



The Trauma Survivors Outcome & Support (TSOS) Pragmatic Trial: Revisiting Effectiveness & Implementation Aims

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TSOS Outline

- Progress: Effectiveness aims
 - 635 patients recruited and randomized
 - Baseline data cleaning and analyses
 - Follow-up ongoing with 75-80% retention
- Progress: Implementation aims
 - Review of TSOS PRECIS-2 Wheel
 - Pragmatic methods for understanding trial implementation processes (RAPICE)
 - Initial Implementation process findings and implications for TSOS PRECIS-2 Wheel

TSOS Aims

- 1) Conduct pragmatic trial to determine intervention effectiveness – hypotheses are the intervention will:
 - A) ↓ PTSD symptoms (PTSD Checklist)
 - B) ↓ Depressive symptoms (PHQ-9)
 - C) ↓ Alcohol use problems (AUDIT)
 - D) ↑ Physical function (SF-12 PCS)
- 2) Understand trial implementation
- 3) Dissemination of results through American College of Surgeons' policy



TSOS Progress Effectiveness Aims: Baseline Data Cleaning and Analyses

TSOS Study Design

- Cluster randomized stepped wedge design
- 25 US trauma centers
- EHR PTSD screen
- Baseline PTSD & comorbidity assessment
- All sites begin recruiting controls
- Intervention “turned on” at each site

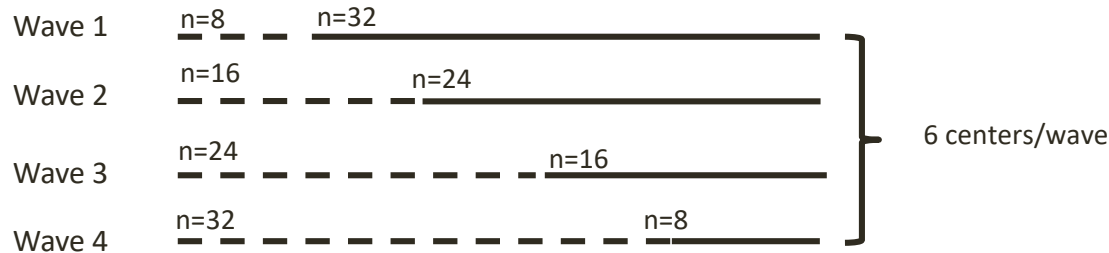
TSOS Stepped Wedge Cluster Randomized Design

--- Patients Unexposed to intervention

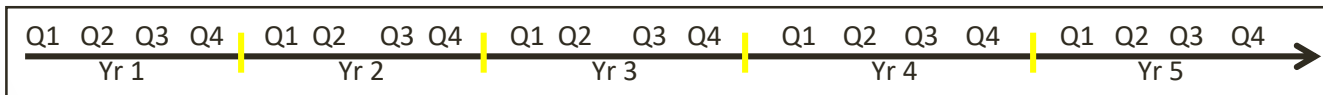
— Patients Exposed to intervention

← Follow-up Period →

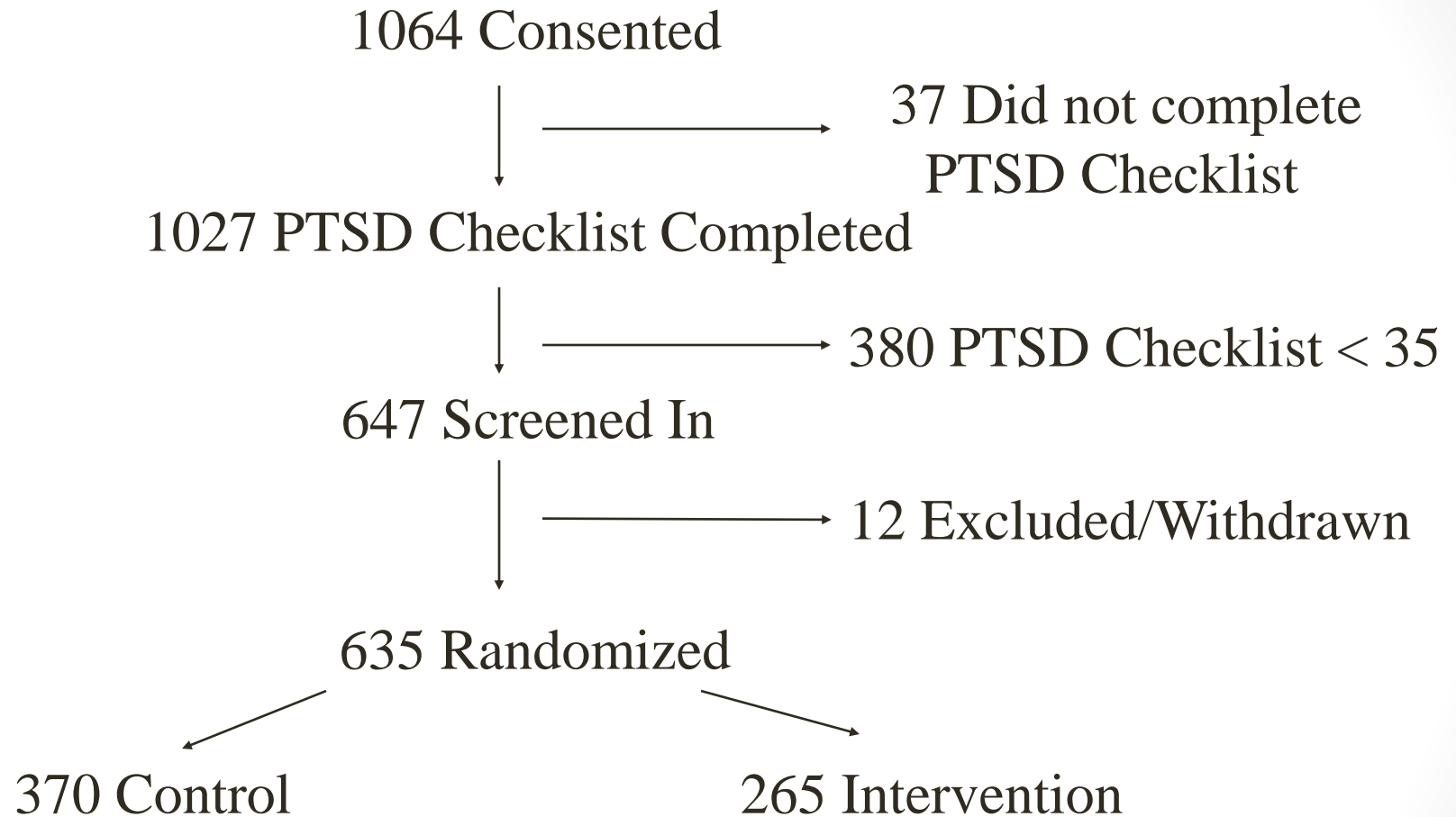
← Accrual period →



Period 0 Period 1 Period 2 Period 3 Period 4



Results: TSOS Patient Flow



TSOS Baseline Control vs. Intervention (N=635)

