Non-inferiority of a Relational Agent - Woebot -

to reduce symptoms of depression relative to CBT skills group: A randomized controlled trial among adolescents seeking outpatient mental health care

Athena Robinson, PhD¹; Andre Williams, PhD¹; Stephanie J. Rapoport, MA¹; Autumn Birch, MA¹; Laura Lang, MPH²; Nicole Wells, PhD²; Valerie Forman-Hoffman, PhD, MPH¹; Megan Flom, PhD¹; Mary Margaret Gleason, MD²

Background

Despite increases in adolescent depression and anxiety¹, access to outpatient mental health services remains inadequate², with youth waiting months for care³. Evidence-based digital psychotherapeutic interventions may improve access⁴, however their feasibility in outpatient mental health clinics & clinical efficacy relative to clinician-delivered services remains unstudied.

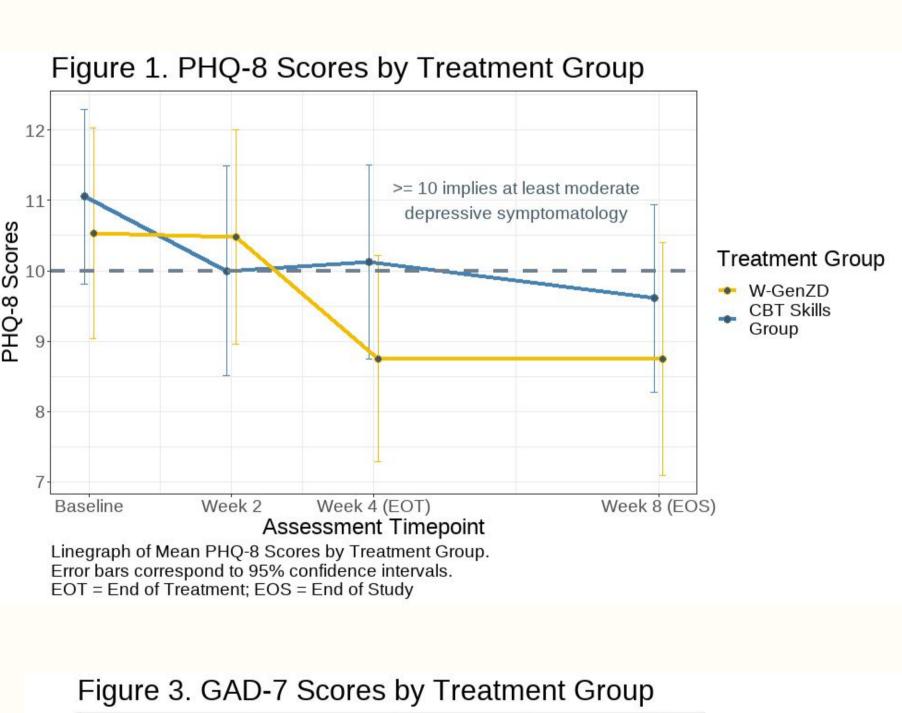
Among adolescents seeking care for depression and/or anxiety from a children's hospital (CH), investigate the feasibility and non-inferiority (NI) after 4-weeks of access to: W-GenZD, a smartphone- delivered, cognitive behavioral therapy (CBT)-based application guided by Woebot, an interactive relational agent compared to CBT **Skills Group**, delivered by a clinician via telehealth, the gold-standard intervention⁵

