# A Randomized Controlled Feasibility Study of CBT Skills Group and W-GenZD, a Relational Agent-Guided Digital Intervention, Among Adolescents Seeking Outpatient Care for **Anxiety and/or Depression**

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## Background

Dramatic escalations of depression and anxiety among adolescents<sup>1</sup> further exacerbate unmet mental health care needs as the ability for healthcare systems to meet demand continues to be a barrier to care. Digital mental health interventions (DMHIs) provide promise as first line low intensity interventions, such as within stepped care paradigms, but require feasibility and efficacy testing.<sup>3</sup> Research reported preliminary efficacy of W-GenZD,<sup>4</sup> a mobile application featuring a relational agent Woebot that delivers cognitive behavioral therapy (CBT). Further evaluation of W-GenZD among adolescents with symptoms of depression and/or anxiety is warranted.

# Objective

Examine the feasibility and satisfaction associated with W-GenZD and telehealth-delivered CBT skills group, among a sample of adolescents seeking care for depression and/or anxiety from a children's hospital outpatient mental health clinic that uses a stepped care approach to triage patients depending on presenting level of need.

### Methods

The study randomized 141 adolescents aged 13-17 years to either W-GenZD or telehealth CBT skills group. Adolescents presented seeking care for depression and/or anxiety and were deemed appropriate for routine level of care in the stepped care model. Analyses in the intent-to-treat (ITT) population were conducted, yielding group estimates for:

- Intervention Feasibility, measured by the Usage Rating Profile-Intervention Revised (URP-IR<sup>5</sup>; range 6-36) at 4-weeks end-of-treatment (EOT)
- Intervention Satisfaction, measured by the Client Satisfaction Questionnaire (CSQ-8<sup>6</sup>; range 8-32) at 4-weeks EOT

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

#### Results

Key findings presented in poster's center panel.

#### Conclusions

This RCT, the first of its kind to investigate W-GenZD, a relational agent-delivered DMHI, and telehealth-delivered CBT skills group in an outpatient children's hospital setting. Findings support the feasibility of integration of the DMHI into this ecosystem's established stepped care paradigm, as well as satisfaction of W-GenZD among this sample of adolescents seeking care for depression and/or anxiety. Findings have important implications for adolescents, parents, and providers as an effective, acceptable feasible DMHI offers promise in addressing the adolescent mental health crisis.

Groundbreaking randomized controlled trial comparing a mental health-focused relational agent, Woebot, to clinician-delivered CBT Skills Group reports feasibility and satisfaction scores among adolescents seeking outpatient mental health care.

