

Background

Behavioral Health (BH) is defined as X. Commonly delivered in Y settings, and in the United States' health care system often are inaccessible to populations who would benefit from BH interventions due to reason A- (cite), reason B (cite), and reason C (cite).

Primary Care (PC) is often a seen as a secondary health care setting that provides primary intervention for both physical and behavioral needs. PC access and utilization are associated with better outcome A - C.

BH interventions in PC have the shown potential to 1) loneliness and 2) depression as this setting have the added benefit of primary intervention or initial identification while the patient is potentially more motivated in PC rather than waiting for a referral (cite) or co-located BH/MH on-site (cite).

This small randomized control trial (RCT) aims to understand the feasibility of a BH intervention in Primary Care. The sample consists of 40 participants, equally weighted in the intervention (BH) and control (Treatment-as-usual or TAU). The data-set consists of intervention arm (BH/TAU), participant demographics (Age, Race/Ethnicity, Gender, and Income), measurement of outcomes (primary = loneliness; secondary = depression) at 3 time points (baseline, 3 months follow-up, and 6 months follow-up), and attendance for all 6 intervention session (Intervention arm = BH only).

Decision Logs

Pre-Extract, Transform, and Load (ETL) - Prior to Establishing the Environment

The Pre-Work before starting the assessment began with reviewing the "Skills_Assessment_Instructions.docx" and "data_dictionary.xlsx" files. During Pre-Work for the Assessment, the following thoughts came to mind:

