Mi Propio Camino Intervention RCT for Blood Pressure Medication Adherence

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Statistical Analysis Plan

Prespecified study hypotheses

Primary hypothesis and study endpoint

The primary aim was to determine the efficacy of a group education intervention to promote medication adherence by addressing negative medication beliefs through direct and vicarious experiences with a medication. The primary endpoint is observed medication adherence, measured as the percent of prescribed doses of antihypertension medications take by the patient in a 30-day period leading up to a six-month follow-up visit. The primary hypothesis is:

> H1: Observed adherence to antihypertensive medications measured as the percent of prescribed doses taken in a 30 day period will be greater in the experimental intervention group versus the comparison group at six-month follow-up.
>
> Hypothesis test - two-tailed independent samples t-test

Secondary endpoints under primary aim:

Analysis of effect of the experimental intervention on relevant secondary endpoints will be conducted to provide context to the findings in the primary aim and to inform the development of new study hypotheses. Thirteen secondary hypotheses have been pre-specified under the primary aim. With respect to the trial, the 5 hypotheses marked with "*" correspond to the secondary endpoints of the trials. The remaining hypotheses are listed as prespecified exploratory analyses.

> H2.1: Self-reported extent of adherence, measured by the Morisky Medication Adherence Scale (MMAS), will be higher in the experimental intervention group versus the comparison group at two time points
>
> > H2.1.1: At 1 Month Follow-Up
> >
> > H2.1.2: At 6 Month Follow-Up*
> >
> > Hypothesis test - two-tailed independent samples t-test

H2.2: Self-reported nonadherence due to negative beliefs, measured by the Safran measure of reasons for nonadherence, will be lower in the experimental intervention group versus the comparison group at two time points:

H2.2.1: At 1 Month Follow-Up

H2.2.2: At 6 Month Follow-Up*

Hypothesis test - Fisher's exact test

H2.3: Net medication belief scores about antihypertensive medications will be higher (less negative) in the experimental intervention group versus the comparison group at two time points:

H2.3.1: At Time 0 (on the day of the final intervention visit)

H2.3.2: At 5 Month Follow-Up*

Hypothesis test - two-tailed independent samples t-test

H2.4: The intervention will be associated with lower systolic blood pressure at three time points:

H2.4.1: At Time 0 (on the day of the final intervention visit)

H2.4.2: At 1 Month Follow-Up

H2.4.3: At 6 Month Follow-Up*

Hypothesis test - two-tailed independent samples t-test

H2.5: The intervention will be associated with lower diastolic blood pressure at three time points:

H2.5.1: At Time 0 (on the day of the final intervention visit)

H2.5.2: At 1 Month Follow-Up

H2.5.3: At 6 Month Follow-Up*

Hypothesis test - two-tailed independent samples t-test