<u>Characteristic</u>	<u>Control (n=370)</u>	<u>Intervention (n=265)</u>	<u>P</u>
Female	43%	55%	< 0.01
Non-White	54%	50%	ns
Intentional injury	38%	36%	ns
ICU Admit	62%	56%	ns
Prior PTSD DX	15%	23%	< 0.05
Prior Psych DX	40%	38%	ns
Prior antidepressant	21%	18%	ns
Prior opioids	11%	11%	ns
Age	40 yrs	38 yrs	< 0.05

TSOS Baseline Control vs. Intervention (N=635)

<u>Characteristic</u>	<u>Control (n=370)</u>	<u>Intervention (n=265)</u>	<u>P</u>
PTSD Checklist	50.7	54.0	< 0.01
PHQ-9 Depression	13.9	14.3	ns
PHQ-9 Item 9 Suicide+	24%	25%	ns
AUDIT Alcohol use	7.4	7.2	ns
SF-12 Phys. Function	49.1	49.7	ns

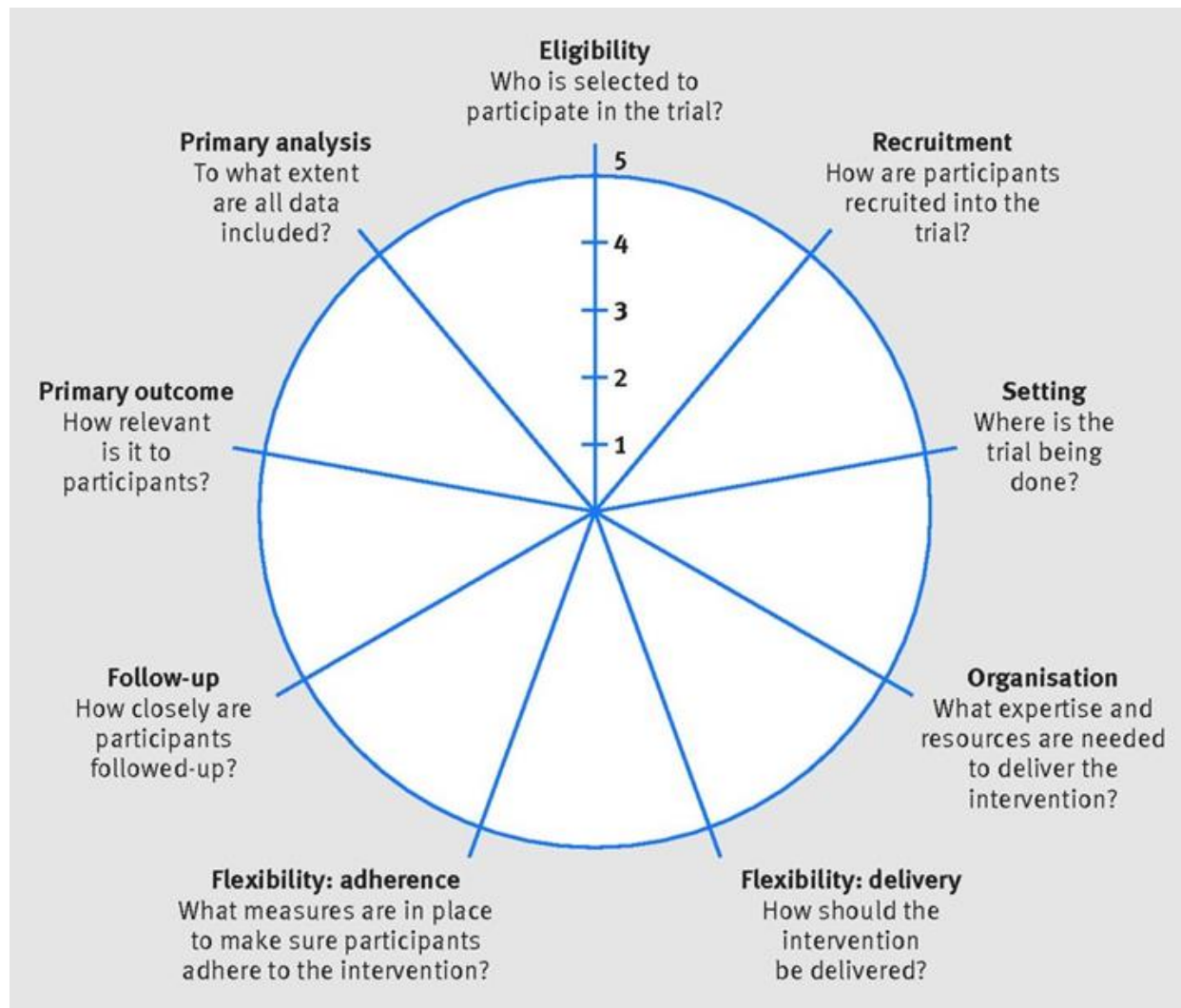


TSOS Follow-up Interview Status

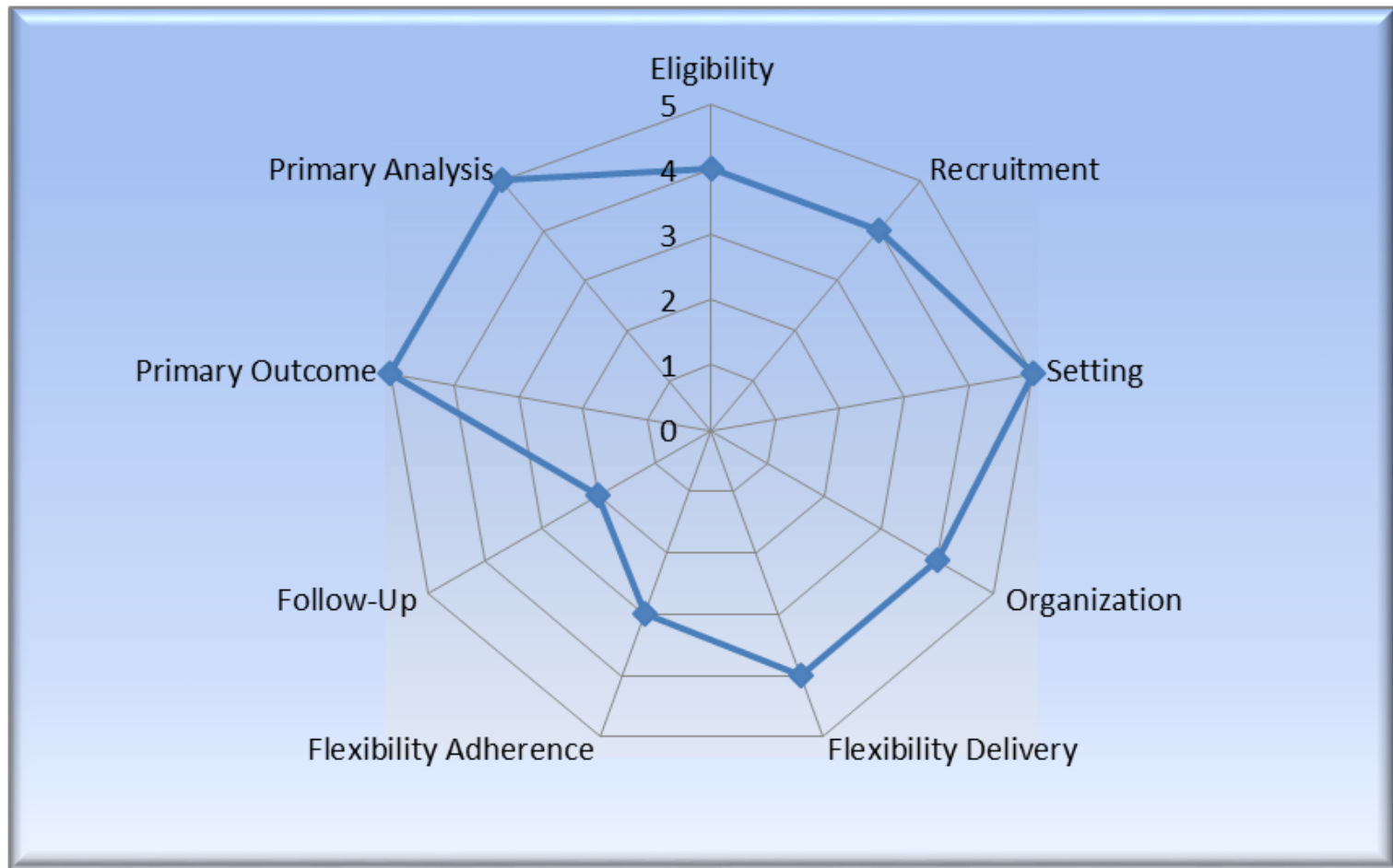
- Primary Outcomes
 - PTSD Checklist
 - PHQ-9
 - AUDIT
 - SF-12/36 Physical Function
- Follow-up
 - 80% 3 month
 - 77% 6 month
 - 75% 12 month


TSOS Progress Implementation Aims

PRECIS-2 Wheel




Original TSOS PRECIS-2 Wheel





From NIH Collaboratory ePCT Training Choosing Endpoints in PCTS (Richesson & Curtis 2/18):

- More pragmatic endpoints...
 - Matter to providers and patients
 - Are captured reliably as part of routine clinical care
 - Do not require central adjudication
 - Are shorter-term in nature



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- More pragmatic endpoints...
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Choosing an endpoint that is not captured reliably as part of routine clinical care or impedes the clinical workflow is not pragmatic!

Washington State Population Level Emergency Department Administrative Data on the Intent-to-Treat Sample

