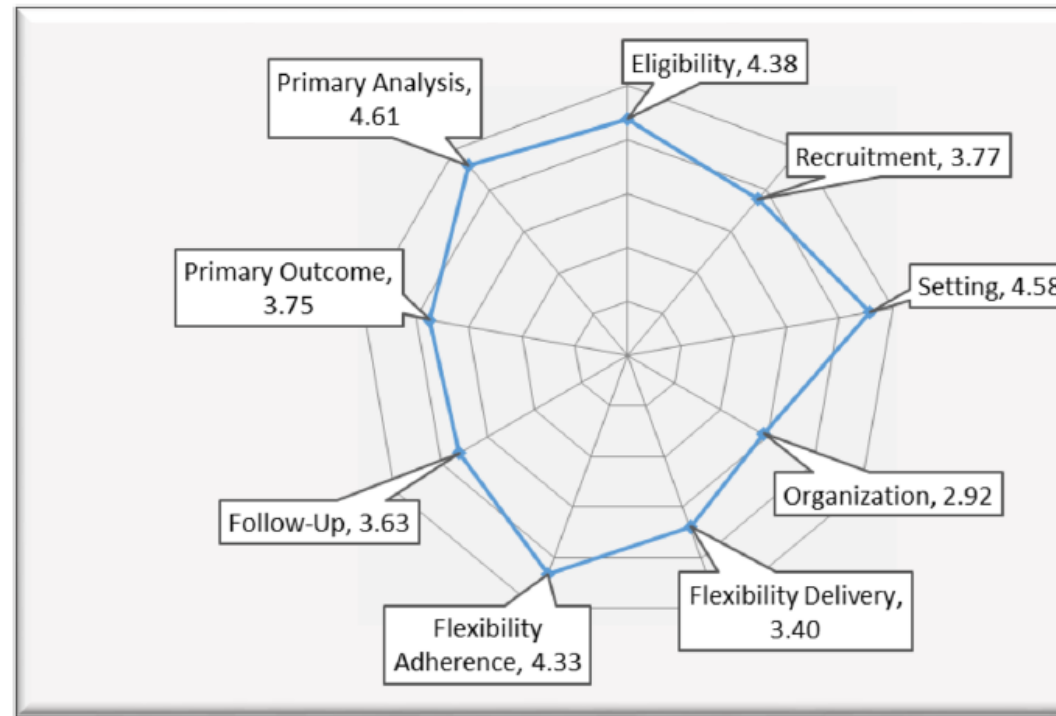
- Kwan BM, Rementer J..., Waxmonsky JA. Adapting Diabetes Shared Medical Appointments to Fit Context for Practice-Based Research (PBR). J Am Board Fam Med. 2020 Sep-Oct;33(5):716-727.

**Table 5. Intervention Content, Delivery, and Training: Adaptations Fit to Context**

Contextual Factors	Invested in Diabetes Practice Characteristics	Corresponding Adaptations
Data capabilities and population management	All practices had electronic health records Some had registries to help identify eligible patients Varied experience with PRO collection and use	Simplified eligibility criteria for patients (any adult with Type II diabetes, no exclusion criteria) for ease of identification Ensured PROs were relevant to clinical care and SMA discussions
Payer mix	Practices vary in payer mix, with different billing and reimbursement practices	Informed guidelines for frequency of prescribing provider visits (at every session/1st/last only etc) Provided documentation templates and common billing codes used for diabetes SMAs
Prior experience with SMAs	Some practices had prior experience delivering and billing for diabetes SMAs	Informed intensity of technical assistance, plans for process mapping; practice coaches spent more time with helping practices determine SMA workflows and staffing
Team-based care	Practice all had behavioral health Some were fully integrated with behavioral health providers and experienced with integrated team-based care; others had collocated care where the behavioral health provider operated independently of the primary care provider	Influenced plans to include behavioral health providers in trainings alongside health educators (in patient-driven condition) and adaptations to mental health and stress and coping content

# How pragmatic is it?

- Glasgow RE, Gurfinkel D, Waxmonsky J..., Kwan BM. Protocol refinement for a diabetes pragmatic trial using the PRECIS-2 framework. BMC Health Serv Res. 2021 Oct 2;21(1):1039.



**Fig. 1** PRECIS-2 ratings of the study protocol by Invested in Diabetes study team. Radar plot showing average study protocol ratings by study team on the nine PRECIS-2 domains, with points closer to center representing explanatory ratings (1) and points closer to the edge representing pragmatic ratings (5). Legend: 1 = very explanatory. 5 = very pragmatic

# Protocol Refinement

- Glasgow RE, Gurfinkel D, Waxmonsky J..., Kwan BM. Protocol refinement for a diabetes pragmatic trial using the PRECIS-2 framework. BMC Health Serv Res. 2021 Oct 2;21(1):1039.

**Table 3** Invested in Diabetes protocol refinements by PRECIS-2 domain, Invested in Diabetes study team, 2018–2021

PRECIS-2 domain	Original protocol	Protocol refinement	Reason for refinement
Eligibility	<ul style="list-style-type: none"><li>• Patients are adults with type 2 diabetes who are existing patients of the practice; excludes pregnancy or plans to become pregnant within 6 months, life expectancy less than 6 months, cognitive inability to participate, plans to leave area within next year.</li></ul>	<ul style="list-style-type: none"><li>• Practices encouraged to recruit any adult with type 2 diabetes they believed would be able to participate in and benefit from SMAs (i.e., no explicit assessment of eligibility criteria; providers review lists of patients to assess suitability)</li><li>• Pregnancy exclusion criterion would be applied analytically based on EHR data.</li></ul>	<ul style="list-style-type: none"><li>• Not typical for practices to ask patients if planning to become pregnant or leave the area prior to offering care;</li><li>• Assessment of cognitive ability, life expectancy, and other “suitability” factors based on provider judgment</li></ul>
Recruitment	<ul style="list-style-type: none"><li>• Practices would recruit patients using existing personnel and processes of care</li></ul>	<ul style="list-style-type: none"><li>• Practices shared strategies used to meet recruitment goals during practice stakeholder calls.</li><li>• Engaged patient stakeholders helped develop marketing materials.</li><li>• Research team provided recruitment fliers and coaching sessions to support recruitment strategies.</li></ul>	<ul style="list-style-type: none"><li>• Recruitment was listed as a top barrier from every practice and they needed extra support and guidance to achieve recruitment goals.</li></ul>
Setting	<ul style="list-style-type: none"><li>• Diverse clinic settings: FQHCs, private practices, and community mental health centers with integrated behavioral health and primary care, including small/large and urban/suburban/rural sites in Colorado.</li><li>• Practices had <math>\geq 100</math> adult patients with type 2 diabetes (able to commit to 72 patients over 2 years, including 60 with complete PRO data)</li></ul>	<ul style="list-style-type: none"><li>• No community mental health centers recruited</li><li>• Allowed “half-sites” to provide 36 patients instead of 72</li><li>• Allowed participating organizations to combine smaller practices into one “site” for randomization purposes</li></ul>	<ul style="list-style-type: none"><li>• Policy-level changes to billing/payment structures for community mental health centers came into effect during practice recruitment.</li><li>• Smaller practices allowed to participate to reach practice recruitment goals and to ensure results were relevant to a greater range of practice sizes</li></ul>



Virtual International Conference  
May 24-26, 2021

Implementation &  
Conduct of Pragmatic  
Research

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# Resources

- <https://www.precis-2.org/>
- <https://coprhcon.learningtimesevents.org/> (2020 and 2021 Archives)
- <https://dicemethods.org>

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Thank you!



Questions? Comments?



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