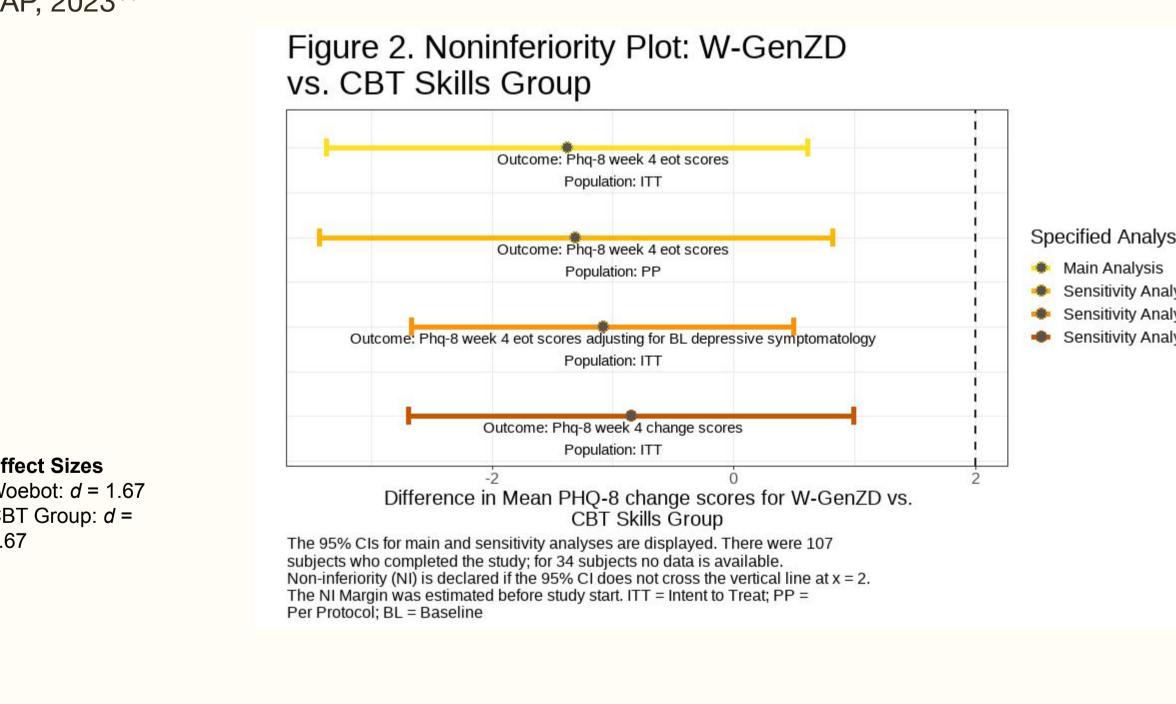
After CH clinical triage visit, adolescents (13-17 years) triaged into standard outpatient mental health care were screened and randomized to W-GenZD or CBT Skills Group. Assessments were at baseline (BL), 4-weeks end=oftreatment (EOT) and 8-weeks end-of-study (EOS), and included:

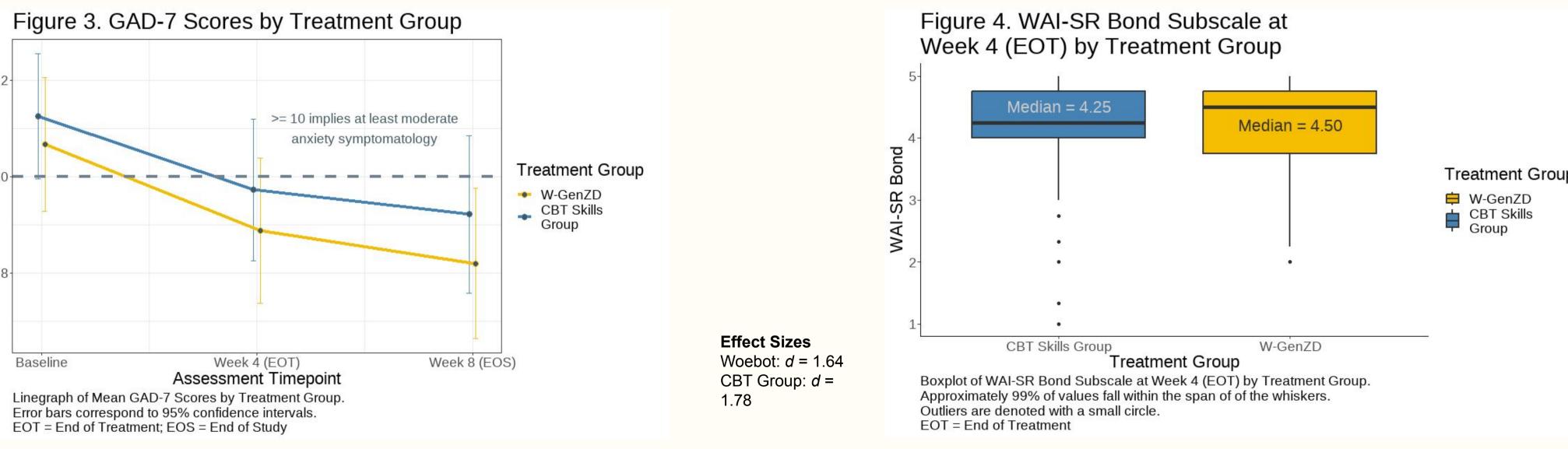
- Patient Health Questionnaire (PHQ-8) 6 \rightarrow depression symptoms
- Generalized Anxiety Disorder (GAD-7)⁷ → anxiety symptoms
- Working Alliance Inventory–Short Form (WAI-SR)⁸ → working alliance
- Usage Rating Profile-Intervention Revised (URP-IR) $^9 \rightarrow$ feasibility
- Client Satisfaction Questionnaire $(CSQ-8)^{10} \rightarrow satisfaction$

Participants (N=141; Woebot n=71 | CBT n=70) were on average 14.60 (1.20) years old, 78% female sex at birth (girl/woman), 49% white, 34% African American, 92% non-Hispanic, and 60% heterosexual.

