Words (and Pronouns) Matter: Increasing LGBTQIA+ Representation and Visibility in Major Depressive Disorder Clinical Trials

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Introduction

- LGBTQIA+ individuals are at increased risk for mental health conditions, including higher rates of depression and suicidality.[1]
- LGBTQIA+ representation in clinical research is unclear due to a lack of data collection on gender and sexual indentity.[2]
- Inclusive data collection practices such as the use of gender inclusive language and questions that capture multiple dimensions of LGBTQIA+ identity can help ensure the recruitment and identification of LGBTQIA+ populations in clinical research.[3]
- This study employed inclusive data collection procedures to assess LGBTQIA+ representation in the Major Depressive Disorder (MDD) clinical trial seeking population, as well as to compare MDD symptom severity and trial eligibility among LGBTQIA+ and non-LGBTQIA+ individuals.

Methods

- The sample includes prospective MDD trial participants recruited by social media advertising.
- After completing a phone screening interview, potentially eligible subjects were scheduled for an in-person prescreening appointment, at which they completed questionnaires that included questions on demographics, treatment and medical history, and current MDD symptoms (based on the PHQ-9).
- Questions were included regarding subjects' sex assigned at birth, gender identity **(Figure 1)**, sexual orientation **(Figure 2)**, and preferred pronouns. LGBTQIA+ status was determined based on responses to these questions **(Table 1)**
- Analyses focused on assessing the prevalence of LGBTQIA+ identifying individuals among prospective trial participants, as well as the association between LGBTQIA+ identity, symptom severity, and trial eligibility.

Table 1. Operationalization of LGBTQIA+ status based on prescreening questionnaire responses

LGBTQIA+ determinants
• Sex assigned at birth does not correspond with gender and/or pronouns
• Gender is anything other than binary male/female (e.g., non-binary, queer)
• Sexual orientation is anything other than heterosexual (e.g., gay, bisexual, pansexual, queer)

Table 2. Sample characteristics

Measure	Full Sample (n=2,246)	LGBTQIA+ (n=401)	Non-LGBTQIA+ (n=1,845)
Age (M (SD))	44 (15)	35 (15)	45 (15)
PHQ-9 Total Score (M (SD))	17 (6)	17 (5)	17 (6)

Results

- Between July 2021 and May 2023, 2,770 prospective MDD trial participants completed a prescreening visit **(Table 2)**, of which data on sexual and gender identity was available for 2,246 (81%). 401 subjects (18%) were identified as LGBTQIA+ **(Figure 3).**
- LGBTQIA+ status was a significant predictor of suicidality (β=.07, p=.002), with LGBTQIA+ identified subjects reporting significantly higher levels of suicidal ideation compared to non-LGBTQIA+ identified subjects **(Figure 4)**.
- LGBTQIA+ status was significantly associated with trial eligibility (β=.07, p=.001); however, this relationship became non-significant when controlling for age, with younger subjects more likely to be eligible for a trial (β=-.02, p<.001) and more likely to identify as LGBTQIA+ (β=-.13, p<.001).
- Of subjects who were found to be eligible for a trial (45%), 20% identified as LGBTQIA+.
- LGBTQIA+ status remained a significant predictor of suicidality among trial eligible subjects (β=-.08, p=.011) and was also a significant predictor of appetite changes (β=.06, p=.046), with LGBTQIA+ subjects more likely to report appetite changes than non-LGBTQIA+ subjects **(Figure 5)**.

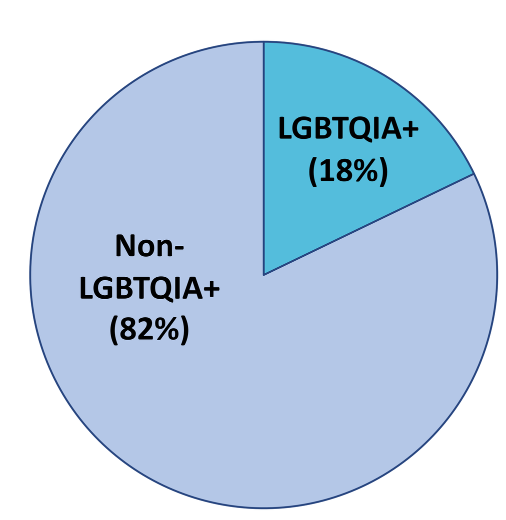


Figure 3. LGBTQIA+ status of subjects who attended a prescreening visit (n=2,246)

