

CELIAC DISEASE PATIENT PERSPECTIVES: CLINICAL TRIAL BARRIERS AND TREATMENT OUTCOMES



Kate Avery^{1*}, Alice Bast¹, Debra Silberg¹
Beyond Celiac, Ambler, Pennsylvania USA
*Corresponding author: kavery@beyondceliac.org

Introduction

Multiple drugs are in development for celiac disease (CD). Regulatory agencies and academic groups have released trial guidelines but these do not explore celiac disease patient preferences.^{1,2}

Methods

An online survey was distributed to a United States (US) advocacy group email list and social media following. Participants were 18+ and self-identified as medically diagnosed with celiac disease. Responses were tabulated and descriptive analyses were performed.

Results

942 participants fully completed the survey. The majority were US residents (89.2%), female (80.8%) and white (94.4%). The most common age groups were 55-64 (19.1%) and 35-44 (18.6%).

Clinical trial participation

- 757 participants (80.4%) indicated they would be willing to participate in a clinical trial for a treatment supplemental to the gluten-free diet (GFD)
 - 58.4% said an endoscopy and biopsy requirement would not affect their participation in a trial
 - 41.2% would be willing to have two endoscopies during a 12 month trial
 - 12.5% are not willing to have an endoscopy during a 12 month trial (Figure 1)

Treatment outcomes

- For treatments that would supplement the GFD, 53.4% of participants said improvement in intestinal healing was the most important outcome. 40.8% indicated symptom improvement was most important (Figure 2)
- 74.9% of participants would take a treatment that improved intestinal healing but did not impact symptoms
- 61.0% would take a treatment that improved symptoms but did not change healing.

Figure 1: Number of Endoscopies in a 12 month Trial

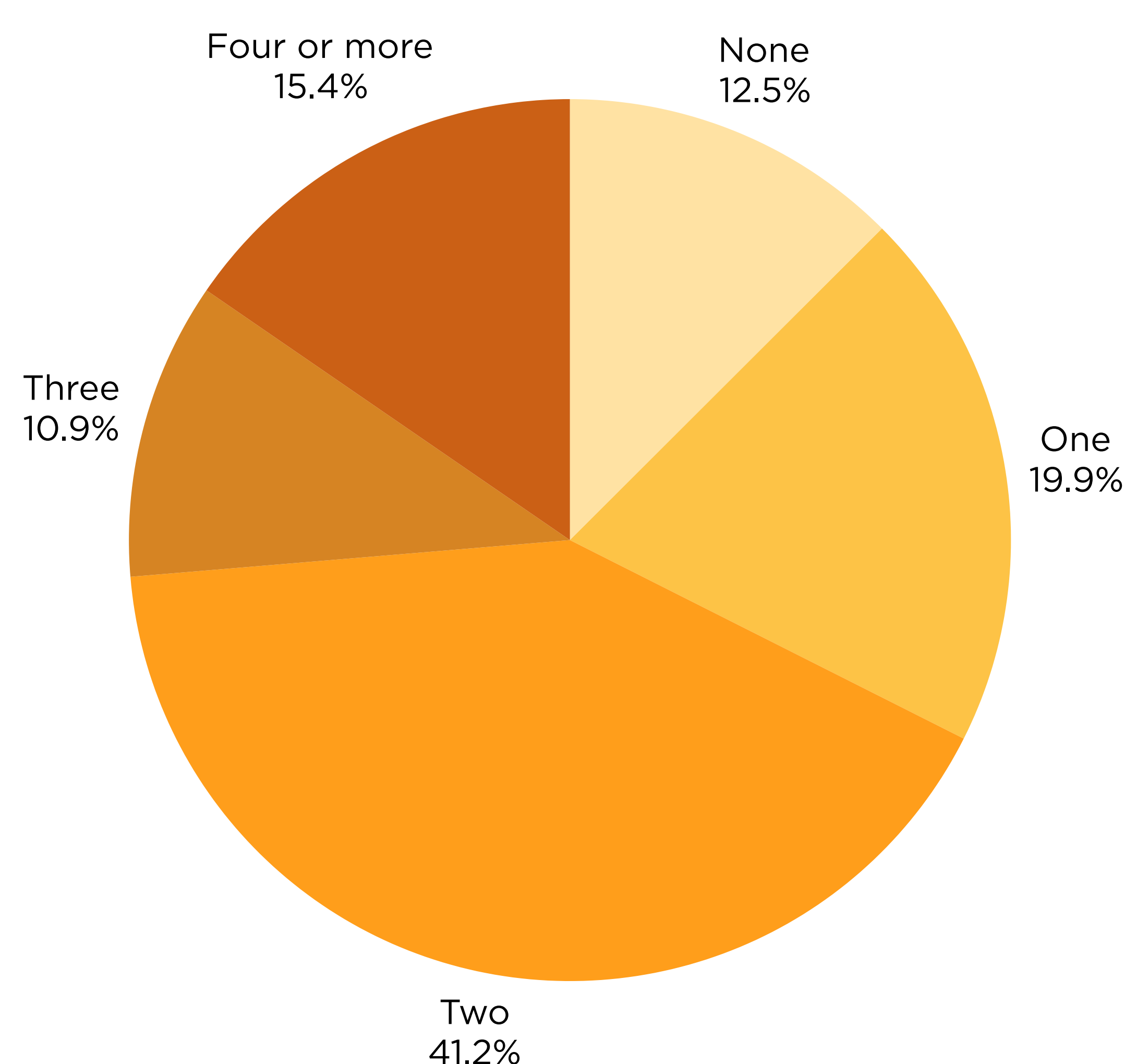


Figure 1 shows the number of endoscopies and biopsies potential participants are willing to undergo during a 12 month clinical trial