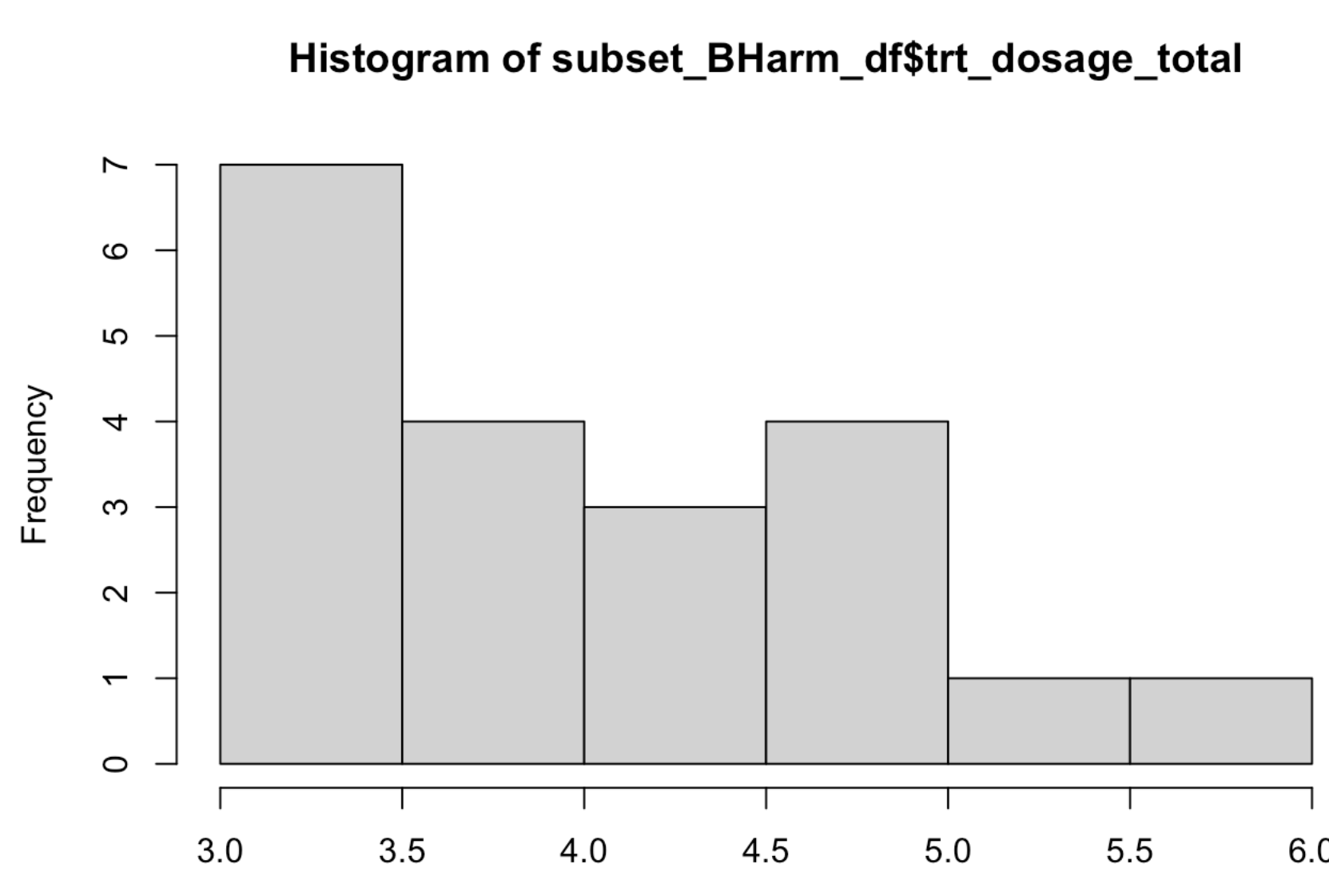
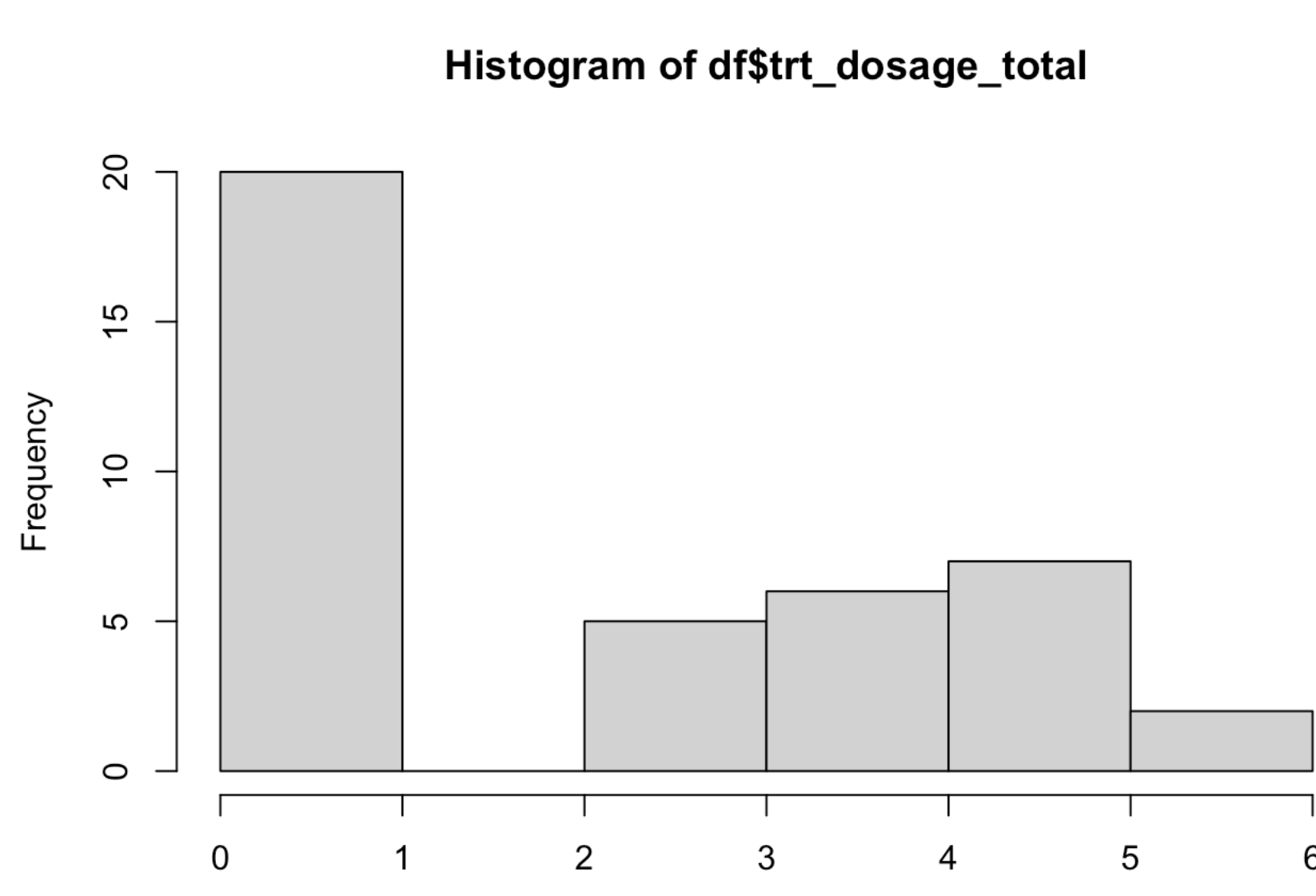
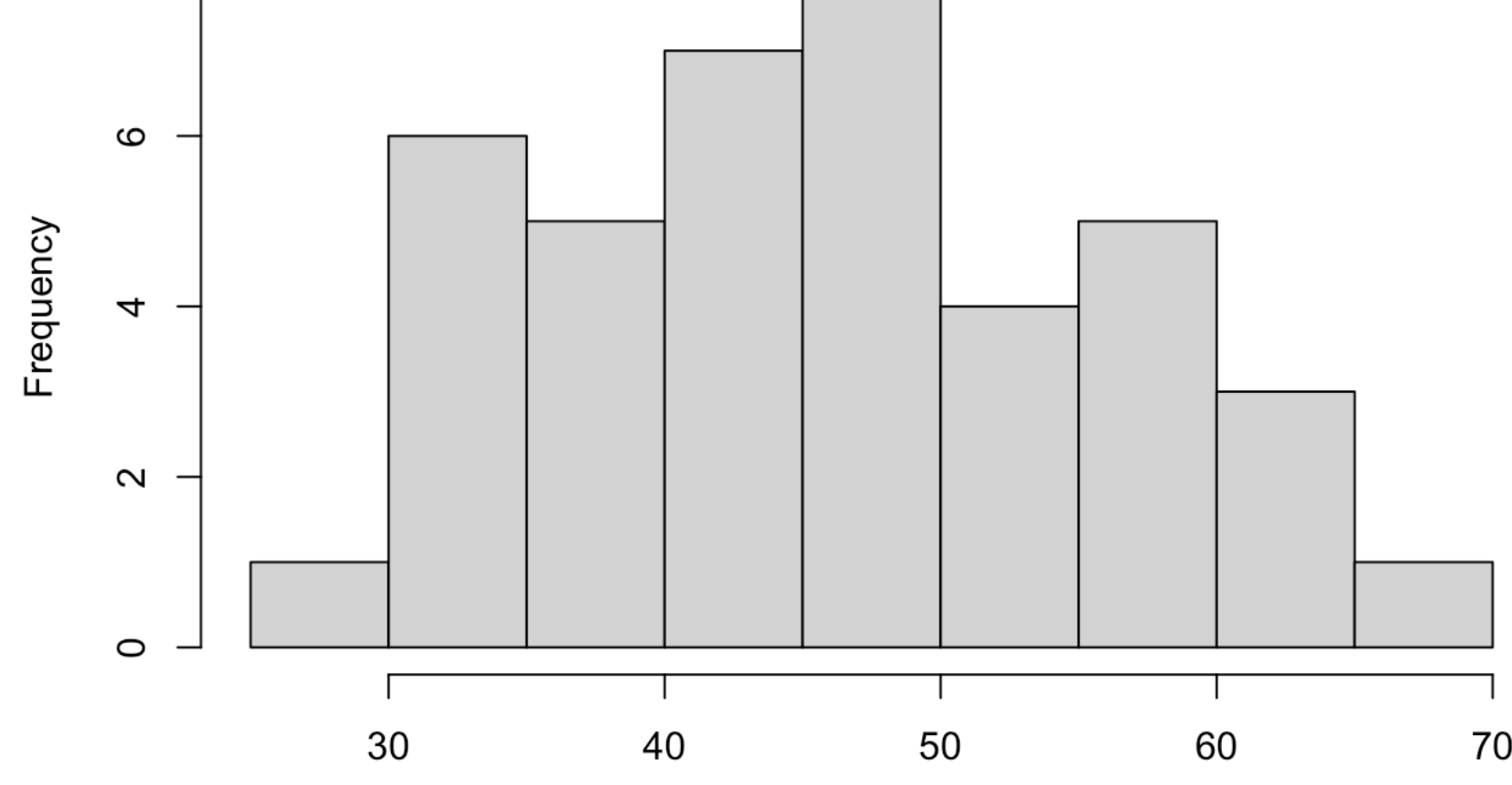
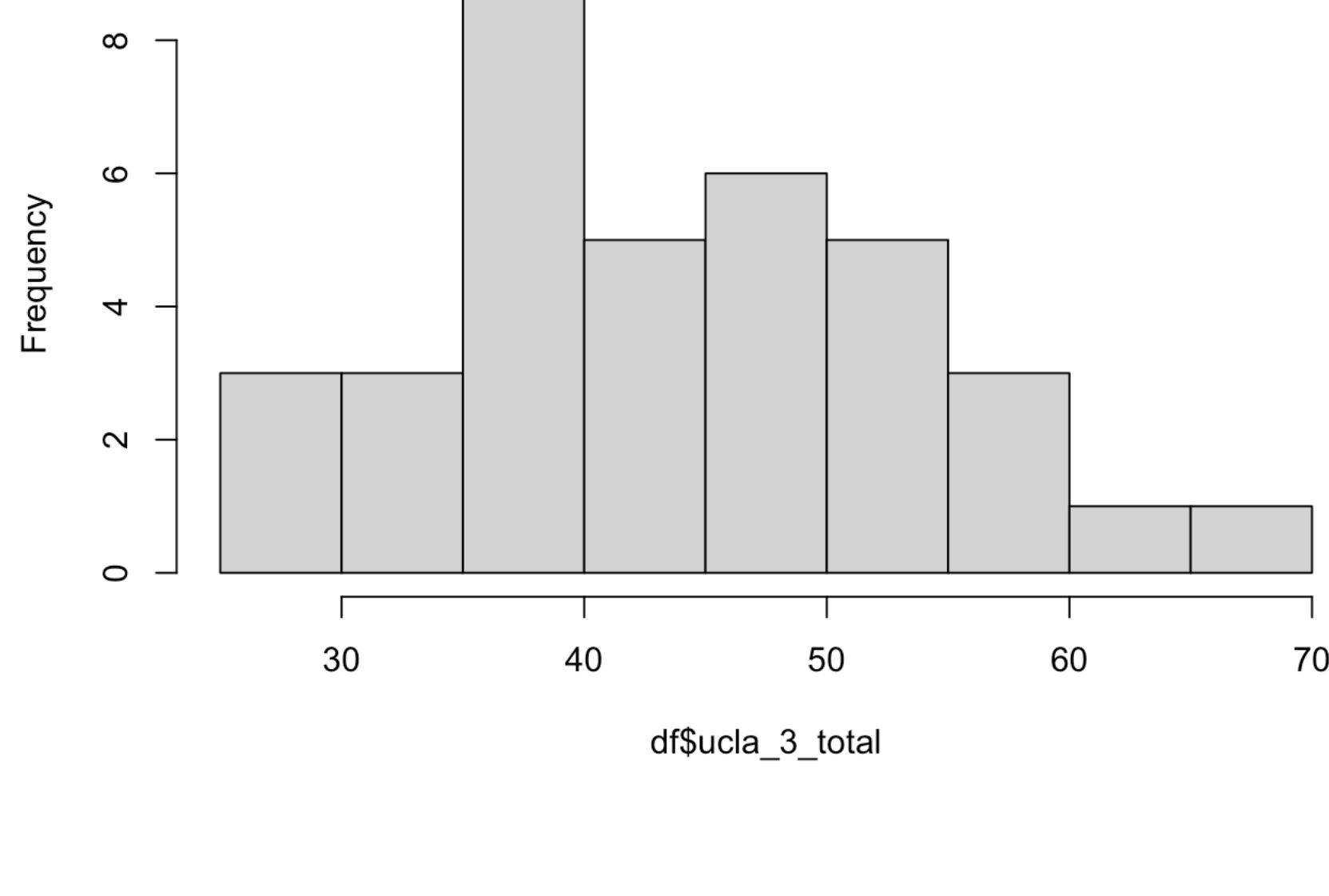
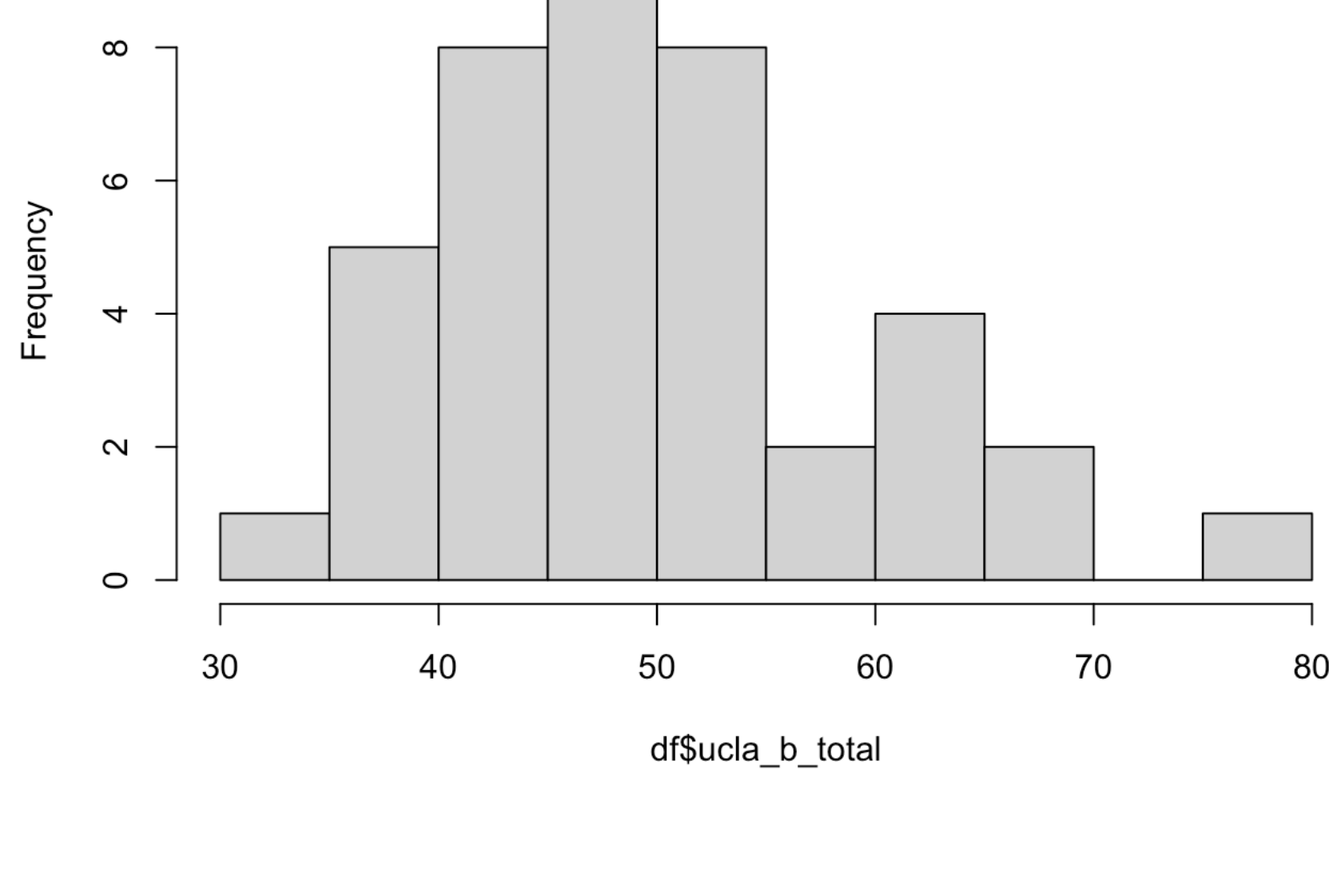