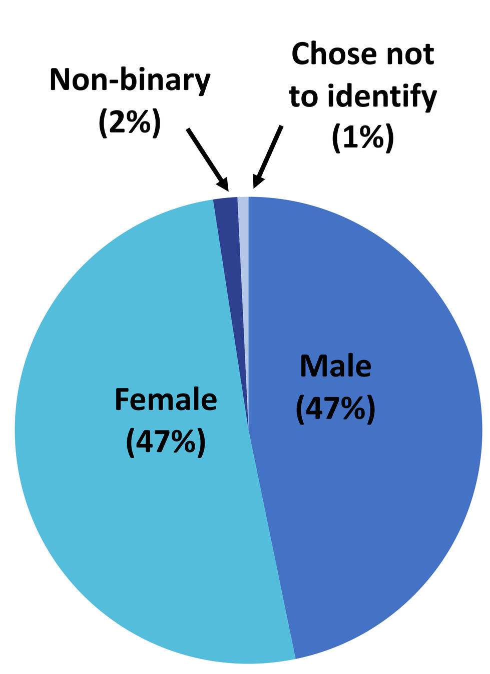


Figure 1. Reported gender identity of subjects who attended a prescreening visit (n=2,246)

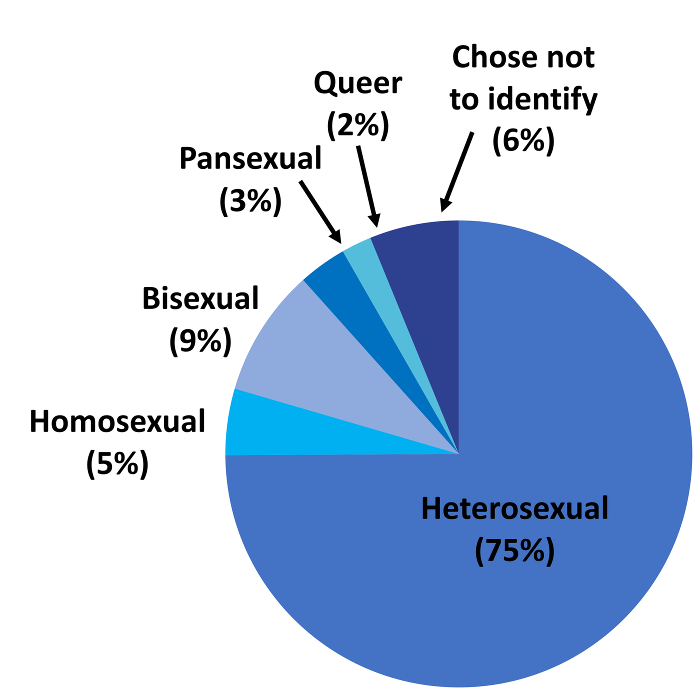


Figure 2. Reported sexual orientation of subjects who attended a prescreening visit (n=2,246)

Figure 4. Percentage of subjects reporting suicidal ideation by LGBTQIA+ status (n=2,246)