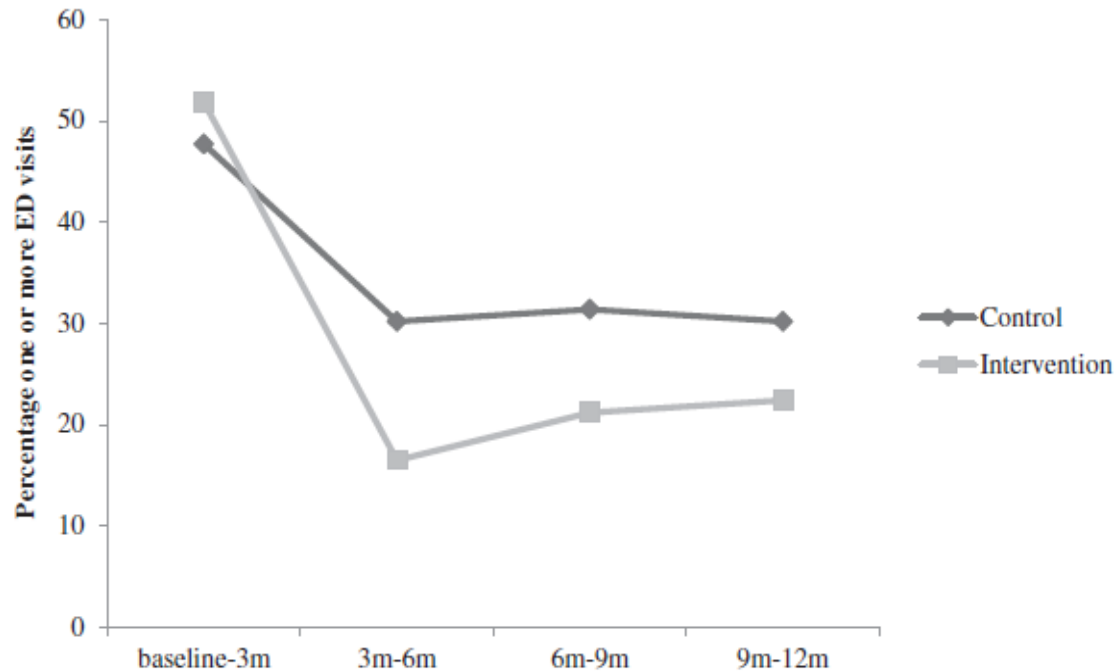
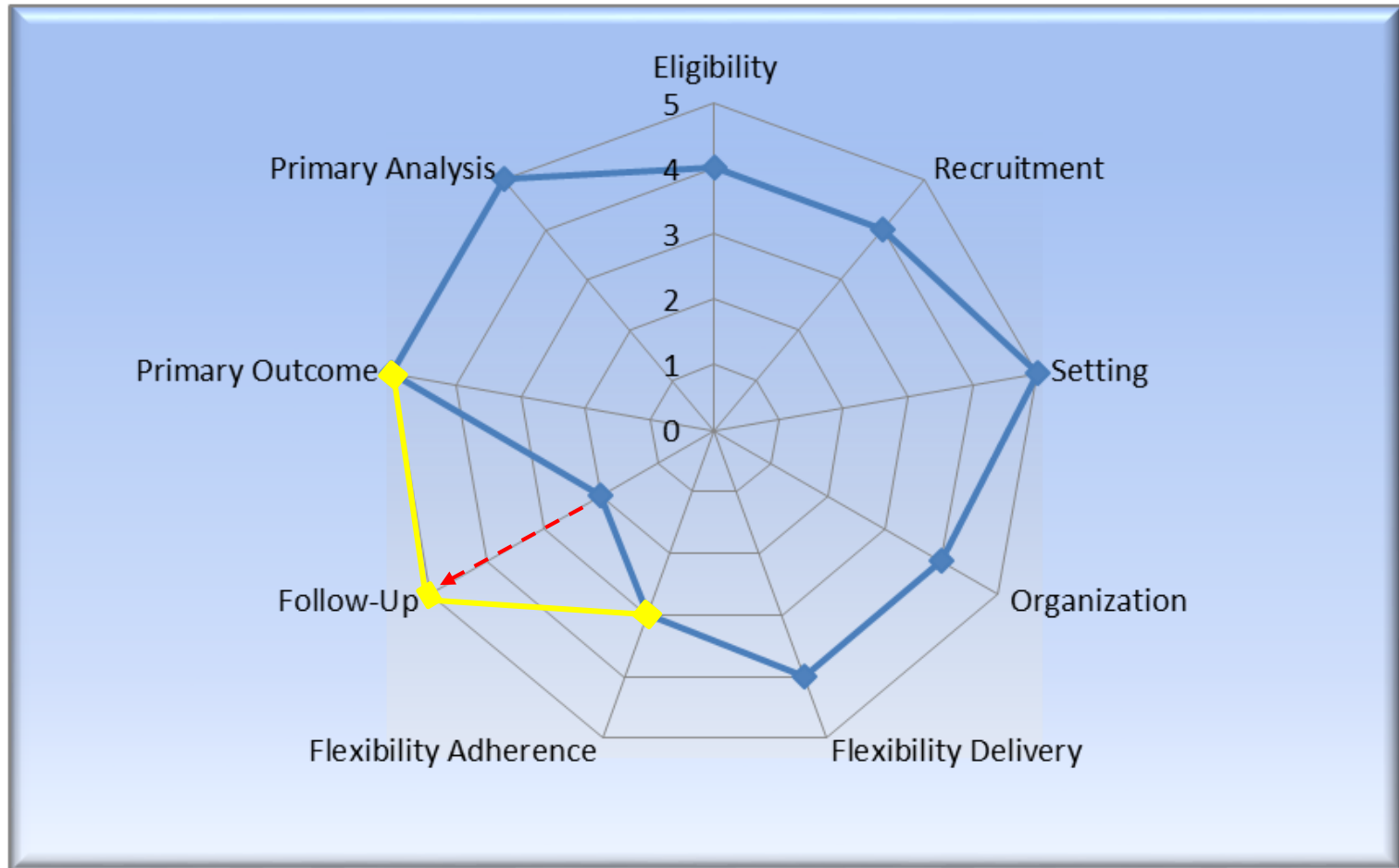


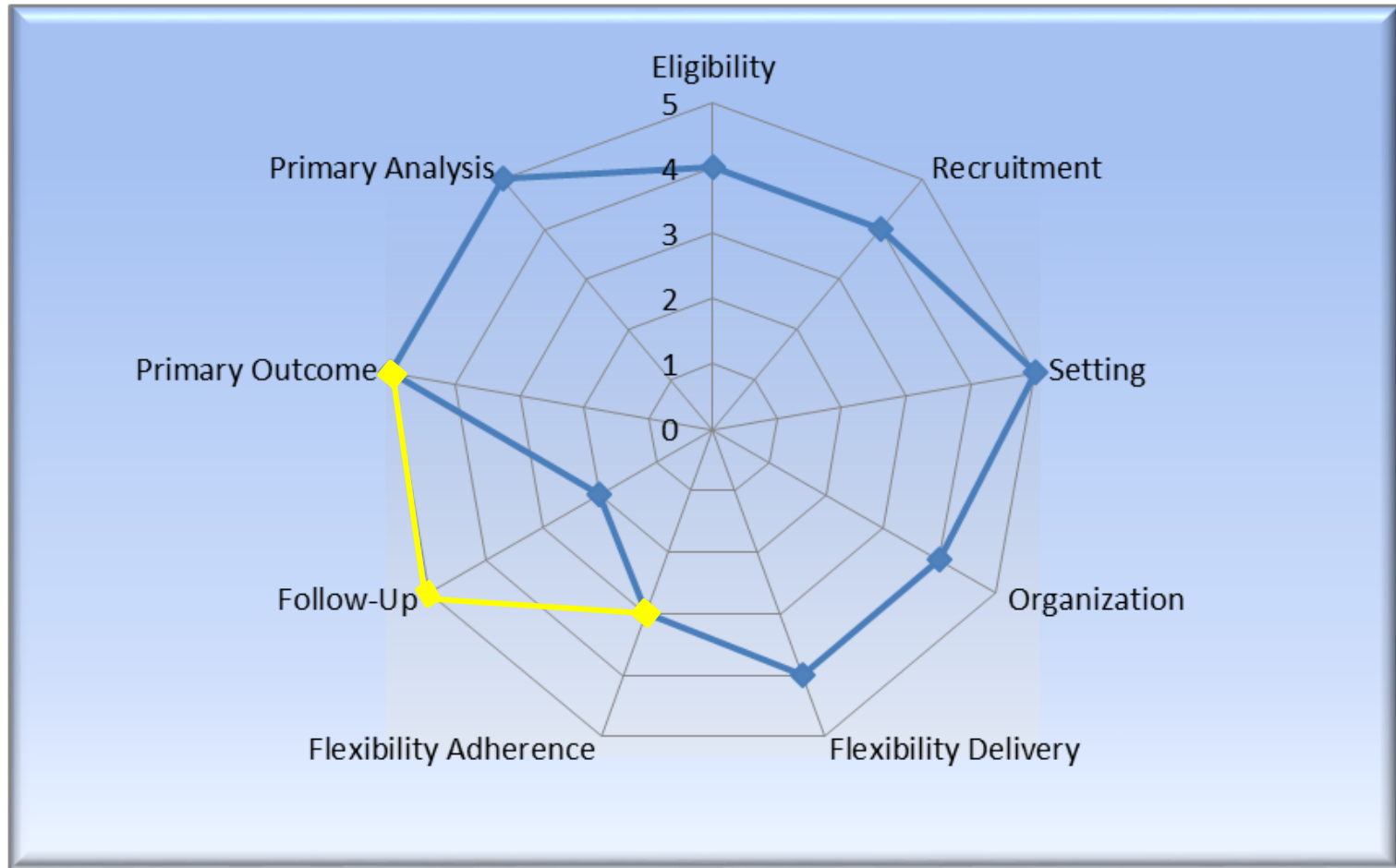
FIGURE 2. Intervention and control group emergency department visits over the course of the 12 months after injury. Note. N = 171 at all time points; ED = emergency department; m = months.

