PRELIMINARY CLINICAL RESEARCH SUMMARY:
Initial Results

Background: Depression and anxiety disorders are highly prevalent amongst adult and pediatric populations (1,2). Cognitive Behavioural Therapy (CBT) can be an effective treatment component for mild to moderate depression and anxiety (3,4). However, limited access to specialist care often decreases the ability for many patients to receive adequate treatment (5). Calmsie creates CBT-based Digital Therapeutics to provide accessible, app-based, prescription solutions **that enhance outcomes for patients with mild to moderate depression** and Generalized Anxiety Disorder (GAD). This ongoing randomized- control study evaluates the efficacy of Calmsie's CBT chatbot. Initial results for the first 6 participants who have completed the 6 week, app-based, daily CBT-programme are discussed below.

Methods: 6 patients (3 female, 3 male) ages 40-60 years diagnosed with mild to moderate depression and/or GAD were recruited to participate in the study. All patients were undergoing standard pharmacological treatment and psychotherapy for their disorder and continued to do so throughout the study duration. **Individuals were paired according to diagnosis and severity and then** randomly placed into either a treatment or control group.

The treatment group participated in daily, individual CBT sessions guided by the therapeutic chatbot for 6-weeks while the control group received a handout on how to cope with symptoms of anxiety and depression. Each participant completed the Generalized Anxiety Disorder Assessment (GAD-7) to determine anxiety severity and the Patient Health Questionnaire (PHQ-9) for depression severity on days 1, 8, 15, 29, and 42. The scores for each of these instruments were evaluated to determine the overall effectiveness of daily engagement with the therapeutic chatbot for six weeks.

Results: The initial PHQ-9 mean score for the treatment group was 17.33, compared to the mean score of 9 for the control group (Fig. 1). The initial GAD-7 mean score for the treatment group equaled 15, while the mean score for the control group was 6 (Fig. 2). At the end of 6-weeks, the PHQ-9 mean score for the

treatment group decreased to 12.5, while the mean score for the control group increased to 10 (Fig.1). The GAD-7 mean score decreased to 13 for the treatment group and increased to 9.5 for the control group (Fig.2). The overall **decrease** in mean scores for the treatment group was 27.9% for PHQ-9 and 13.3% for GAD-7. In contrast, the overall **increase** in mean scores for the control group equalled 11.1% for PHQ-9 and 58.3% for GAD-7.

Adverse Events: No adverse device effects or adverse events including suicide, suicide attempt, self-harm, or harm to others were reported throughout the duration of the study.