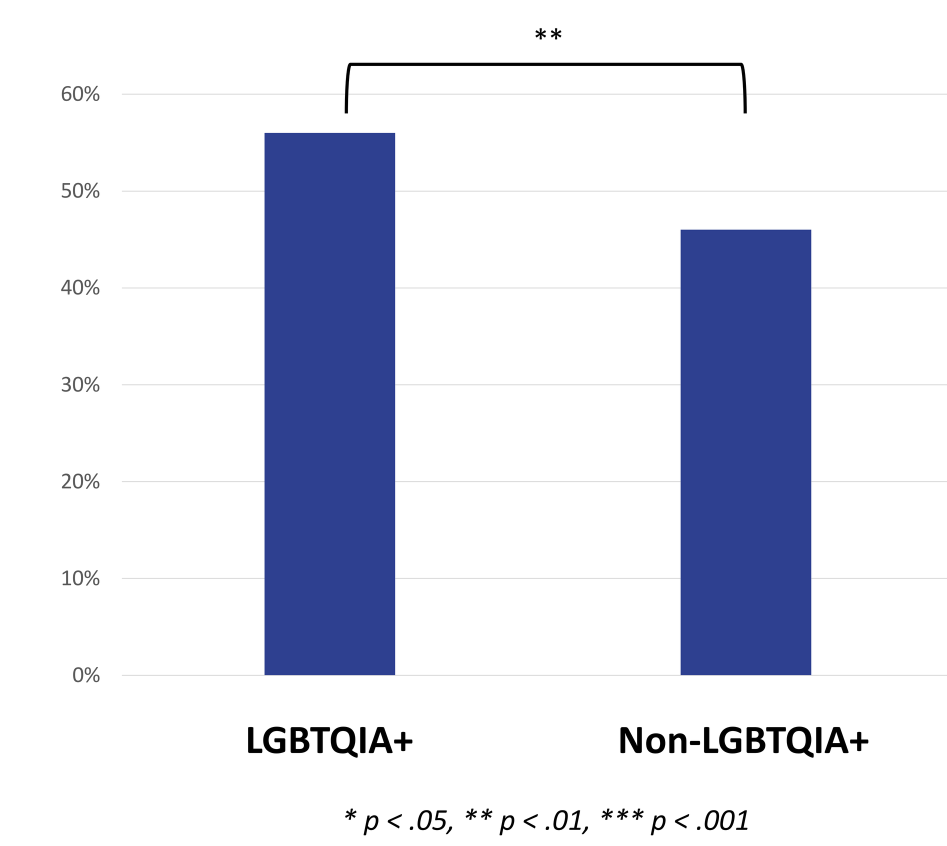
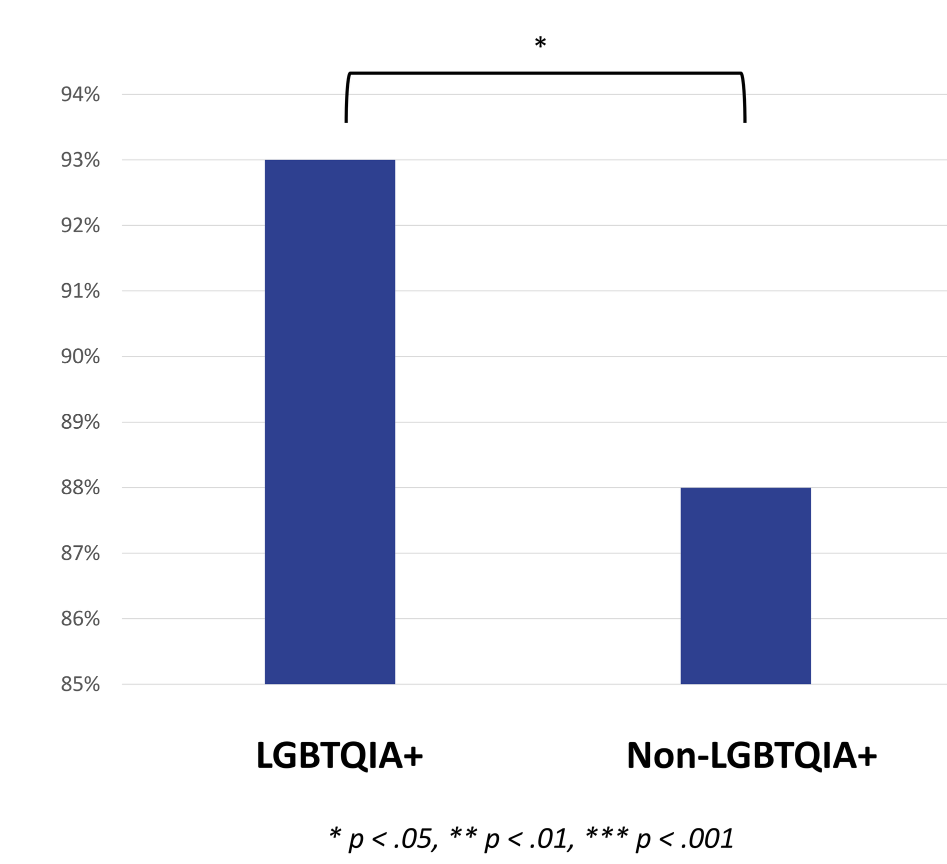


Figure 5. Percentage of eligible subjects reporting appetite changes by LGBTQIA+ status (n=1,011)



Conclusions

- By including questions that reflect a broader spectrum of sexual and gender identities, we were able to identify a percentage of our sample who identified as LGBTQIA+ that was at or above national estimates.[4]
- The results suggest that LGBTQIA+ individuals with MDD are actively seeking out MDD trials, and may be qualifying for these trials at higher rates due to being younger in age than non-LGBTQIA+ individuals.
- Consistent with prior research, our results suggest that LGBTQIA+ individuals are at greater risk for suicidality as well as point to a potential risk for MDD-related appetite changes. These are important risk factors to consider, as some medications have the potential to increase these symptoms.
- Overall, the present findings highlight the need for clinical research to better identify and address the unique health issues faced by this population.

References

1. American Psyhchiatric Association (2017). Mental Health Disparities: LGBTQ. https://www.psychiatry.org/File%20Library/Psychiatrists/Cultural-Competency/Mental-Health-Disparities/Mental-Health-Facts-for-LGBTQ.pdf
2. National Institutes of Health (2015). NIH FY 2016-2020 Strategic Plan to Advance Research on the Health and Well-being of Sexual and Gender Minorities. https://www.edi.nih.gov/sites/default/files/EDI_Public_files/sgm-strategic-plan.pdf
3. Baker, K.E., et al. (2021). Ensuring that LGBTQI+ people count- Collecting data on sexual orientation, gender identity, and intersex status. *New England Journal of Medicine, 384*(13), 1184-1186.
4. GLAAD (2023). Accelerating Acceptance. https://assets.glaad.org/m/23036571f611c54/original/Accelerating-Acceptance-2023.pdf

Disclosures

The authors report no conflicts of interest for this work; all are current employees of Adams Clinical, an independent CNS research site that conducts self-sponsored and industry-sponsored pharmaceutical trials.

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