

A Pilot Study to Assess the Safety, Tolerability, and Efficacy of Virtual Reality for the Treatment of Abdominal Pain in Quiescent Crohn's Disease

NCT06647615

Status	RECRUITING
Phase	Not Applicable
Sponsor	Mayo Clinic
Enrollment	15 participants

Plain Language Summary

This pilot study is testing whether virtual reality (VR) — using an immersive headset experience — can reduce chronic abdominal pain in patients with Crohn's disease that is currently in remission (not actively inflamed but still causing pain).

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

- You have been diagnosed with Crohn's disease confirmed by both endoscopy (camera exam) and biopsy
- Your Crohn's is in remission (low inflammatory markers on blood and stool tests)
- You experience abdominal pain at least weekly

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

- Your abdominal pain is thought to be caused by active or organic bowel disease (not just pain sensitivity)
- You do not have biopsy-confirmed Crohn's disease
- You have a known seizure disorder
- You have visual or hearing impairments that prevent VR use
- You have a pelvic floor disorder causing your symptoms
- You are currently using opioid medications
- You have significant anxiety or depression (HAD score above 11)
- You cannot actively participate in English (the VR program is English-only)

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

Key Eligibility Criteria

Inclusion (1)

- Patients with a diagnosis of endoscopically and histologically confirmed CD with evidence of C-reactive protein \geq 5 mg/dL and fecal calprotectin \geq 150microg/g who also report any abdominal pain at least weekly will be included.

Exclusion (1)

- Patients will be excluded from the study if they do not have biopsy-proven CD, have a known seizure disorder, if symptoms are thought to represent an organic disorder, those with visual or hearing impairments, if symptoms represent a known pelvic floor disorder, if the patient is using opioids, has significant ongoing psychological distress (HAD score \geq 11 for either anxiety or depression), or if the patient can not actively participate in the study for any other reason (e.g., inability to understand English as the VR program as an English only).

Locations (1 total)

Mayo Clinic Florida, Jacksonville, Florida, United States

<https://clinicaltrials.gov/study/NCT06647615>

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