

# Risk of Bias (Critical Appraisal)

## Objective

Evaluate the quality of evidence of included cohort studies or controlled trials.

## Configure Risk of Bias

From administrative settings, select the ROB mode.

**Administrator Settings:** Opioid Use Disorder - Phase I

**Risk of Bias**

**Choose a system:**

- No Selection
- None
- System: SIGN 50, Version: 2011**
- System: Cochrane RoB, Version: 2
- System: JBI, Version: 2020

## Choose Scope

Assess Risk of Bias the study level or the outcome level:

**Administrator Settings:** Opioid Use Disorder - Phase I

**Risk of Bias**

**Choose a system:**  
System: SIGN 50, Version: 2011

**Choose a scope:**  
Some systems allow you evaluate the risk of bias of entire studies or individual outcomes.  
 Entire Study  
 Individual Outcomes

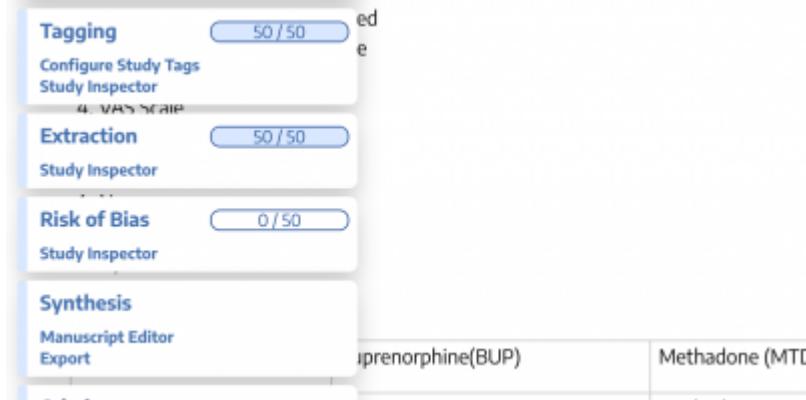
**Select Outcomes:**

Data Element	Timepoint	RoB
% Change employed	Outcome	<input type="checkbox"/>
% abstinence	Outcome	<input checked="" type="checkbox"/>
% change insured	Outcome	<input checked="" type="checkbox"/>
% negative urine sample	Outcome	<input type="checkbox"/>
Anxiety	Outcome	<input type="checkbox"/>
COWS Scale	Outcome	<input checked="" type="checkbox"/>
Confusion	Outcome	<input type="checkbox"/>

## Start Assessing Risk of Bias

## Navigate to ROB Module

After selecting the system and scope, reviewers can begin assessing ROB. You may need to refresh. Once the page reloads, ROB will appear in the navigation menu.



## Read study and select study type

Depending on the selected ROB system, you may need to select a Cohort Study or Controlled Study to begin assessment.

The screenshot displays a study abstract from the journal 'ADDICTION RESEARCH REPORT'. The title is 'Initiating buprenorphine treatment for opioid use disorder during short-term in-patient 'detoxification': a randomized clinical trial.' The authors listed are Michael Stein<sup>1,2</sup>, Debra Herman<sup>2,3</sup>, Micah Conti<sup>2</sup>, Bradley Anderson<sup>2</sup> & Genie Bailey<sup>3</sup>. The study was conducted at Boston University School of Public Health, Boston, MA, USA; Department of General Medicine and Addictions Research, Butler Hospital, Providence, RI, USA; and Department of Psychiatry and Human Behavior, The Warren Alpert Medical School of Brown University, Providence, RI, USA. The abstract section discusses the effectiveness of linking people from short-term in-patient managed withdrawal programs ('detoxification') to long-term, primary care-based buprenorphine. The design was a single-site randomized controlled trial comparing buprenorphine initiation during an opioid withdrawal program and linkage to office-based buprenorphine (LINK) after discharge with standard withdrawal management (WM).

## Assess study bias

Fill out the ROB questions as you read through the uploaded study.

Risk of Bias: Opioid Use Disorder - Phase I

**Patient-centered Outcomes in Participants of a Buprenorphine Monthly Depot (BUP-XR) Double-blind, Placebo-controlled, Multicenter, Phase 3 Study.**

**ORIGINAL RESEARCH**

**Patient-centered Outcomes in Participants of a Buprenorphine Monthly Depot (BUP-XR) Double-blind, Placebo-controlled, Multicenter, Phase 3 Study**

Walter Ling, MD, Vijay R. Nadipelli, MS, Caitlyn T. Solem, PhD, Naoko A. Ronquest, PhD, Yu-Chen Yeh, MS, Susan M. Learned, MD, Vishal Mehta, MD, and Christian Heidbreder, PhD

**Objectives:** Opioid use disorder (OUD) is associated with physical, social, psychological, and economic burden. This analysis assessed the effects of BUP-XR (extended-release buprenorphine), a subcutaneously injected, monthly buprenorphine treatment for OUD compared with placebo on patient-centered outcomes measuring meaningful life changes.

**Methods:** Patient-centered outcomes were collected in a 24-week, phase 3, placebo-controlled study assessing the efficacy, safety, and tolerability of BUP-XR 300/500 mg (8 × 300 mg) and 300/100 mg (2 × 300 mg followed by 4 × 100 mg) injections in treatment-seeking participants with moderate-to-severe OUD. Measures included the

**Results:** Participants receiving BUP-XR ( $n = 389$ ) versus placebo ( $n = 98$ ) had significantly greater changes from baseline on the EQ-5D-5L index (300/300 mg: difference = 0.0636,  $P = 0.003$ ), EQ-5D-5L visual analog scale (300/300 mg: difference = 5.9,  $P = 0.017$ ; 300/100 mg: difference = 7.7,  $P = 0.002$ ), and SF-36v2 physical component summary score (300/300 mg: difference = 3.8,  $P < 0.001$ ; 300/100 mg: difference = 3.2,  $P = 0.002$ ). Satisfaction was significantly higher for participants receiving BUP-XR 300/300 mg (88%,  $P < 0.001$ ) and 300/100 mg (88%,  $P < 0.001$ ) than placebo (69%). Employment and percentage of insured participants increased by 10.8% and 4.1% with BUP-XR 300/300 mg and 10.9%

**Risk of Bias Assessment:**

- Internal Validity:**
  - Well covered (Yes): ● Comment
  - Adequately addressed: ● Comment
  - Poorly addressed: ● Comment
  - Not addressed (no): ● Comment
  - Not reported: NA Comment
- An adequate concealment method is used:**
  - No Selection: Comment
  - Well covered (Yes): ● Comment
  - Adequately addressed: ● Comment
  - Poorly addressed: ● Comment
  - Not addressed (no): ● Comment
  - Not reported: NA Comment

**Comments (0)**

You can monitor your progress, skip studies (and return to them later), and leave comments!

## Risk of Bias Visuals

By completing Risk of Bias, you automatically generate **Risk of Bias visuals: Domain Distribution** and **Stoplight diagrams** on Synthesis.

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