Zatzick, Russo, Thomas et al 2018

TSOS PRECIS-2 Wheel



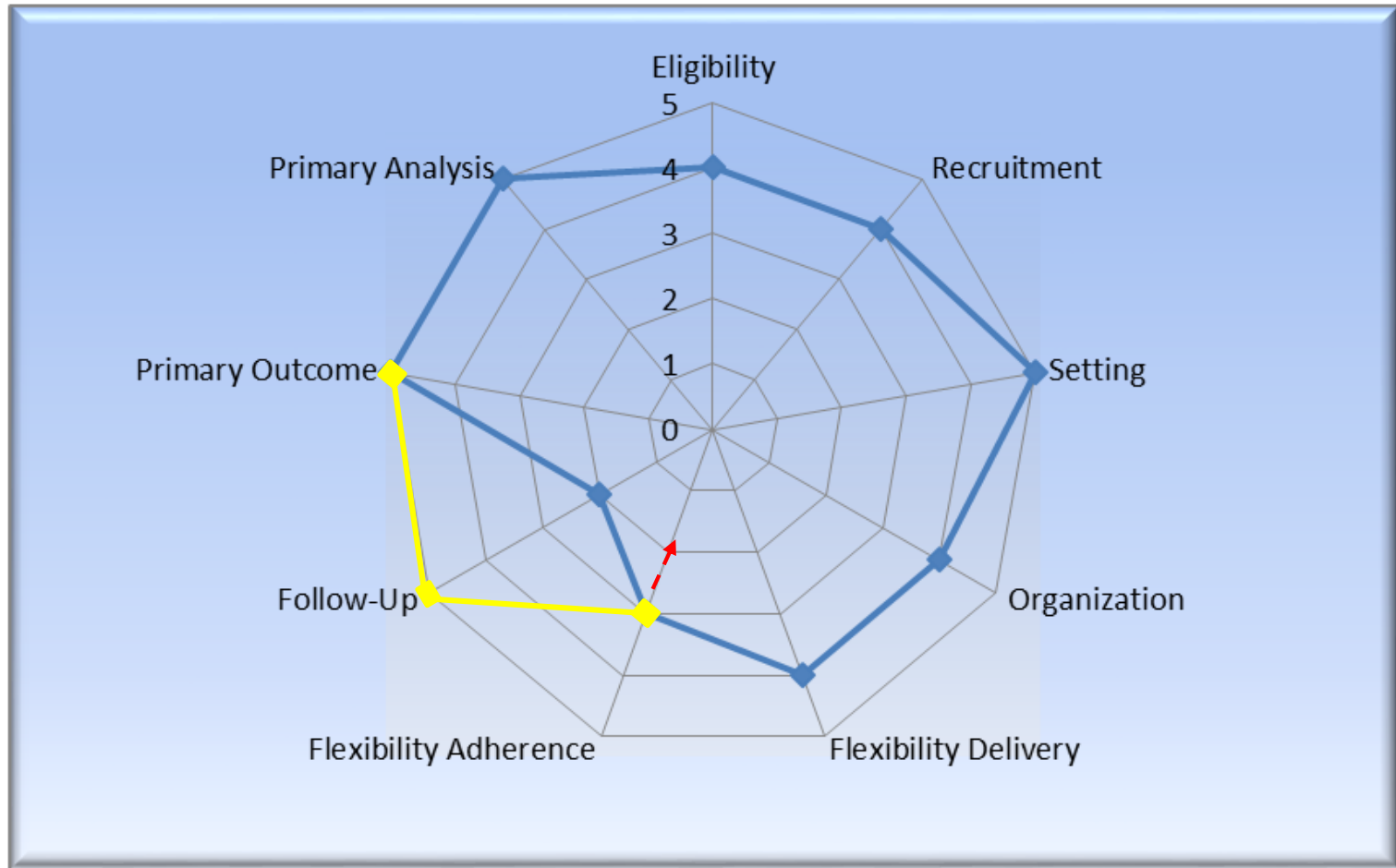
TSOS PRECIS-2 Wheel



Pragmatic Implementation Process Assessment: Methods Development

- Process assessments common in implementation science informed studies
- Often involve in-depth mixed methods
 - Semi-structured interviews
 - In-depth qualitative coding/analyses
- Not workflow integrated

TSOS PRECIS-2 Wheel





What Constitutes a Pragmatic Mixed Method for Implementation Process Assessments?

