BETTER HEALTH: DURHAM

NCT03052959

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Statistical Analysis Plan

BETTER HEALTH: DURHAM

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Technical details

Software used for the analysis: R or SAS

1. Analysis populations

Intent to treat population: *In intervention arm, all participants with baseline and follow-up survey data will be included in the ITT population*

Per protocol population: *In intervention arm, only participants who have baseline and follow-up survey data AND who completed a prevention practitioner visit will be included in the per-protocol population*

Safety population: *n/a*

2. Missing Data

Describe procedures to be used for dealing with premature discontinuation from the study or treatment and the handling of spurious or missing data (e.g. use of multiple imputation, random effects models or complete case analyses). Describe any possible biases these techniques may introduce. Describe the underlying assumptions (e.g. Missing At Random) in both statistical and non-statistical terms. Describe procedures to be used for describing the pattern of permanent (i.e. dropout) or transient missing data.

Individuals without a primary outcome measurement will be removed from the study. We believe any covariate information will be Missing at Random, however we prefer to avoid any form of imputation.

3. Final Analyses

Individual-level data

Main binary exposure: Immediate vs. wait-list (wait-list being reference group)

Primary outcome will be examined as a rate (calculated for each individual participant):
Rate denominator is number of eligible CDPS actions at baseline.
Rate numerator is number of eligible CDPS actions at baseline that are accomplished at follow-up according to self-report.

Other covariates of interest: age, age category (ref: 40-49), sex, BMI, household income (ref: 60K+), difficulty making ends meet (y vs. n), ethnicity (ref: white), education (ref: some college or more), employment (ref: full-time), marital status (ref: married/common-law), food security (ref: food secure), MOS social supports

Notes:
- In the model, natural logarithm of the denominator will be treated as an offset term.

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- In the model, continuous measures such as age will be incorporated as continuous covariates
- The covariates mentioned above may not be adjusted for. We will decide a priori, rather than deciding based on balance assessment.

1. Please provide a table of baseline characteristics, as shown below (Table 1).

2. Please provide table of crude outcome information, as shown below (Table 2).

3. Please provide figure of outcome distribution, overall and by immediate and waitlist groups (Figure 1).

4. Please provide table of crude outcome information by clusters, as shown below (Table 3).

5. Univariate regression
Implement a mixed Poisson regression model with a random intercept term.
The random effects are cluster-specific (arising from a normal distribution with mean 0 and unknown variance) to account for the dependency among outcomes of individuals within the same cluster:
- outcome is the primary rate measure described above, where natural logarithm of the denominator will be treated as an offset term
- exposure is the main binary measure described above
- incorporate a cluster-specific random effect arising from a normal distribution with mean 0 and unknown variance

Please provide output similar to Table 4 below.

6. Multivariable regression
If suitable:
Implement a mixed Poisson multivariable regression model with a random intercept term (similar to above).
Please provide output similar to Table 5 below.

4. Protocol Deviations

Describe PDs and note how these will affect the analysis

5. Tables, listings and graphs:

Provide mock-ups for tables, listings and graphs

a. Subject Disposition

- number of patients screened
- number deemed ineligible, by reason for ineligibility
- number of patients eligible
- number of patients consented
- number of participants randomized to each arm

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- number of participants who withdrew consent
- number of participants lost to follow-up
- number of patients analyzed in each arm by intention to treat/per protocol approach

b. Baseline Characteristics

Table 1.

Characteristics	Entire study population (n=)	Immediate (n=)	Waitlist (n=)	Standardized difference (comparing immediate against waitlist)
Age in years				
Sex				

- All continuous variables to be reported as means and standard deviations, as well as medians and IQRs; categorical data to be presented as frequencies and percentages.

c. Primary Outcome

Describe analysis method (from protocol) as well as the results you expect to see (whether in table format or otherwise) from the primary outcome analysis.

Primary outcome will be examined as a rate (calculated for each individual participant):
Rate denominator is number of eligible CDPS actions at baseline.
Rate numerator is number of eligible CDPS actions at baseline that are accomplished at follow-up according to self-report.

Table 2. Crude outcome table at 6 months

Characteristic	Entire study population (n=)	Immediate (n=)	Waitlist (n=)	Standardized difference (comparing immediate against waitlist)
Primary outcome				

- Please provide mean, standard deviation, median, and IQR

Figure 1. Plot outcome distribution, overall and by immediate and waitlist groups

Table 3. Crude outcome table, by clusters at 6 months

Primary Outcome	Immediate	Waitlist
Cluster 1 (n)		
…		
Cluster K (n)		

Table 4. Univariate Poisson random effects regression model results

Primary Outcome	Estimate	Standard Error	95% CI	p-value
Immediate (vs. Waitlist)				
Random Effect variance (variability in cluster intercepts)				

- Also calculate estimate of Residual Intra-Class Correlation

Table 5. Multivariable Poisson random effects regression model results

Primary Outcome	Estimate	Standard Error	95% CI	p-value
Immediate (vs. Waitlist)				
Covariate 1				
Covariate 2				
. . .				
Random Effect variance (variability in cluster intercepts)				

- Also calculate estimate of Residual Intra-Class Correlation

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