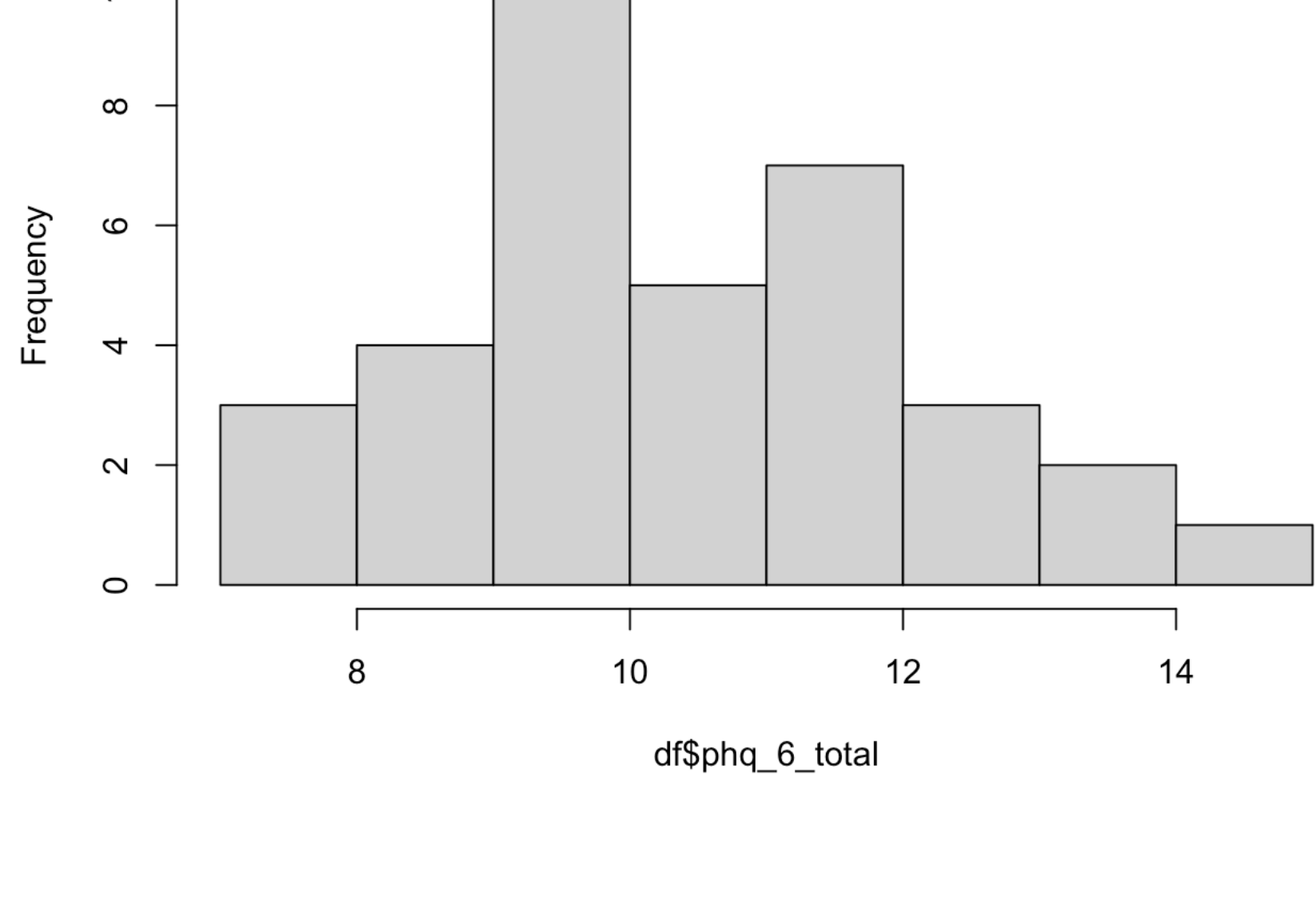
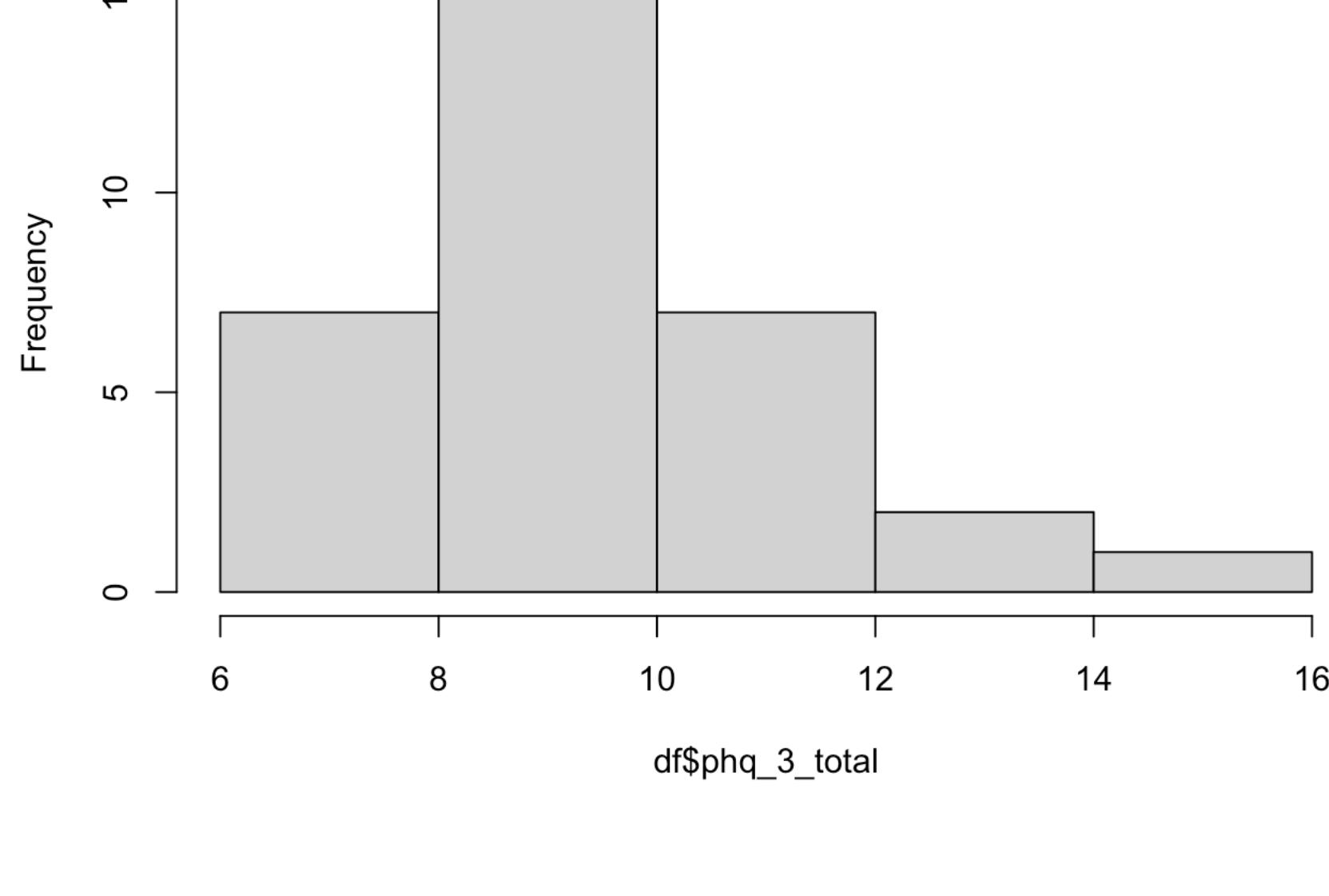
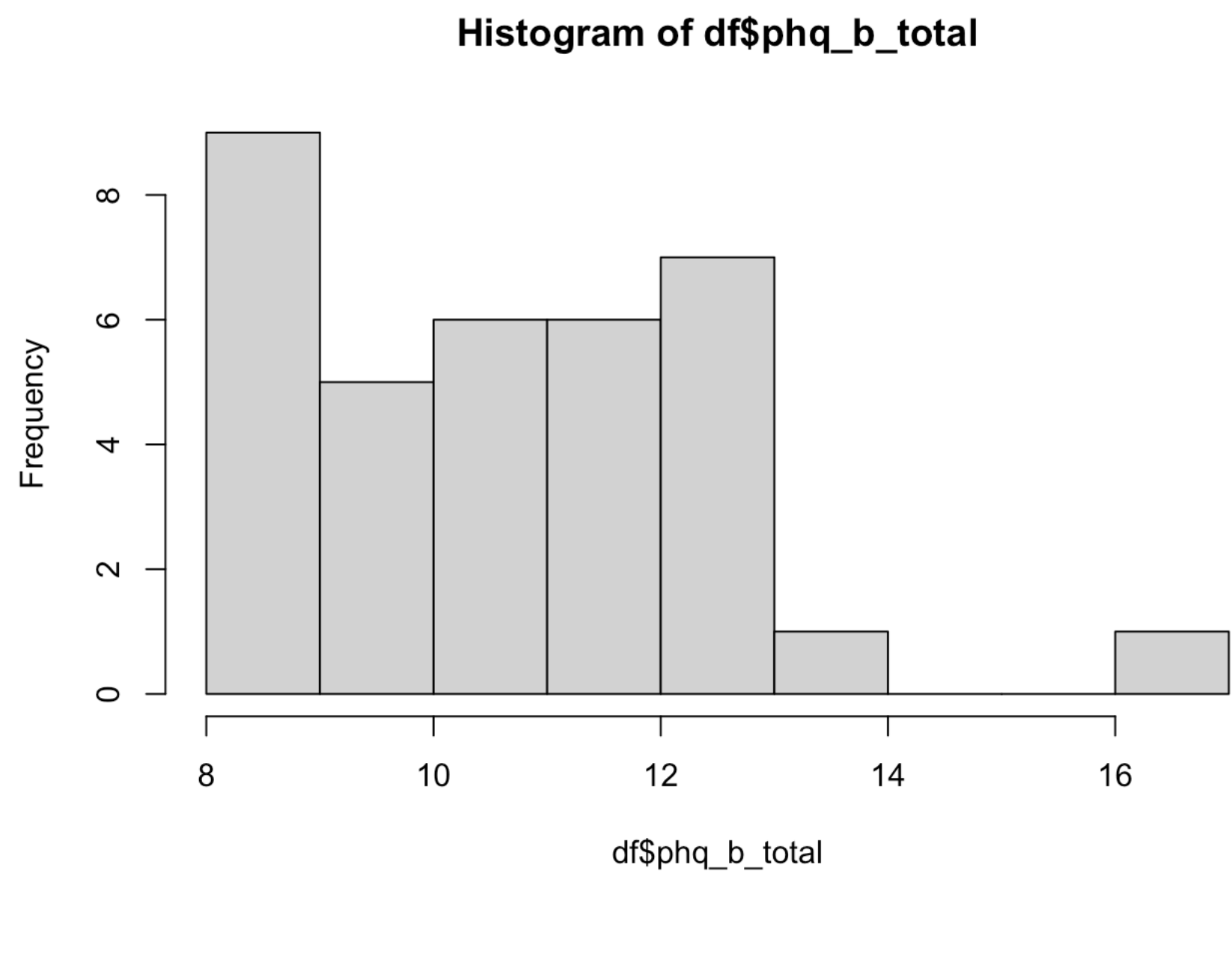
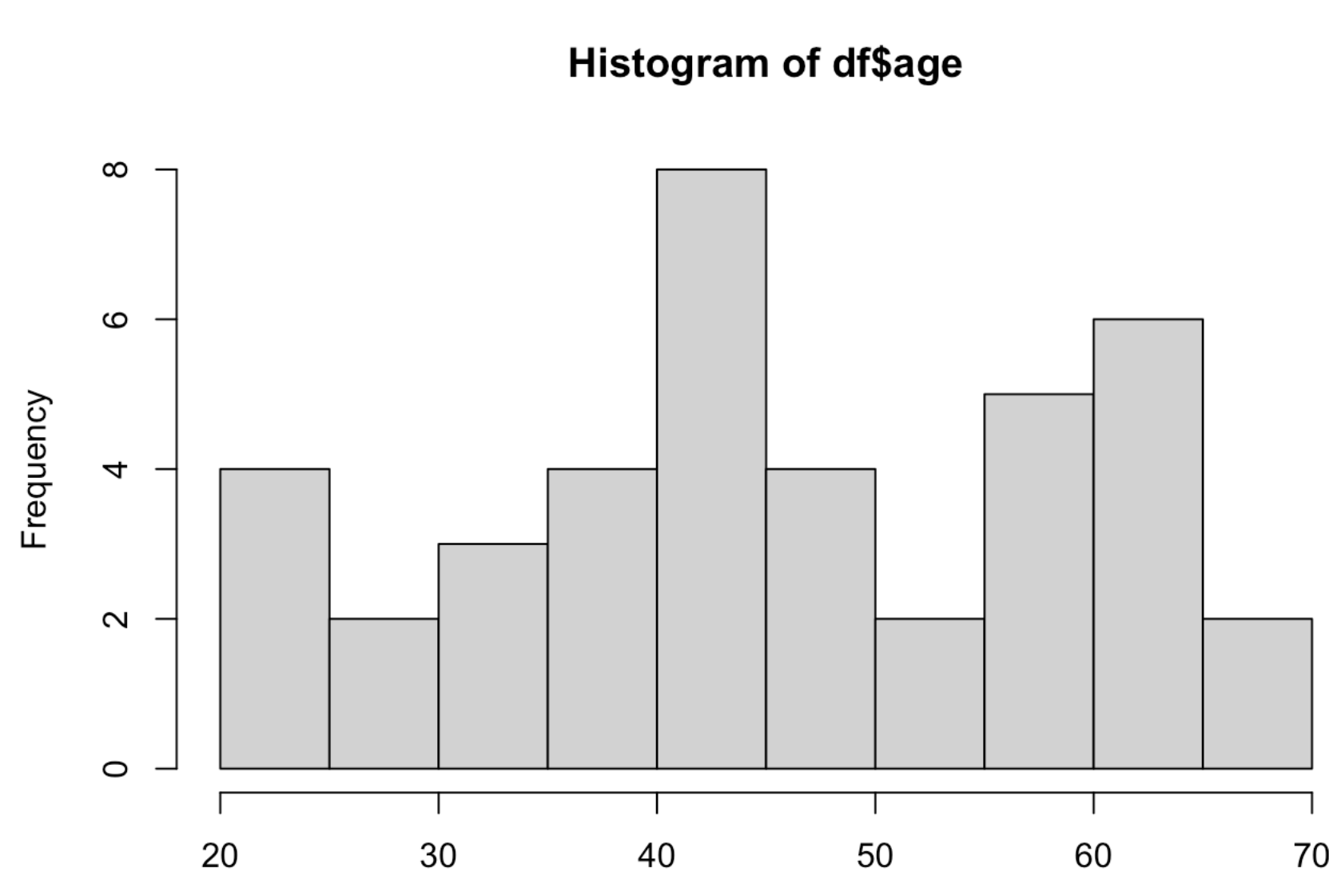
- What are the standard bins or categories for the following known continuous variables to measure the outcomes (primary = loneliness; secondary = depression):
 - Age (for this research aim: Behavioral Health Interventions in Primary Care),
 - PHQ-9 (measure for secondary outcome = depression),
 - and UCLA - L20 (measure for primary outcome = loneliness)
- NOTE:** Gender outputs - Question what source(s) for outputs or standards for Gender were used? I've seen Gender reported as Gender Identify (a specific operationally defined construct with consistent industry standards) and Sexual Identity. I would suggest aligned with Office of Management and Budget's demographic standards back in 2024.
- Additional Calculated field for Race/Ethnicity since a "self-described" output would likely result in small Ns.
- Caution:** Given the small sample size, external publications of findings should follow data suppression standards (such as Journals or Governmental entities).

