PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

FINAL RESEARCH REPORT

<Title of Your Report>

<Author names with academic degrees in this format: Jane Doe, MD, MPH1,2>

AFFILIATIONS:

1<Your department/division, facility/clinic, city, state, and country (if outside the United States)—for example, Surgical Outcomes Research Center, Department of Surgery, University of Washington, Seattle>

2<Your department/division, facility/clinic, city, state, and country (if outside the United States)>

Original Project Title: <Original title of report, if applicable>

PCORI ID: <PCORI ID>

HSRProj ID: [<](https://hsrproject.nlm.nih.gov/view_hsrproj_record/20143375)ID, if applicable>

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# ABSTRACT

**Background:** <Type your report background here>

**Objective {or Objectives, if more than one}:** <Type your specific aims here>

**Methods:** <Type your study methods here>

**Results:** <Type your study results here. Present numerical outcomes as the difference between groups and 95% confidence interval.>

**Conclusions:** <Type your study conclusions here>

**Limitations:** <Type your study limitations here>

***Note:*** *This template contains all the paragraph styles you need to write your report. To access these styles:*

* *On a Windows PC, open Microsoft Word. On the Home tab of the ribbon, click the dialog box launch button at the bottom right of the Styles gallery to open the* ***Styles Pane****.*
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*In the Styles Pane, simply click the style you want to apply (e.g., Heading 1, 1-Body Text, 1-Bullet 1) and start typing.*

# BACKGROUND

<Type the background for your report.>

## <Type Your Heading 2 Text Here>

<Type text beneath this heading.>

### <Type Your Heading 3 Text Here>

<Type text beneath this heading.>

Type your heading 4 text here. <Type text after this heading.>

Type your heading 5 text here. <Type text after this heading.>

***Note:*** *The “Background” section must conclude with your study’s specific aims and hypotheses.*

# PARTICIPATION OF PATIENTS AND OTHER STAKEHOLDERS

<Type the text for this section of your report.>

***Note:*** *The “Participation of Patients and Other Stakeholders” section should describe how you identified, recruited, and retained stakeholders; the type and number of stakeholders involved; and the engagement activities that occurred or are ongoing. Describe and provide examples of how you obtained and considered patient and stakeholder feedback and how it influenced your study. If your study did not involve patients or stakeholder engagement, please explain why.*

# AIM 1

<Type a brief introduction to the “Aim 1” section.>

## Methods

<Type an introduction to the methods used in aim 1. For each subsection, you may simply refer to the Study Protocol or Research Plan, if applicable, with the text “See Study Protocol” or “See Research Plan.”>

### Overview

<Summarize the aim 1 design.>

### Setting

<Summarize the aim 1 setting.>

### Participants

<Summarize the participants in aim 1.>

### Interventions and Comparators or Controls

<Summarize the aim 1 interventions and comparators or controls.>

### Outcomes

<Summarize the aim 1 outcomes.>

### Covariates

<Summarize the aim 1 covariates.>

### Sample Size Calculations and Power

<Summarize the aim 1 sample size calculations and power.>

### Time Frame for Aim 1

<Summarize the aim 1 time frame.>

### Data Collection and Sources

<Summarize the aim 1 data-collection process and data sources.>

### Analytical and Statistical Approaches

<Summarize the analytical and statistical approaches to aim 1.>

### Changes to the Original Study Design

<Summarize changes to the original aim 1 study design. Confirm IRB (if applicable) and PCORI approval, and explain the reasons for the design modifications you were required to make or that became necessary during the study.>

## Results

<Summarize the results of aim 1. Results that pertain to the study as a whole should appear in the main “Overall Results” section.>

## Discussion

<Briefly summarize the discussion of aim 1 here. A discussion that pertains to the study as a whole should appear in the main “Overall Discussion” section.>

# AIM 2

## Methods

<Type an introduction to the methods used in aim 2. For each subsection, you may simply refer to the Study Protocol or Research Plan, if applicable, with the text “See Study Protocol” or “See Research Plan.”>