Table 1. Descriptives of Feasibility and Satisfaction at 4-Weeks EOT

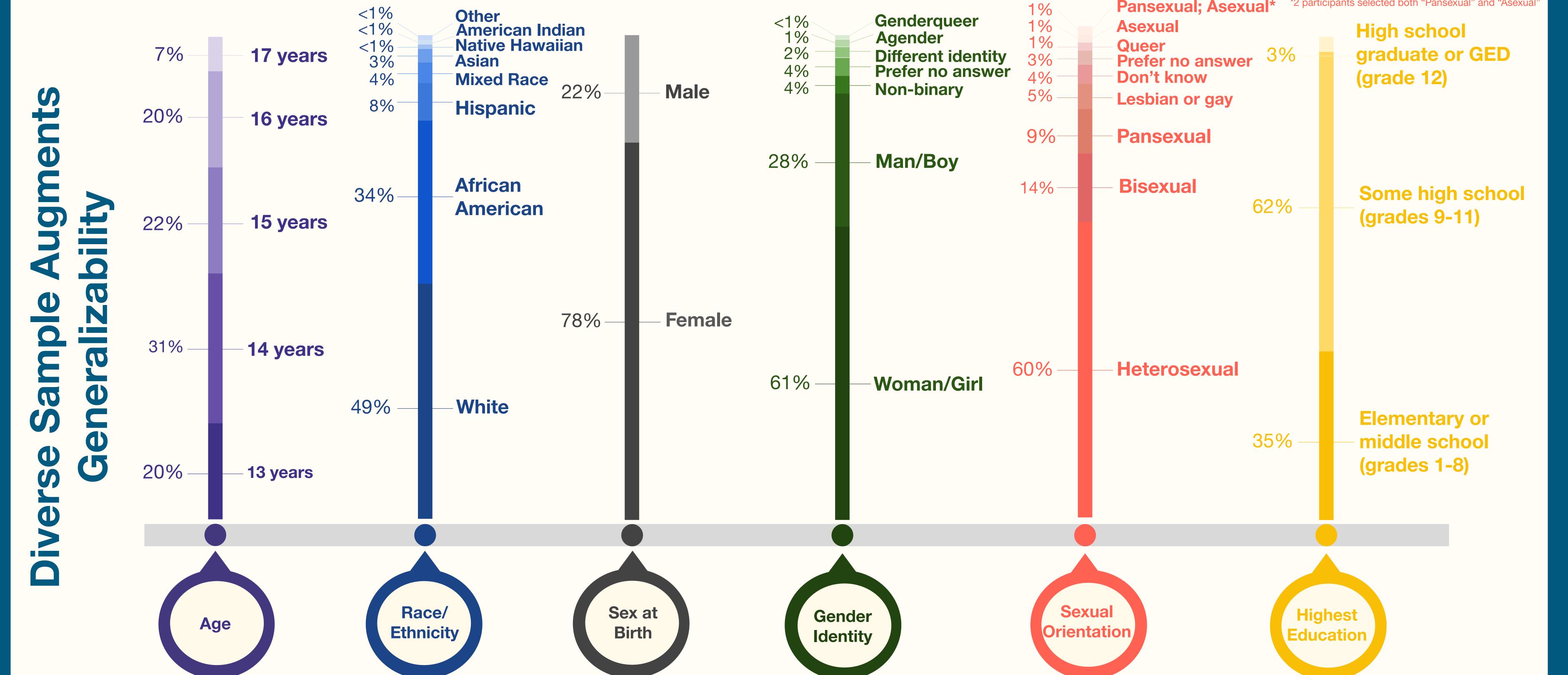
Intervention Group	FEASIBILITY {URP-IR Scale Range: 6-36}			SATISFACTION {CSQ-8 Scale Range: 8-32}			
	n	Median (IQR)	Interpretation	n	Mean (SD)	Interpretation	
W-GenZD	52	29.50 (5.25)	Appears  • Feasible	52	23.08 (5.51)	Appears  • Satisfied	
CBT Skills Group	55	30.00 (4.50)	<ul> <li>Similar across groups</li> </ul>	55	22.49 (5.54)	<ul> <li>Similar across groups</li> </ul>	

#### Table 2. Frequencies of CSQ-8 Item Responses at Week 4 (EOT)

	<b>W-GenZD</b> (n=52)		CBT Group (n=55)	
Satisfaction Survey Items (CSQ-8)	n (%)		n (%)	
Satisfaction Survey Items (CSQ-0)	Reply	Reply	Reply	Reply
	1 or 2	3 or 4	1 or 2	3 or 4
1. How would you rate the quality of service you have received?	12 (23%)	40 (77%)	11 (20%)	44 (80%)
2. Did you get the kind of service you wanted?	9 (18%)	42 (82%)	8 (15%)	45 (85%)
3. To what extent has our program met your needs?	21 (44%)	27 (56%)	20 (37%)	34 (63%)
4. If a friend were in need of similar help, would you recommend our program to him/her?	5 (10%)	43 (90%)	4 (8%)	47 (92%)
5. How satisfied are you with the amount of help you have received?	23 (45%)	28 (55%)	24 (45%)	29 (55%)
6. Have the services you received helped you to deal more effectively with your problems?	6 (12%)	43 (88%)	12 (24%)	39 (76%)
7. In an overall, general sense, how satisfied are you with the service you have received?	18 (35%)	34 (65%)	15 (28%)	38 (72%)
8. If you were to seek help again, would you come back to our program?	7 (14%)	42 (86%)	9 (18%)	42 (82%)

Note. Items are rated on a Likert scale from "1" indicating the lowest degree of satisfaction to "4" indicating the highest.

Figure 1. Sample Self-Identity Characteristics



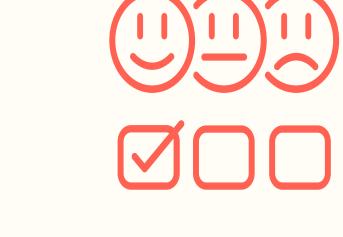
### Intervention 1: CBT Skills Group

- 4, 60-minute televideo groups led by a licensed mental health clinician
- Each session focused on a CBT skill, plus active practice
- Topics included:



Toolbox

(relaxation strategies



Accept Your

Feelings

(emotional awareness,

distress tolerance)