Treatment Arm		URP-IR Feasibility		CSQ-8 Satisfaction	
	n	Median (IQR)	n	M (SD)	
W-GenZD	52	29.50 (5.25)	52	23.08 (5.51)	
CBT Skills Group	55	30.00 (4.50)	55	22.49 (5.54)	







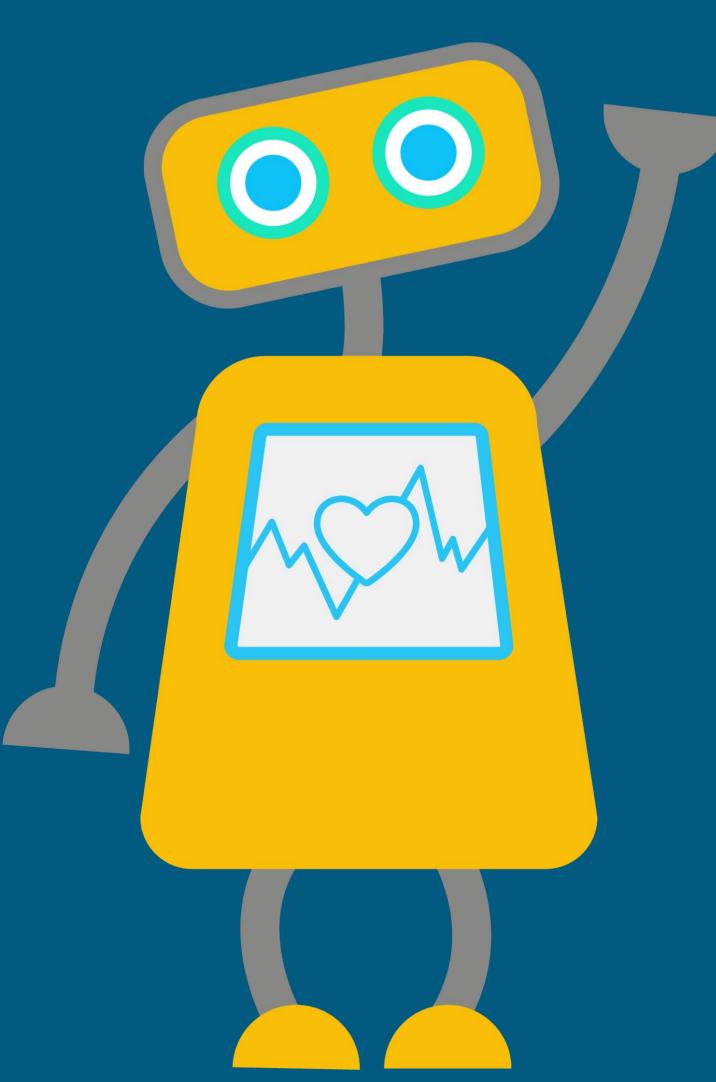
Note. Intention-to-Treat (ITT) analytic sample included all participants who were randomized and who were evaluable on treatment (i.e., had primary outcome data at EOT).

W-GenZD yielded reductions in depressive symptoms that were non-inferior to those yielded by cliniciandelivered CBT skills group via telehealth, among adolescents seeking outpatient mental health care.

KEYFINDINGS

- First ever RCT comparing W-GenZD, with Woebot a relational agent, to human-delivered cognitive behavioral therapy (CBT) Skills Group.
- W-GenZD was non-inferior to CBT Skills Group in reducing PHQ-measured depression at 4-weeks end-of-treatment.
- W-GenZD and CBT Skills Group appeared to have similar:
 - o Intervention feasibility and satisfaction
 - o Intervention adherence
 - o Therapeutic working alliance, including affective bond, with either W-GenZD or the CBT Skills Group therapist





Author's Disclosures This study was funded by Woebot Health, which covered the cost of on-site staffing, participant payments, and the platform for electronic data capture. Dr. Gleason received research funding from the Hampton Roads Biomedical Research Consortium and Dr. Wells and Dr. Gleason received research funding from Woebot for this study. Acknowledgements We would like to thank Robbert Zusterzeel, M.D., Ph.D., M.P.H., Alison Darcy, Ph.D., and Adam Platt, M.Sc., as well as our study participants and their families.