### Overview

<Summarize the aim 2 design.>

### Setting

<Summarize the aim 2 setting.>

### Participants

<Summarize the participants in aim 2.>

### Interventions and Comparators or Controls

<Summarize the aim 2 interventions and comparators or controls.>

### Outcomes

<Summarize the aim 2 outcomes.>

### Covariates

<Summarize the aim 2 covariates.>

### Sample Size Calculations and Power

<Summarize the aim 2 sample size calculations and power.>

### Time Frame for Aim 1

<Summarize the aim 2 time frame.>

### Data Collection and Sources

<Summarize the aim 2 data-collection process and data sources.>

### Analytical and Statistical Approaches

<Summarize the analytical and statistical approaches to aim 2.>

### Changes to the Original Study Design

<Summarize changes to the original aim 2 study design. Confirm IRB (if applicable) and PCORI approval, and explain the reasons for the design modifications you were required to make or that became necessary during the study.>

## Results

<Summarize the results of aim 2. Results that pertain to the study as a whole should appear in the main “Overall Results” section.>

## Discussion

<Briefly summarize the discussion of aim 2 here. A discussion that pertains to the study as a whole should appear in the main “Overall Discussion” section.>

***Note:*** *If your report has more than 2 aims, duplicate this section as needed.*

# OVerall RESULTS

<If needed, please find our Table Templates [here](https://originreview.org/table-templates/). To use them, copy the shell you need and paste it into this report.>

<*Please suppress line numbers for tables, table titles, notes, and legends. To suppress line numbers, select the desired lines in the report. In the Menu Ribbon, choose Layout and then click the Line Numbers dropdown arrow. Select the option to ‘Suppress for Current Paragraph.’.>*

Figure 1. <Type Brief Descriptive Figure Title>

<To edit this figure, click twice in each text box, then edit the text as appropriate. Once you are finished, please save this diagram as a picture object and replace it the text boxes with the Figure object in the final submitted report.>

**Participant Flow Diagram**

## Enrollment

## Allocation

## Follow-up

## Analysis

Analyzed (n = x)

 Excluded from analysis <give reasons> (n = x)

Analyzed (n = x)

 Excluded from analysis <give reasons> (n = x)

Lost to follow-up <give reasons> (n = x)

Discontinued intervention <give reasons> (n = x)

Lost to follow-up <give reasons> (n = x)

Discontinued intervention <give reasons> (n = x)

Allocated to intervention (n = x)

 Received allocated intervention (n = x)

 Did not receive allocated intervention <give reasons> (n = x)

Allocated to intervention (n = x)

 Received allocated intervention (n = x)

 Did not receive allocated intervention <give reasons> (n = x)

Excluded (n = x)

  Not meeting inclusion criteria (n = x)

  Declined to participate (n = x)

  Other reasons (n = x)

Assessed for eligibility (n = x)

Randomized (n = x)

# Overall DISCUSSION

<Type your study discussion under the following headings.>

## Summary of Results

<Summarize the results of your study.>

## Results in Context

<Provide context for your study’s results.>

## Potential to Affect Healthcare Decision-Making

<Discuss your study’s potential to affect health care decision-making.>

## Lessons Learned

<Describe the lessons learned from your study.>

## Generalizability

<Discuss how/whether the results of your study can be generalized to different or larger populations.>

## Subgroup Analyses/Heterogeneity of Treatment Effects

<Described the subgroup analyses/heterogeneity of treatment effects in your study. **>**

## Study Limitations

<Describe the limitations of your study.>

## Future Research

<Describe future research on this topic.>

# CONCLUSIONS

<Type your conclusions.>

# REFERENCES

<References should follow AMA Manual of Style, 11th edition, and must be numbered according to the order of appearance in the text. For further guidance, please refer to the [Instructions for Awardee](https://www.pcori.org/sites/default/files/PCORI-Draft-Final-Research-Report-Instructions.pdf).>

1. <Type reference>

2. <Type reference>

# ACKNOWLEDGMENTS

***Note:*** *This section is optional.*

# PUBLICATIONS SUPPORTED BY PCORI AWARD

***Note:*** *This section is optional.*

<List related publications.>

# Data Sharing Plan

***Note:*** *This section is optional.*

< If you have a data sharing plan, explain when and where data will be available, the expected makeup of the datasets, and the approximate date of deposit per [PCORI’s Policy for Data Management and Data Sharing](https://www.pcori.org/about/governance/policy-data-management-and-data-sharing). If you do not have a data sharing plan, please remove this entire Data Sharing Plan section.>

# APPENDIX/APPENDICES

***Note:*** *This section is optional. List the Appendices here but upload them as separate files.*

Appendix A. <Title of Appendix A>