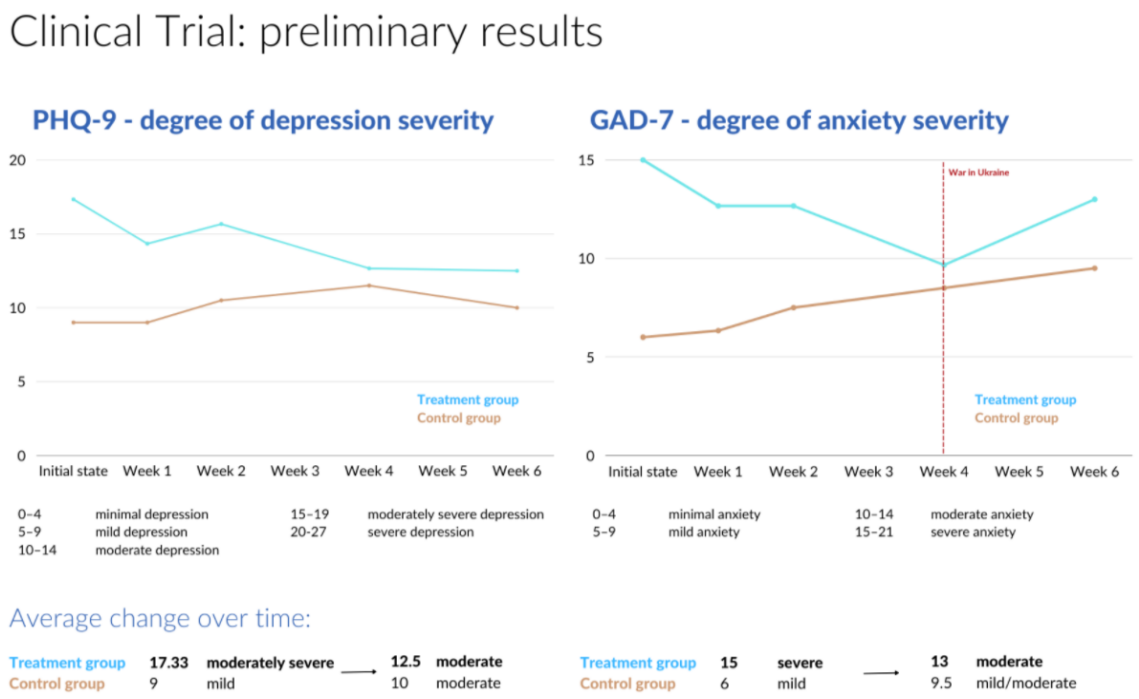

Figure 1.

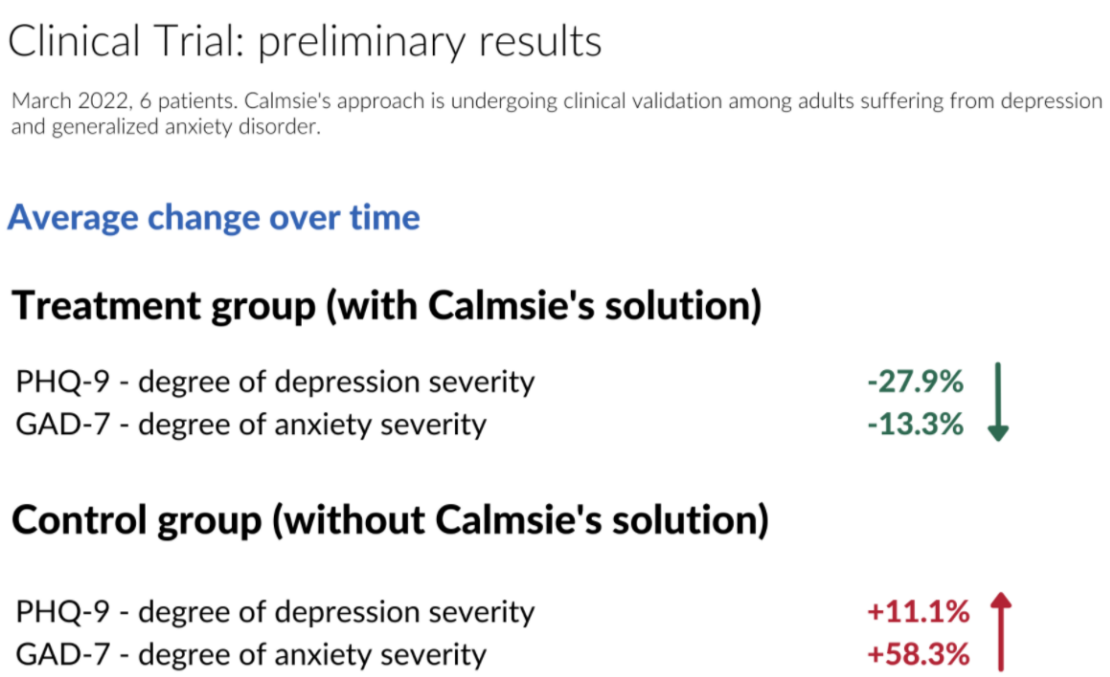

Figure 2.

Conclusion: The initial results indicate that daily use of Calmsie's therapeutic chatbot over six weeks reduces symptoms of depression and anxiety in adults. In contrast, the degree of severity for depression and anxiety in the control group, which was not using the therapeutic chatbot, increased over 6 weeks. This suggests that Calmsie's therapeutic chatbot can be a safe and effective tool in the management of depression and anxiety disorders.

References

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