STATISTICAL ANALYSIS PLAN

TRIAL NAME

Principal Investigator(s):

Lead Statistician:

Version Number: 0.0
Version Date:

Summary of Changes from Previous Version

Date	Description of Change (Include specific sections affected)	Rationale for Change

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Primary Outcome	Brief Description of Measure	Outcome Measured By	Time Frame

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Secondary Outcome	Brief Description of Measure	Outcome Measured By	Time Frame

2.3 Exploratory (Tertiary) Outcomes

Tertiary Outcome	Brief Description of Measure	Outcome Measured By	Time Frame

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Cost Outcomes	Brief Description of Measures	Measured By	Time Frame

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Covariates and Moderators	Definition	Role	Data Source

4. DEFINITION OF STUDY SAMPLES

4.1 Inclusion and Exclusion Criteria

We will require all participants to meet all the following inclusion criteria to participate in the trial.

Inclusion Criteria	Rationale and Source

Participants who meet any of the exclusion criteria at baseline will be excluded from study participation.

Exclusion Criteria	Rationale

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