

Development of Novel Psychological Assessment Tools and Anxiety Intervention for Phenylketonuria

NCT06560736

Status	RECRUITING
Phase	Not Applicable
Sponsor	University of Missouri-Columbia
Enrollment	30 participants

Plain Language Summary

This study develops and tests new psychological assessment tools and a brief anxiety-reduction therapy program specifically designed for young people aged 10–17 who have phenylketonuria (PKU), a metabolic condition requiring a strict lifelong diet, and who experience anxiety or depression.

****You may be eligible if...****

- You are a young person aged 10–17 with a confirmed PKU diagnosis, along with at least one parent or guardian
- You were identified through newborn screening with a high phenylalanine blood level and started treatment within 30 days of birth
- You or your parent reports interest in a short therapy program for anxiety or depression
- You live in Missouri, Kansas, or Illinois

****You may NOT be eligible if...****

- You have a significant intellectual disability or language difficulties that would prevent therapy participation
- You plan to receive other psychotherapy during the study
- You plan to change your psychiatric or PKU medications during the study
- You have active thoughts of suicide requiring immediate treatment

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (4)

- Youth 10-17 years old and at least one parent/guardian
- Formal diagnosis of PKU (as confirmed/reported by caregiver): identified by newborn screening with PKU as evidenced by a blood Phe level $\geq 360 \mu\text{mol/L}$; received treatment within the first 30 days of life.
- Interest in receiving a brief, psychotherapeutic skills program to prevent and treat symptoms of anxiety and/or depression, according to parent- and youth-report
- Located in Missouri, Kansas, or Illinois.

Exclusion (4)

- Have significant intellectual disability ($\text{IQ} < 70$) or significant expressive or receptive language that would interfere with psychotherapy, according to parent- or youth-report
- Plans to receive non-study psychotherapy during the course of study participation, according to parent- or youth-report
- Plans to change current psychoactive or PKU-related medication during the course of study participation, according to parent- or youth-report
- Have active suicidal ideation that would necessitate immediate treatment or require higher level of care than brief psychotherapy, according to parent- or youth-report

<https://clinicaltrials.gov/ct2/show/study/NCT06560736>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).

