Bridge Project - Data Analysis Plan

Overview

This document describes the statistical analysis plan for the MI Bridge trial and the ReDirection trial.

where relevant, we will compare these two models using a likelihood ratio test and retain the better performing model for interpretation. we will use a significance threshold of .05 for all tests.

Missing data will not be imputed. We will use all valid data from participants, including those who drop out of the study.

For linear mixed effects models, we will use Satterthwaite degrees of freedom for inferential tests for coefficients.

This document provides verbal descriptions for the planned analyses, and the accompanying R script provides the base code that will be used for the analyses.

Sample size planning

Based on the rate of recruitment in a pilot study, we estimate that it will be feasible for each of the two planned studies to recruit approximately N = 60 participants. To assess the statistical power of the planned studies, using this sample size, we conducted a simulation based on the variance in the main outcome variables measured in the pilot study (specifically, motivation to seek care and SSAS sum scores). In these simulations, we assessed the primary model used to examine this outcome measure (described below).

The simulation addressing motivation to seek care suggests that with the present design, the study would have approximately 83% power to detect a relatively small effect of b = 0.25 for the effect of time spent in treatment.

```
power_simulation
```

```
Power for predictor 'time_after', (95% confidence interval):
      83.10% (80.63, 85.37)

Test: t-test with Satterthwaite degrees of freedom (package lmerTest)
      Effect size for time_after is 0.25

Based on 1000 simulations, (0 warnings, 0 errors)
alpha = 0.05, nrow = 450

Time elapsed: 0 h 1 m 38 s
```

In short, the planned study will have adequate power for modestly sized effects on motivation to seek care (primary outcome in Study 1b).

The simulation addressing SSAS sum scores suggests that with the present design, the studies would have approximately 98% power to detect a relatively small effect of b = 1.50 for the effect of time spent in treatment.

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power_simulation_ssas
```

```
Power for predictor 'time_after', (95% confidence interval):
      98.20% (97.17, 98.93)

Test: t-test with Satterthwaite degrees of freedom (package lmerTest)
      Effect size for time_after is 1.5

Based on 1000 simulations, (0 warnings, 0 errors)
alpha = 0.05, nrow = 450

Time elapsed: 0 h 1 m 44 s
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In short, the planned studies will have adequate power for modestly sized effects on motivation to seek care (primary outcome in Study 2b and a secondary outcome in Study 1b).

We will recruit participants until we have reached a total of N = 60 non-dropout participants for each study (Study 1b and Study 2b). For Study 1b, we define a "dropout" as someone who takes part in fewer than 1 weekly measurement. For Study 2b, we define a "dropout" as someone who takes part in fewer than 2 weekly measures.

Study 1b: Bridge

Primary analyses

Treatment acceptance (care seeking)

Rated motivation to seek treatment

Ratings of motivation to seek treatment will be modeled with a linear mixed effects model, with a dummy coded treatment predictor (0 = waitlist, 1 = MI), indicating whether treatment has commenced, a time predictor (starting at 0, and counting each weekly measurement point), and a time-since-treatment predictor (starting at 0, and counting up at each measurement point after treatment begins). The treatment coefficient represents the immediate effect of commencing the treatment. The time predictor captures the overall linear effect of the passage of time in the study, and the time-since-treatment coefficient captures the linear effect of spending time in the treatment.

Motivation for change

Responses on the Change Questionnaire will be modeled using a mixed-effects model like the one above used for rated motivation to seek treatment.

Secondary analyses

Do you think you will actually seek care? (dichotomous)

Responses to the dichotomous question of whether the participant intents to seek treatment in the next month will be modeled using a mixed-effects model like the one above used for rated motivation to seek treatment. However, this model will be a logistic regression, rather than a linear regression.

Sexual urges (SSAS)

Scores on the SSAS will be modeled using a mixed-effects model like the one above used for rated motivation to seek treatment.

CSAM usage

Self-reported CSAM usage, measured by the SChiMRA+ (total number of reported hours per week), will be modeled using a mixed-effects model like the one above used for rated motivation to seek treatment.

Depression (PHQ-9)

Scores on the PHQ-9 are measured pre-treatment and post-treatment. These scores will be modeled in a series of linear mixed effects models. The first model will model fixed effects for treatment condition and an indicator for the timing of the measurement (pre and post), with random intercepts for each participant. The second model will add the interaction between the two fixed effects (i.e., condition and timing of measurement). We will compare the models and retain the better fitting one.

