RCT OF AN ONLINE MENTAL HEALTH INTERVENTION AMONG OLDER PLWH DURING THE COVID-19 PANDEMIC

Jeff Berko

Mazonson & Santas, Inc.
Larkspur, CA, USA

CROI 2021

RCT OF AN ONLINE MENTAL HEALTH INTERVENTION AMONG OLDER PLWH DURING THE COVID-19 PANDEMIC

Jeff Berko, MPH[1]; Peter Mazonson, MD, MBA[1]; Duncan Short, PhD[2]; Cassidy A. Gutner, PhD[2]; Maile Karris, MD[3]; Gregory Huhn, MD[4]; Lynsay MacLaren, PA-C, MPH, MPAS, AAHIVS[5]; Theoren Loo, MS[1]; Sarah-Marie Chan, BS[1]; Frank Spinelli, MD, FACP[2]; Andrew Zolopa, MD[2,6]

[1] Mazonson & Santas, Inc., Larkspur CA; [2]ViiV Healthcare, Raleigh, NC; [3]UC San Diego Medical Center, San Diego, CA; [4] Cook County Health, Chicago, IL; [5]Whitman-Walker Health, Washington, DC; [6]Department of Medicine, Stanford University, Stanford, CA

BACKGROUND

Background

- Older adults (age 50+) living with HIV (OALWH) may experience elevated levels of depression, anxiety and loneliness

- Online mindfulness lessons have the potential to address these problems and enhance access, especially during the COVID-19 pandemic

- The objective of this randomized controlled trial was to determine the effectiveness of online mindfulness lessons in reducing feelings of depression, anxiety and loneliness among OALWH

Conference on Retroviruses and Opportunistic Infections; March 6-10, 2021; Virtual

Berko et al. CROI 2021; Virtual. Session Oral-04, SubSession ID 3018

4

Background – The ADHOC Study

- The Aging with Dignity, Health, Optimism and Community (ADHOC) study is a prospective, observational, longitudinal cohort study launched in 2018

- Data collected from 1,047 OALWH prior to COVID-19 showed:
  - Depression prevalent in 21% of the population
  - Anxiety in 21%
  - Loneliness in 51%

- Research suggests that the COVID-19 pandemic might exacerbate these issues[1-4]

1. Czeisler MÉ. Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic — United States, June 24–30, 2020. MMWR Morb Mortal Wkly Rep. 2020;69. doi:10.15585/mmwr.mm6932a1

2. Wang C, Pan R, Wan X, et al. A longitudinal study on the mental health of general population during the COVID-19 epidemic in China. Brain Behav Immun. 2020;87:40-48. doi:10.1016/j.bbi.2020.04.028

3. Spoorthy MS, Pratapa SK, Mahant S. Mental health problems faced by healthcare workers due to the COVID-19 pandemic–A review. Asian Journal of Psychiatry. 2020;51:102119. doi:10.1016/j.ajp.2020.102119