Figure 2: Most Important Treatment Outcome

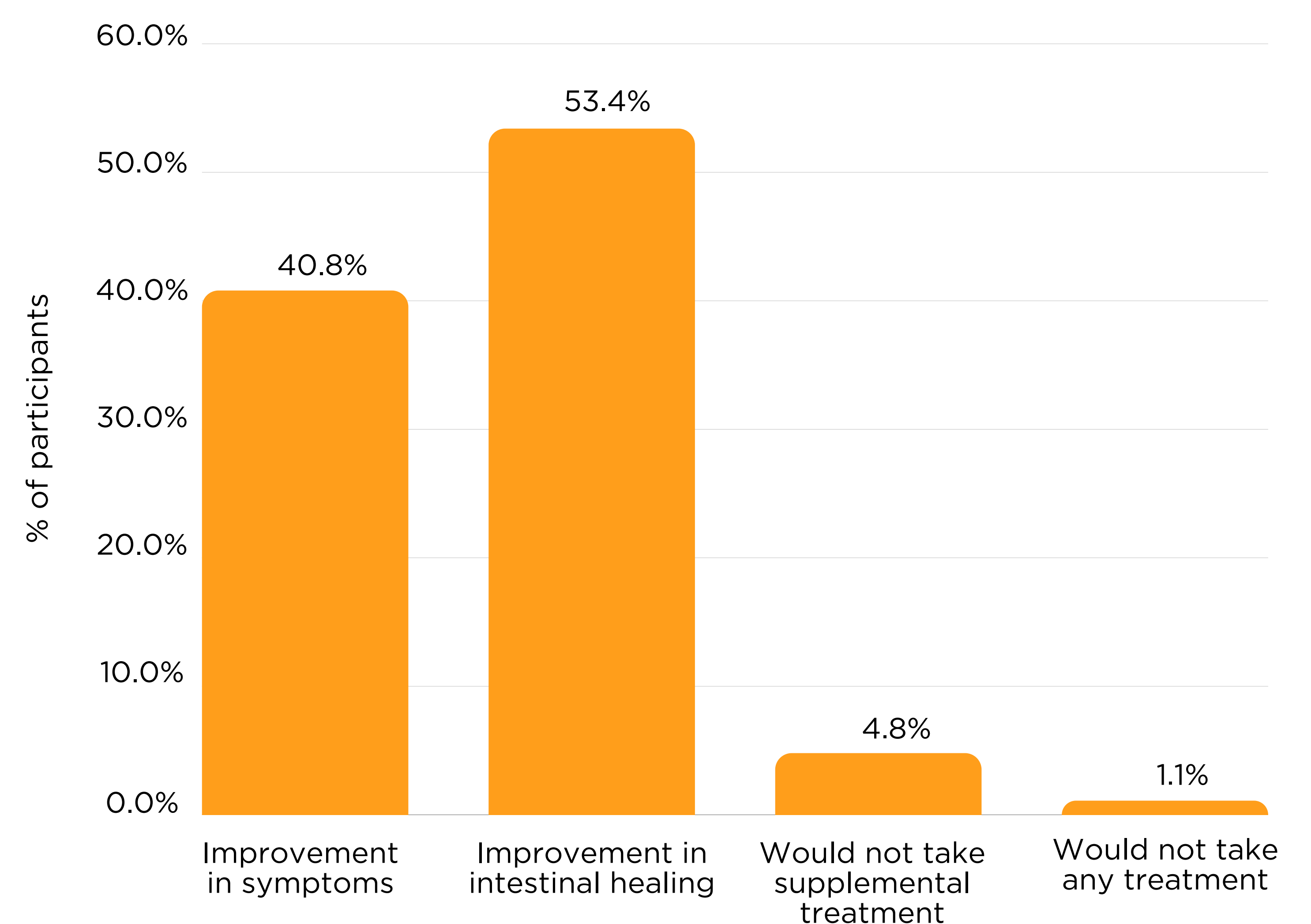


Figure 2 shows the most important treatment outcome from a treatment supplemental to the gluten-free diet

Conclusions

Endoscopy and biopsy may not be a major barrier to CD patient participation in trials. Intestinal healing is an important outcome for CD patients when considering treatments beyond the GFD. More research is needed with a more diverse population to further understand patient preferences and how they might differ between demographic groups.

References

- ¹Lebwohl B, Ma C, Lagana SM, et al. Standardizing Randomized Controlled Trials in Celiac Disease: An International Multidisciplinary Appropriateness Study. *Gastroenterology*. 2024;166(1):88-102. doi:10.1053/j.gastro.2023.08.051
- ²US Food and Drug Administration. Draft Guidance Celiac Disease: Developing Drugs for Adjunctive Treatment to a Gluten-Free Diet. 2022