Post-ETL

Make Calculated Fields

- Age (bins)
- Race/Ethnicity (New Variable Names/Labels)
 - Preserves the Categories with new field; one-hot encoding for select all option not needed
- PHQ-9 Total (by time points)
 - PHQ-9 X Sub-categories (by time points)
 - [PHQ-9: Validity of a Brief Depression Severity Measure](#) (Kroenke, Spitzer, and Williams (2001))
 - Validation suggests bins of PHQ-9 scores of 5== mild, 10 == moderate, 15 ==moderately severe, and 20 severe depression
- UCLA-LS-20 Total (by time points)
- UCLA-LS-20 X Sub-categories (by time points)
 - [UCLA - LS Scale Article](#) (Gosling et al. (2024))
 - Sensitivity analysis suggests exploring cutoff at >= 39; >=43; and >=53
- Attendance (bins)
 - Preserve time-point attendance; additional overall attendance output for high-level trend (signal and keeps option for treatment dosage effects).
 - Prop = (full dose/yes+ 1/2 partial dose/partial)/ total dosage (all 6 sessions)

Note: Create a Flag for records missing 1 or more elements (UCLA-LS-20; PHQ-9; Race/Ethnicity)



Tables 1: Pilot Sample Characteristics (N=40)

Demographic and Baseline Characteristics by Treatment		
Characteristics	Intervention (N(%))	Treatment-as-Usual (N(%))
Age (bin)		
20 - 34 years old	5 (25%)	4 (20%)
35 - 49 years old	8 (40%)	7 (35%)
50 - 64 years old	6 (30%)	5 (25%)
64 years old or older	1 (5%)	4 (20%)
Gender		
Female	7 (35%)	12 (60%)
Male	5 (25%)	4 (20%)
Nonbinary	3 (15%)	2 (10%)
Prefer not to say	5 (25%)	2 (10%)
Intervention Dosage		
Control	0 (0%)	20 (100%)
Full Treatment	13 (65%)	0 (0%)
Partial Treatment	7 (35%)	0 (0%)
Race/Ethnicity		
AIJAN	2 (10%)	1 (5%)
Asian American	1 (5%)	2 (10%)
Black/AA	2 (10%)	2 (10%)
Latinx	2 (10%)	4 (20%)
MENA	2 (10%)	1 (5%)
Multiracial	2 (10%)	3 (15%)
NHPI	0 (0%)	1 (5%)
Prefer Not to Say	2 (10%)	0 (0%)
Race Not Listed	3 (15%)	2 (10%)
White	4 (20%)	4 (20%)
Annual Household Income in USD (Mean(SD))		
	42077.3 (6683.2)	77162 (13272.7)
PHQ-9 at 3 months (Mean(SD))		
	10.5 (2.3)	9.1 (1.3)
PHQ-9 at 6 months (Mean(SD))		
	10.6 (2.2)	11.1 (1.4)
PHQ-9 at baseline (Mean(SD))		
	10.7 (1.7)	11.5 (2.1)
Total Dosage of Treatment (Mean(SD))		
	4.2 (0.9)	0 (0)
UCLA - LS - 20 at 3 months(Mean(SD))		
	42.1 (11.2)	46.3 (8.5)
UCLA - LS - 20 at 6 months (Mean(SD))		
	45.9 (9.9)	47.7 (10.6)
UCLA - LS - 20 at baseline (Mean(SD))		
	47.9 (10.2)	52 (8.9)

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Skills Assessment Documentation:

Rationale for Specific Output of R

Below is the R Code created to assess the following skills of the author (myself):

- Ability to handle and prepare real-world data,
- strategies behind analysis choices,
- interpretation of results in context of a small, pilot RCT,
- and overall clarity and accessibility of the communication of the above.

I believe this documentation shows through the RMD function 1) in line comments and choices for project/team documentation and replicability, 2) use of a repository to decrease staff time needed to tailor communication findings to various outputs, and 3) RMD output with PowerPoint Presentation (PPT), Word Document or PDF (industry standard or open source static documents to review), and Webpage (HTML) for easy intra-team QA/QI for the shared potential increase audience comprehension through multiple outputs with click of a button.

Key Research Questions

- How well were participants retained? What is implied about the feasibility of a larger trial?

A: Among n=20 participants, treatment dosage average treatment dosage was 4.15 (SD = 0.919) out of 6 sessions. *This suggests across the entire treatment dosage (6 sessions) attendance and presumed dosage of treatment is feasible in for this intervention design.* Qualitatively, n = 13 (65%) completed roughly 4 or more sessions (Full Treatment).

Note: Sample Characteristics of the N= 40 are proportions for strata across intervention arm except for Age, Gender, Race/Ethnicity, and average annual household income Income (USD). Average scores for PHQ-9 and UCLA-LS-20 were similar across intervention arm, both at moderate severe depression and between 43 and 52 loneliness score.

Test the effect of possibly differences in demographic characteristics (i.e., income) and their relationship with other covariates (Race/Ethnicity and Age) on the causal pathway.

- Does the intervention seem to reduce loneliness (primary) or depression (secondary)?

A: Cohen's d showed a small effect, further testing is recommended.

Generalized Linear Models or Mixed Model Repeat Measure ([MMRM](#)) or ANOVA to look into the variance for further exploration. Would suggest just starting with tailor test for small sample sizes - Wilcoxon Signed Rank Test and treat Outcome as continuous for an initial test for significance. Larger sample would warrant a GLM or model with less rigid parameter requirements.

- Are there participant characteristics (e.g., baseline loneliness or depression severity, attendance, or demographic characteristics) that appear to be associated with outcomes or that may influence how we interpret the intervention's effects?

Mixed Model Repeat Measure ([MMRM](#)) with Demographic Characteristics Age, Race/Ethnicity, Gender, and Income since those may be the most different between arms (Fisher's Test?). Again - would want to refer to the assumed relationships and interactions (DAG == causal pathway).

References

Gosling, Corentin J., Romain Colle, Ariane Cartigny, Fabrice Jollant, Emmanuelle Corruble, and Ariel Frajerman. 2024. "Measuring Loneliness: A Head-to-Head Psychometric Comparison of the 3- and 20-Item UCLA Loneliness Scales." *Psychological Medicine* 54 (14): 3821-27. <https://doi.org/10.1017/S0033291724002083>.

Kroenke, Kurt, Robert L. Spitzer, and Janet B. W. Williams. 2001. "The PHQ-9." *Journal of General Internal Medicine* 16 (9): 606-13. <https://doi.org/10.1046/j.1525-1497.2001.016090606.x>.