4. Simon NM, Saxe GN, Marmar CR. Mental Health Disorders Related to COVID-19–Related Deaths. JAMA. 2020;324(15):1493. doi:10.1001/jama.2020.19632
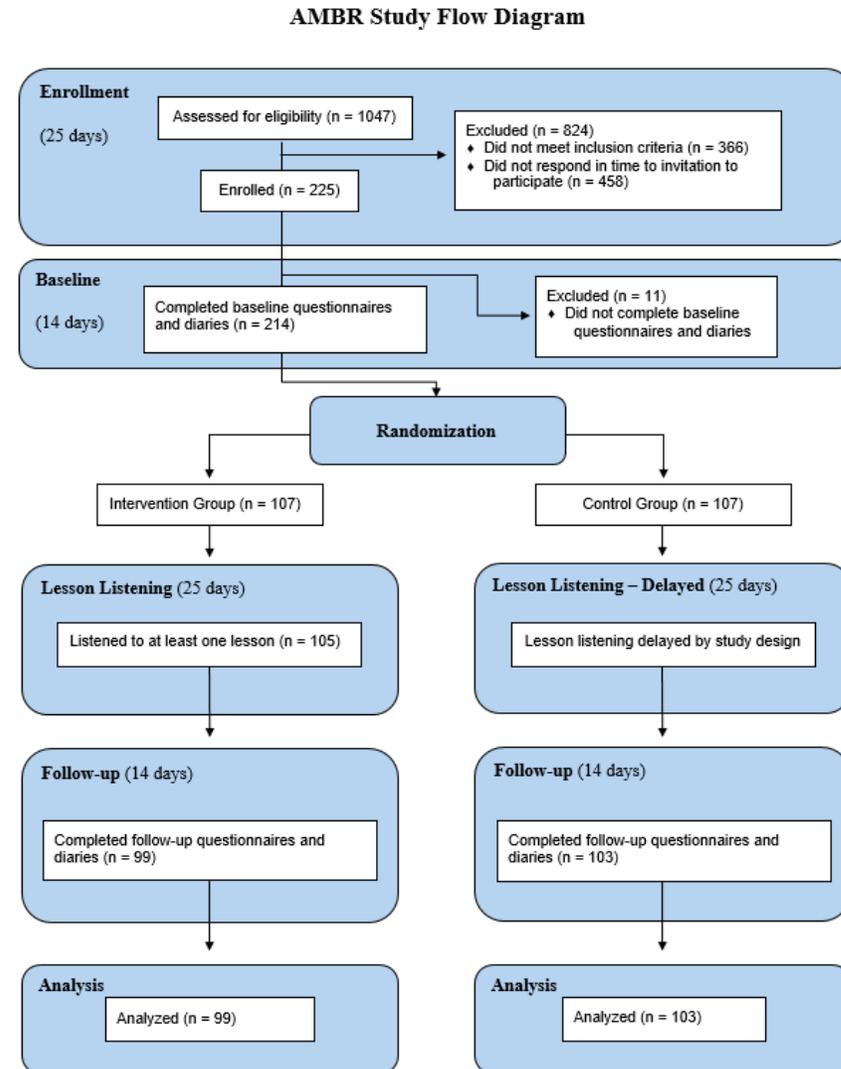
Conference on Retroviruses and Opportunistic Infections; March 6-10, 2021; Virtual

Berko et al. CROI 2021; Virtual. Session Oral-04, SubSession ID 3018

5

METHODS

Methods – The AMBR Study

- This randomized controlled trial, the ADHOC Mindfulness-Based Research (AMBR) study, was conducted between May and August, 2020

- OALWH with any degree of self-reported loneliness were eligible to participate

- Three key outcomes:
  - Depression – measured using the Center for Epidemiologic Studies Depression Scale (CES-D-10)
  - Anxiety – measured using the Generalized Anxiety Disorder (GAD-7)
  - Loneliness – measured two ways: the Three-Item Loneliness Scale (3IL), and a Daily Diary that asked "How lonely did you feel today?"

- Statistical analysis
  - Two sample t-tests were used to compare group scores at follow-up

Conference on Retroviruses and Opportunistic Infections; March 6-10, 2021; Virtual

Berko et al. CROI 2021; Virtual. Session Oral-04, SubSession ID 3018

7

Methods – CONSORT Flow Diagram

- 225 participants enrolled

- 214 were randomized (107 in each arm)

- 93% (N=99) of the intervention group completed follow-up, as did 96% (N=103) of the control group

AMBR Study Flow Diagram

Conference on Retroviruses and Opportunistic Infections; March 6-10, 2021; Virtual

Berko et al. CROI 2021; Virtual. Session Oral-04, SubSession ID 3018

8

Methods – The Mindfulness Lessons

- Previous research has shown that an audio series of 20-minute online mindfulness lessons can help ameliorate depression, anxiety and loneliness[1,2]