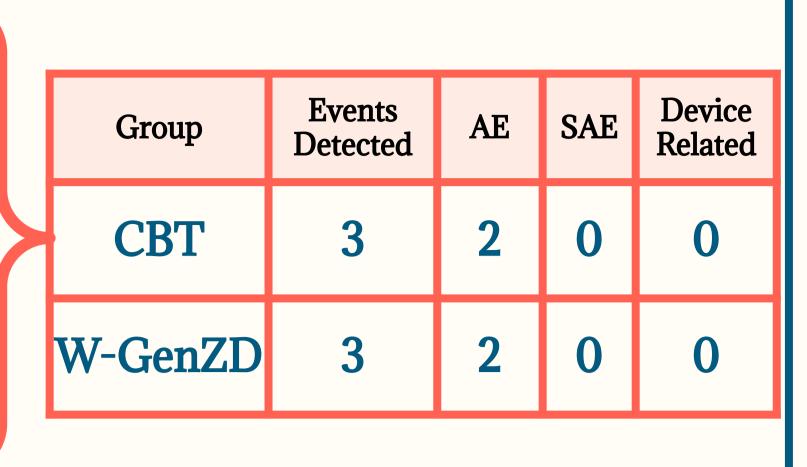
Disclaimer W-GenZD has not been evaluated, cleared or approved by FDA. It is not intended to diagnose, monitor, treat or prevent any disease. It may be considered as an adjunct to