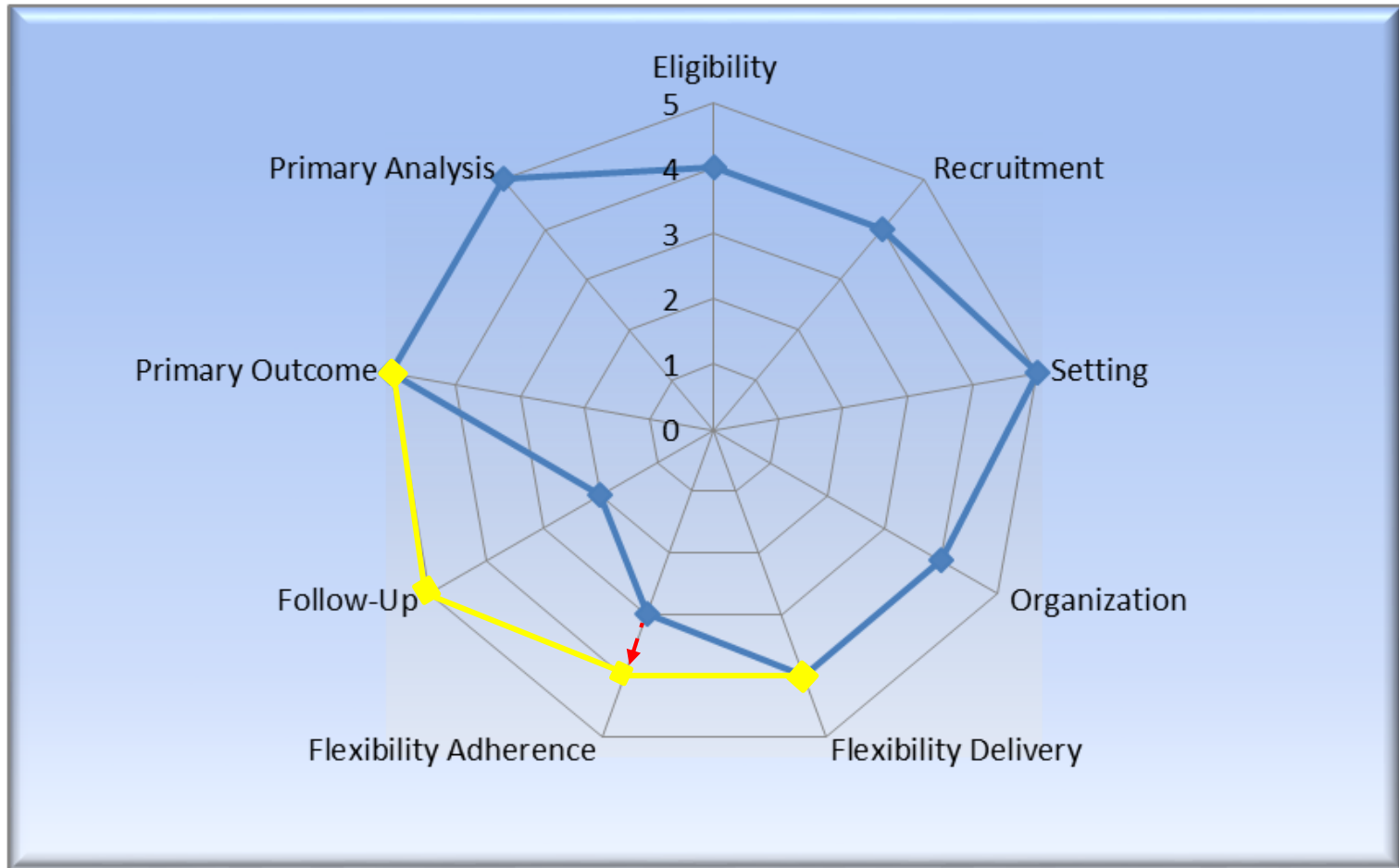
- Minimize cost per subject randomized
- Captured reliably as part of routine pragmatic trial roll-out
- Do not require central adjudication

Methods Development: Rapid Assessment Procedure Informed Clinical Ethnography (RAPICE*)

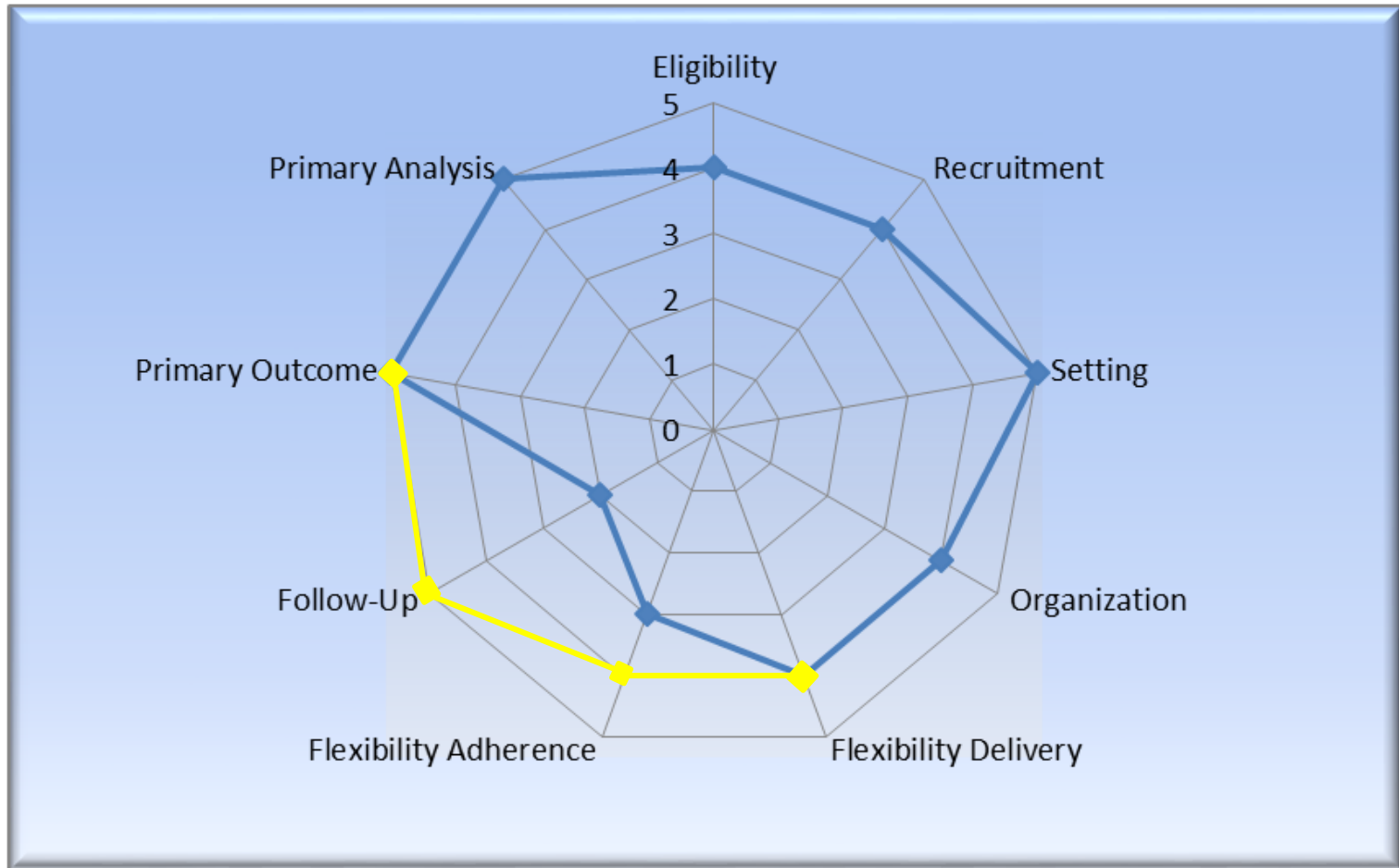
- TSOS research team spends hundreds of hours immersed in trauma care system clinical context
- Front line clinician-researcher conducts participant observation
- Field notes & jottings taken, logs recorded
- Field data regularly reviewed (e.g., monthly) with mixed-method expert consultant
- Themes related to trial roll-out and sustainable implementation iteratively discussed & documented
- RAPICE procedures do not drive up costs of trial