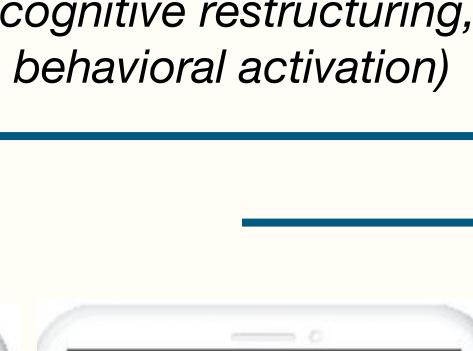
Challenge Negative Thoughts

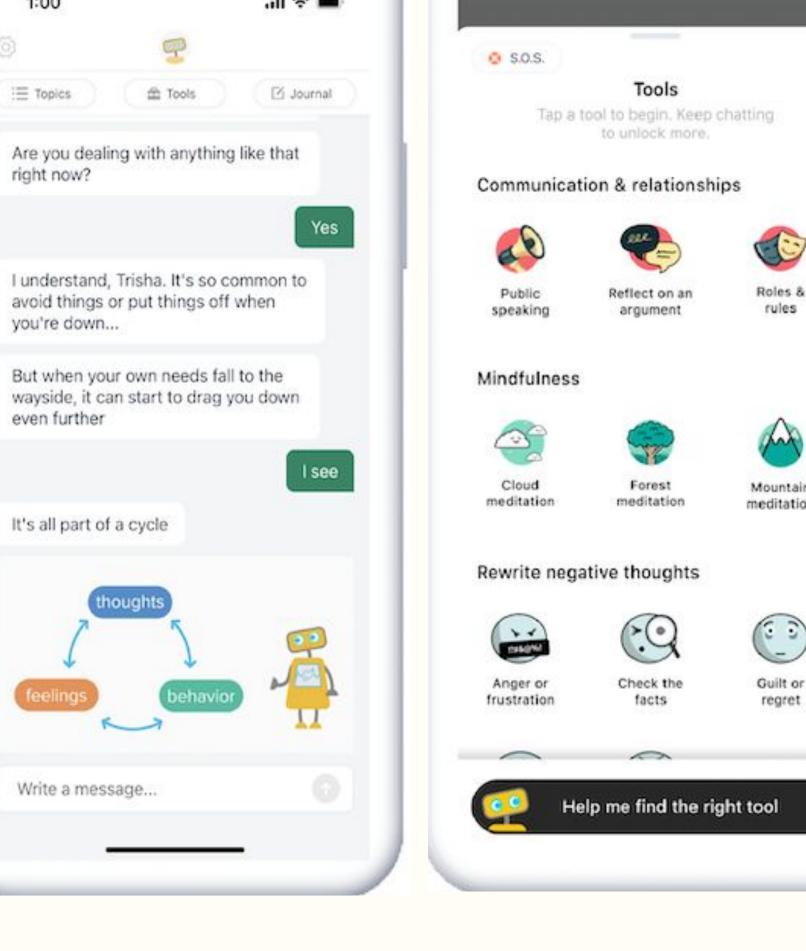
(automatic thoughts)

Problem-Solve (cognitive restructuring,

### Intervention 2: W-GenZD

- W-GenZD hosts 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

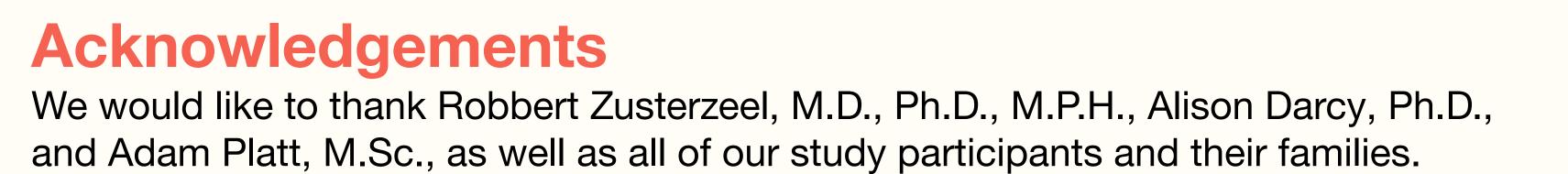
**CBT Skills Group** 

W-GenZD

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

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participant payments, and the platform for electronic data capture. Dr. Gleason received research funding from the Hampton Roads Biomedical Research Consortium and Drs Gleason and Wells, and Laura Lang received research funding to support this study from Woebot Health.





#### Disclaimer

Woebot for Adolescent Mood & Anxiety (W-GenZD-01) is an investigational medical device. It has not been evaluated, cleared, or approved by the FDA.

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