Safety Monitoring: Methods & Results-







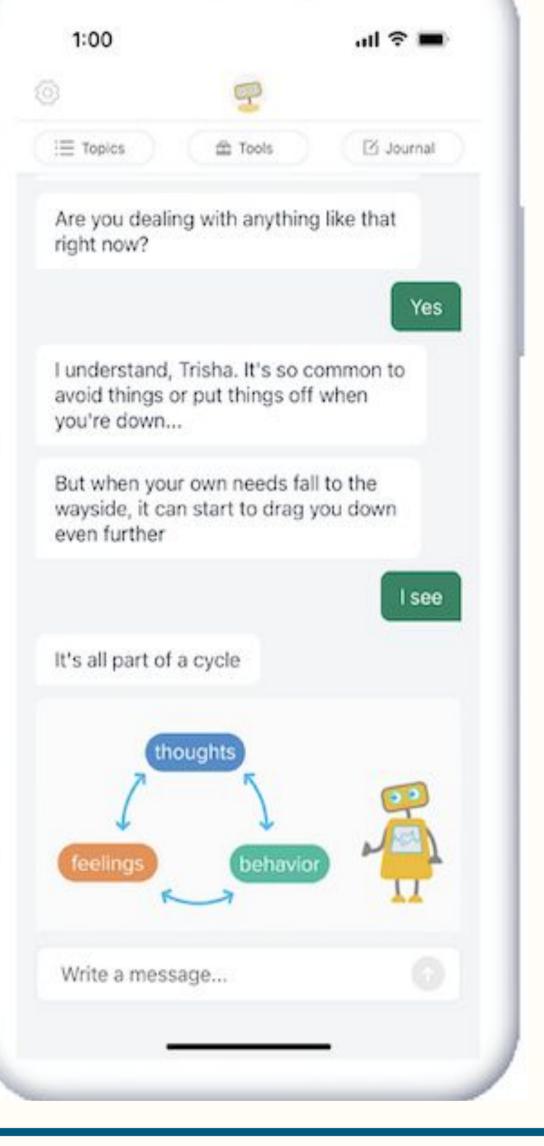


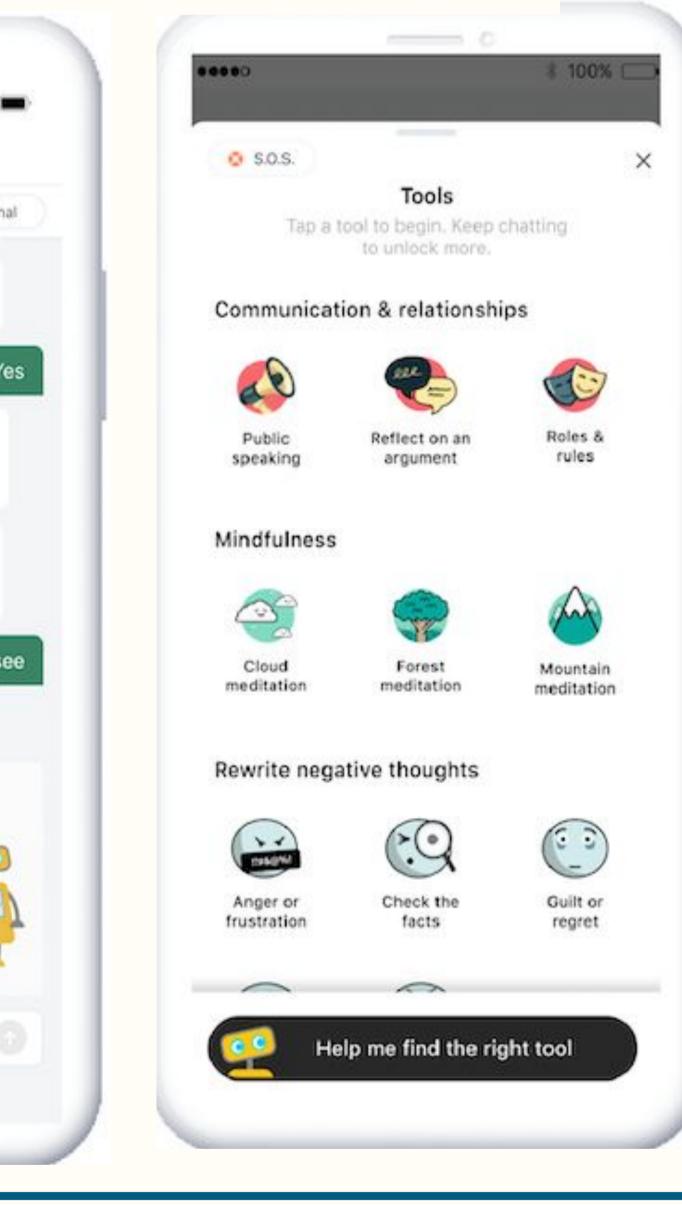
Intervention 1: CBT Skills Group

- Lead by a licensed mental health clinician
- 4, 60-minute telehealth groups
- Each session focused on a CBT skill, plus active practice
- Topics included:
- 1. Build a coping toolbox (relaxation strategies, mindfulness),
- 2. Accept your feelings (emotional awareness, distress tolerance),
- 3. Challenge negative thoughts (automatic thoughts), and
- 4. Problem-solve (cognitive restructuring; behavioral activation)

Intervention 2: W-GenZD

- W-GenZD contains Woebot, a guided self-help relational agent that guides users through a CBT-based program
- Offers evidence-based emotion management techniques, mood tracking, empathy and psychoeducation
- Participant journeys tailored in real-time, to endorsed needs and mood in the moment
- Interface centers on goal-oriented, text-based conversations with Woebot.





Intervention Adherence

W-GenZD CBT Skills Group

Intervention Adherence was defined a-priori as: CBT Group: 2 of 4 sessions attended; Woebot Group: 2 of 4 weeks app used

D'Brien D, Harvey K, Howse J, et al. Barriers to managing child and adolescent mental health problems: a systematic review of primary care practitioners' perceptions. Br J Gen Pract. ³ Steinman KJ, Shoben AB, Dembe AE, & Kelleher KJ. How long do adolescents wait for psychiatry appointments? *Community Ment Health J.* 2015;51(7):782-9.

⁴ Bennett CB, Ruggero CJ, Sever AC, & Yanouri L. eHealth to redress psychotherapy access barriers both new and old: A review of reviews and meta-analyses. *J. Psychother. Integr.* 5 David D, Cristea I, Hofmann SG. Why cognitive behavioral therapy is the current gold standard of psychotherapy. Front Psychiatry. 2018;9:4. Doi: 10.3389/fpsyt.2018.00004. 6 Kroenke K, Strine TW, Spitzer RL, Williams JBW, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. J Affect Disord. 2009;114(1-3):163–73. doi:

Spitzer ÅL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006;166(10):1092–1097. Doi:

T, Wilmers F, Leonhart R, Linster HW, Barth J. Working Alliance Inventory-Short Revised (WAI-SR): psychometric properties in outpatients and inpatients. Clin Psychol Psychother. 2010:17(3):231-9. doi: 10.1002/cpp.658. ⁹ Briesch AM, Chafouleas SM, Neugebauer SR, Riley-Tillman TC. Assessing influences on intervention implementation: revision of the usage rating profile-intervention. *J Sch Psychol*.

Attkisson CC, & Zwick R. The Client Satisfaction Questionnaire: Psychometric properties and correlations with service utilization and psychotherapy outcome. Eval Program. 1982; 5(3), , Williams A, Rapoport SJ, et al. A randomized controlled feasibility study of CBT Skills Group and Woebot for Adolescents, a relational agent-guided digital interventic among adolescents seeking outpatient care for anxiety and/or depression. Presented at the 2023 American Academy of Pediatrics (AAP) National Conference & Exhibition, Washington