*Palinkas & Zatzick ADPM, 2018

TSOS PRECIS-2 Wheel



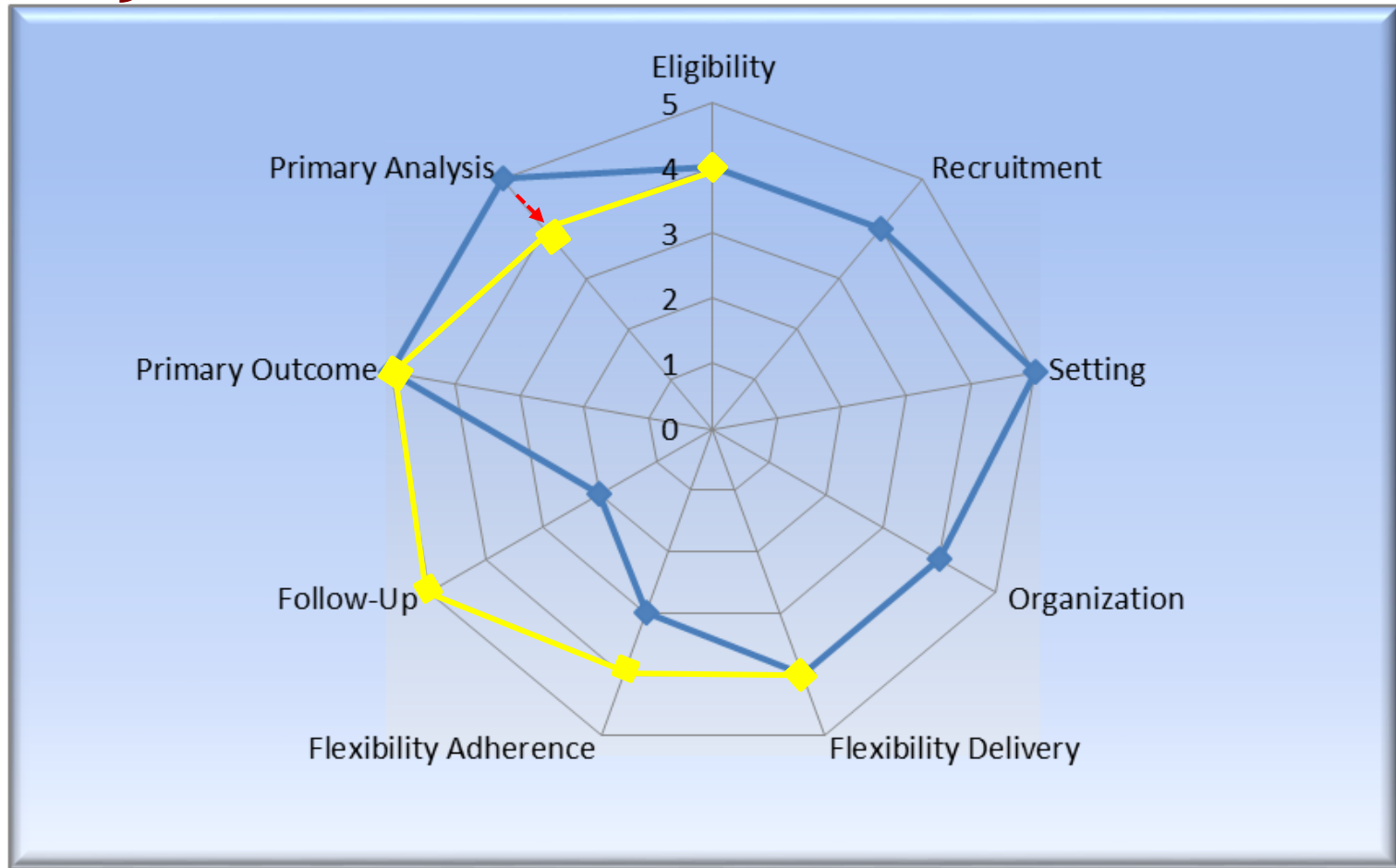
TSOS PRECIS-2 Wheel



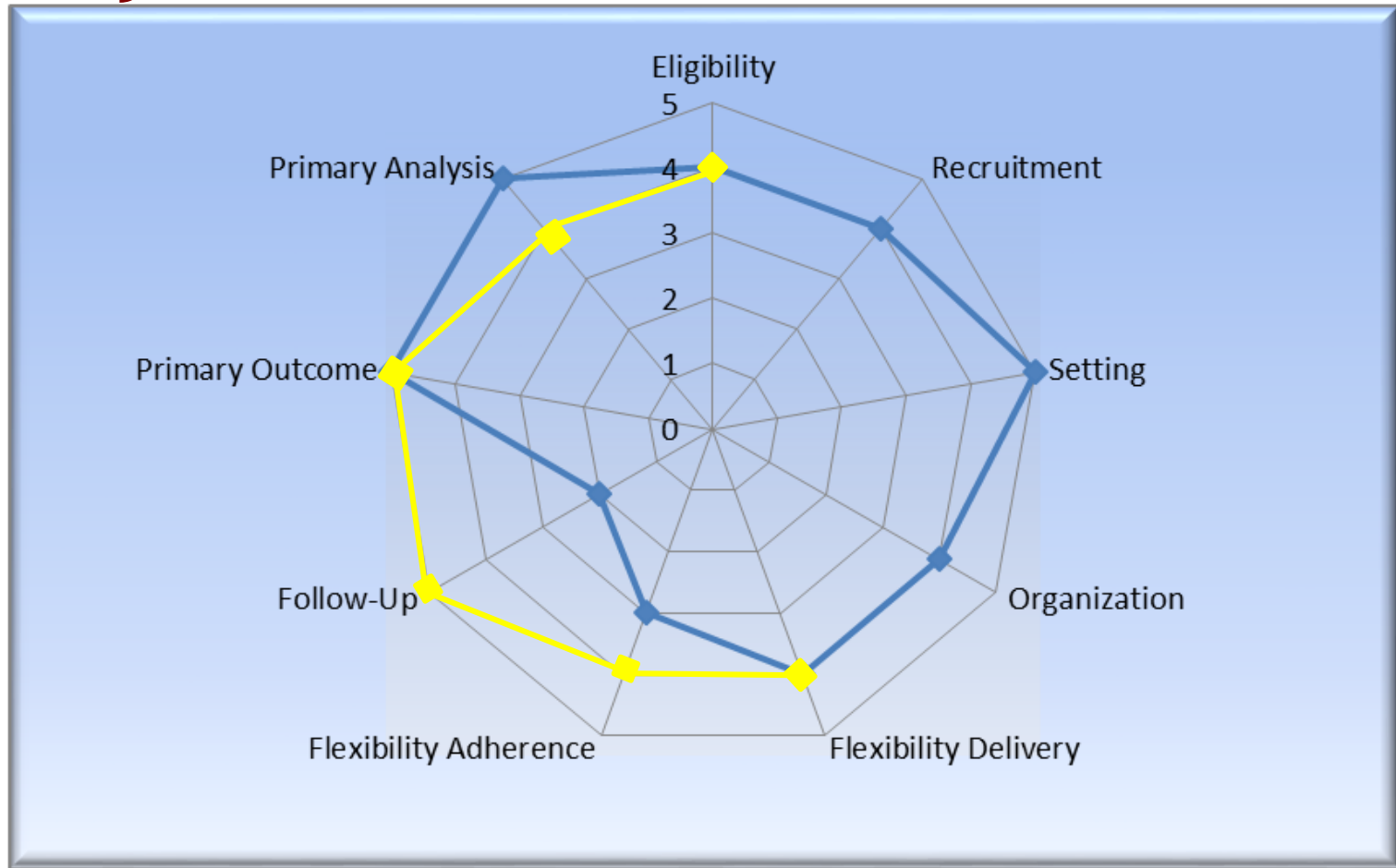
TSOS RAPICE Implementation Process Assessment: Preliminary Findings