Mediating effect of MI on motivation to seek treatment through motivation to change

We will examine the potential mediating role of motivation to change (Change Questionnaire) on motivation to seek care and whether the participants indicates they are likely to actually seek care (dichotomous). To do so, we will take a mixed effects longitudinal mediation approach (similar to that of Park et al, 2017, 10.1037/dev0000235), wherein we will fit mixed effects models predicting the mediator and outcome variables using dummy coded treatment predictor (0 = waitlist, 1 = MI), indicating whether treatment has commenced, a time predictor (starting at 0, and counting each weekly measurement point), and a time-since-treatment predictor (starting at 0, and counting up at each measurement point after treatment begins). We will then estimate the indirect effect of time-since-treatment through motivation to change on the outcome variables, using parametric bootstrapping. The mediator will be person mean centered for these models, in order to capture the within-person effects.

Dynamic risk (ACUTE-2007)

Scores on the ACUTE-2007 will be modeled using a mixed-effects model like the one above used for rated motivation to seek treatment.

Hypersexuality (HBI-19)

Scores on the HBI-19 are measured pre-treatment and post-treatment. These scores will be modeled with an approach like those used for the PHQ-9 scores above.

Moderating effect of autistic traits (RAADS-14) on treatment effectiveness

We will examine the potential moderating role of autistic traits (measured by the RAADS-14, at baseline) on the effectiveness of the treatment on the primary outcomes (motivation to change and motivation to seek treatment). For each variable, we will fit two linear mixed effects models: in the first, we will add grand mean centered RAADS-14 sum scores as a predictor to the model used to assess the effect of the treatment on the primary outcomes (see above); in the second, we will add two-way interaction terms between RAADS-14 sum scores and the dummy coded treatment predictor (0 = waitlist, 1 = MI) and the time-since-treatment predictor (starting at 0, and counting up at each measurement point after treatment begins). For each outcome variable, we will compare the base model used to assess each outcome (see above) and these two additional models and retain the best performing model for interpretation.

Study 2b: ReDirection

Sample size planning

Primary analyses

Sexual urges (SSAS)

scores on the SSAS will be modeled with a linear mixed effects model, with a dummy coded treatment predictor (0 = waitlist, 1 = redirection), indicating whether treatment has commenced, a time predictor (starting at 0, and counting each weekly measurement point), and a time-since-treatment predictor (starting at 0, and counting up at each measurement point after treatment begins). the treatment coefficient represents the immediate effect of commencing the treatment. the time predictor captures the overall linear effect of the passage of time in the study, and the time-since-treatment coefficient captures the linear effect of spending time in the treatment.

CSAM usage

Self-reported CSAM usage will be modeled using a mixed-effects model like the one above used for SSAS scores.

SChiMRA B (Other behaviors related to sexual interest in children)

Self-reported interactingbehaviors related to sexual interest in children (total number of hours in the last week) will be modeled using a mixed-effects model like the one above used for SSAS scores.

Depression (PHQ-9)

Scores on the PHQ-9 are measured pre-treatment and post-treatment. These scores will be modeled in a series of linear mixed effects models. The first model will use fixed predictors for treatment condition and an indicator for the timing of the measurement (pre and post), with random intercepts for each participant. The second model will add the interaction between the two fixed predictors. We will compare the models and retain the better fitting one.

Secondary analyses

Dynamic risk (ACUTE-2007)

Scores on the ACUTE-2007 will be modeled using a mixed-effects model like the one above used for SSAS scores.

Hypersexuality (HBI-19)

Scores on the HBI-19 are measured pre-treatment and post-treatment. These scores will be modeled with an approach like those used for the PHQ-9 scores above.

Mediating effect of treatment on CSAM usage through sexual urges (SSAS)

We will examine the potential mediating role of sexual urges on the use of CSAM. To do so, we will take a mixed effects longitudinal mediation approach (similar to that of Park et al, 2017, 10.1037/dev0000235), wherein we will fit mixed effects models predicting the mediator and outcome variables using dummy coded treatment predictor (0 = waitlist, 1 = ReDirection), indicating whether treatment has commenced, a time predictor (starting at 0, and counting each weekly measurement point), and a time-since-treatment predictor (starting at 0, and counting up at each measurement point after treatment begins). We will then estimate the indirect effect of time-since-treatment through SSAS scores on CSAM usage, using parametric bootstrapping. The mediator will be person mean centered for these models, in order to capture the within-person effects.

Moderating effect of autistic traits (RAADS-14) on treatment effectiveness

We will examine the potential moderating role of autistic traits (measured by the RAADS-14, at baseline) on the effectiveness of the treatment on the primary outcome (SSAS scores). We will fit two linear mixed effects models: in the first, we will add grand mean centered RAADS-14 sum scores as a predictor to the model used to assess the effect of the treatment on the primary outcomes (see above); in the second, we will add two-way interaction terms between RAADS-14 sum scores and the dummy coded treatment predictor (0 = waitlist, 1 = ReDirection) and the time-since-treatment predictor (starting at 0, and counting up at each measurement point after treatment begins). We will compare the base model used to assess each outcome (see above) and these two additional models and retain the best performing model for interpretation.