- Recurrent intervention and research staff turnover across sites
- Consistent observation that some patients do not engage in the intervention
- Implementation process assessment informs a priori secondary hypotheses that suggest per protocol modifications to the original ITT analyses

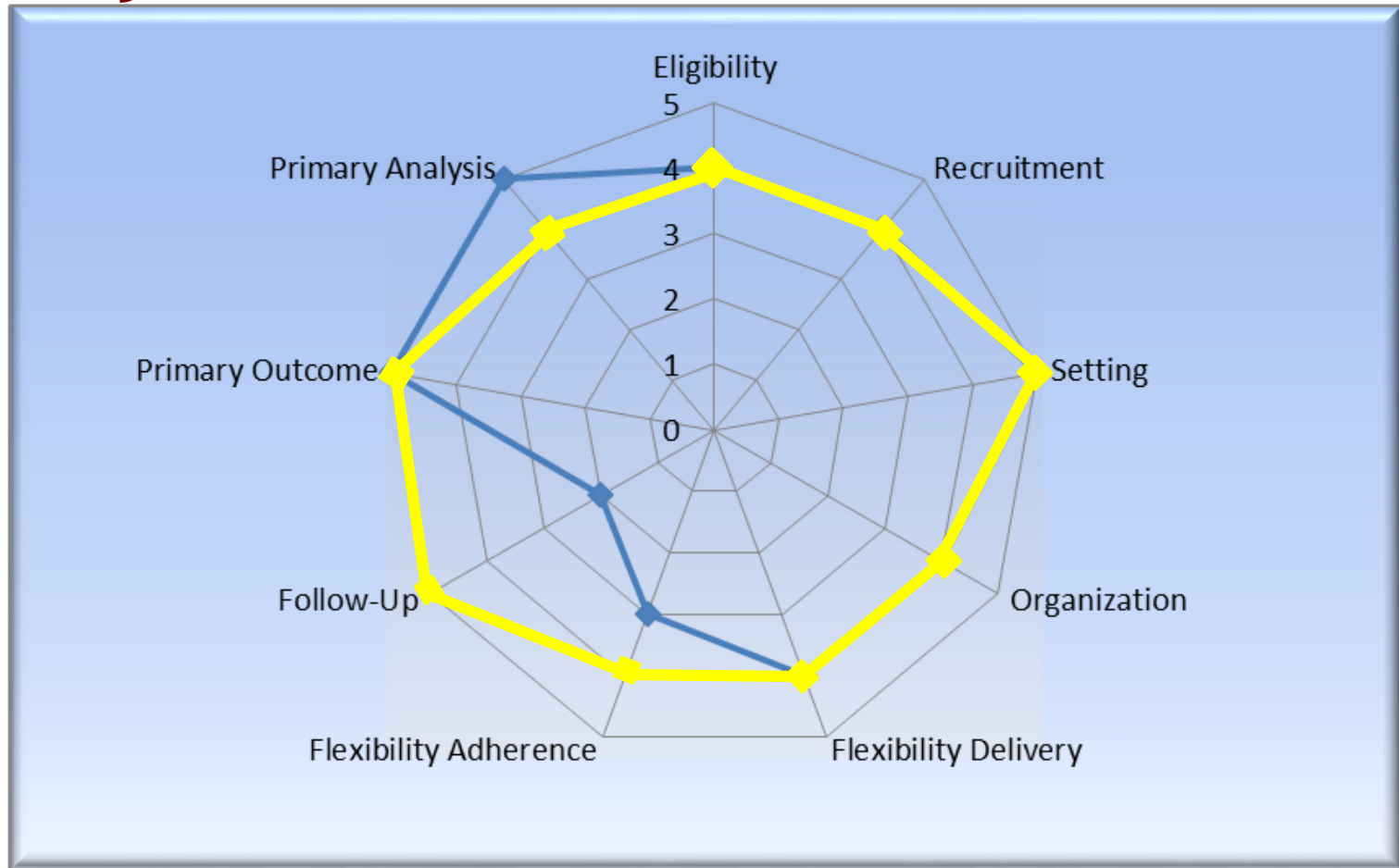
Trauma Survivors Outcomes & Support (TSOS) PRECIS-2 Wheel



Trauma Survivors Outcomes & Support (TSOS) PRECIS-2 Wheel



Trauma Survivors Outcomes & Support (TSOS) PRECIS-2 Wheel





Summary: TSOS Progress on Effectiveness & Implementation Aims

- Effectiveness
 - Baseline data cleaned and analyses have begun
 - Follow-up interviews ongoing with 75-80% completion
- Implementation
 - Pragmatic implementation process methods developed
 - TSOS implementation process assessment ongoing
 - Key implications for multiple TSOS PRECIS-2 domains