- Participants were allotted 25 days to listen to up to 14 lessons

- Participants could listen at any time they liked, from any internet connected device, including a mobile app.
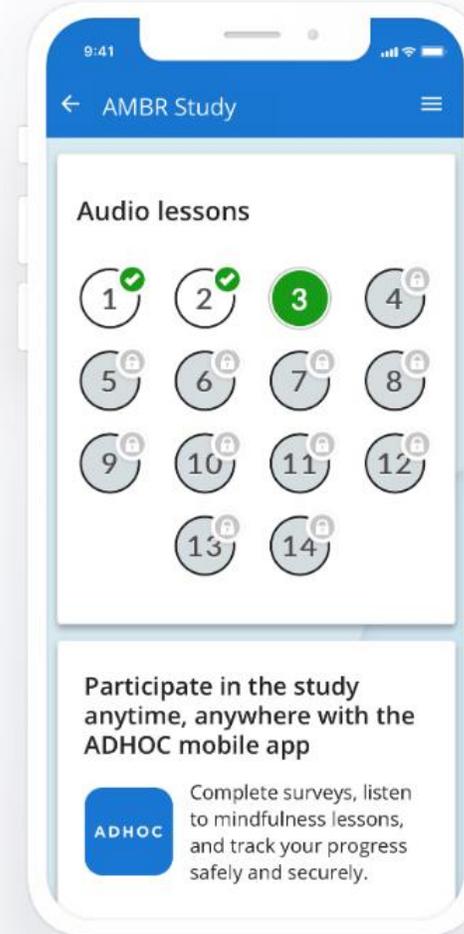
[1] Lindsay et al. Mindfulness training reduces loneliness and increases social contact in a randomized controlled trial, PNAS, 2019, https://www.pnas.org/content/116/9/3488

[2] Lindsay et al. How Mindfulness Training Promotes Positive Emotions: Dismantling Acceptance Skills Training in Two Randomized Controlled Trials, JPSP, 2020, http://dx.doi.org/10.1037/pspa0000134

Conference on Retroviruses and Opportunistic Infections; March 6-10, 2021; Virtual

Berko et al. CROI 2021; Virtual. Session Oral-04, SubSession ID 3018

9

RESULTS

Results – Participants and Lesson Listening Behavior

- Participant Demographics:
  - Mean (SD) age = 60.4 (5.9)
  - 89% male
  - 69% White
  - 74% gay
  - No statistically significant differences between groups at baseline
- Lesson Listening Behavior

Lessons Completed	N	%
0-9	9	8%
10-13	7	7%
14	91	85%
Total	107	100%

92% completed at least 10 lessons

Results – Mean depression, anxiety and loneliness scores following an online mindfulness intervention

	Intervention N	Control N	Intervention Mean (SD)	Control Mean (SD)	p-value	Difference	Cohen's d
Depression[a]							
All participants	99	103	10.2 (5.8)	12.8 (6.9)	< 0.01	20.3%	0.41
Depressed at baseline (CESD ≥ 8)	76	68	11.8 (5.6)	16.0 (5.8)	< 0.01	26.3%	0.75
Anxiety[b]							
All participants	99	103	5.2 (4.3)	6.7 (5.0)	0.03	22.4%	0.32
Anxious at baseline (GAD ≥ 5)	67	66	6.2 (4.2)	8.6 (4.5)	< 0.01	25.9%	0.55
Loneliness[c]							
All participants (3IL)	99	103	6.0 (1.9)	6.3 (1.8)	0.26	4.7%	0.16
Lonely at baseline (3IL ≥ 6)	69	64	6.8 (1.6)	7.3 (1.5)	0.06	6.8%	0.33
All participants (Diary)	99	103	2.7 (1.5)	3.1 (1.6)	0.07	12.9%	0.26
Lonely at baseline (Diary)	69	64	3.0 (1.4)	3.7 (1.5)	< 0.01	18.9%	0.55

[a] Measured using the CES-D-10, which ranges from 0-30 with higher scores indicating more severe depression.

[b] Measured using the GAD-7, which ranges from 1-21, with higher scores indicating more severe anxiety.

[c] Measured using the Three-Item Loneliness scale, which ranges from 3-9, with higher scores indicating more loneliness, and using a Daily Diary, which asked "How lonely did you feel today?" on a 1-7 scale, with higher scores indicating more loneliness, each day for three days. Responses were averaged across the three days.

Conference on Retroviruses and Opportunistic Infections; March 6-10, 2021; Virtual

Berko et al. CROI 2021; Virtual. Session Oral-04, SubSession ID 3018

12

Results – Supplementary analyses of key subpopulations

	Intervention N	Control N	Intervention Mean (SD)	Control Mean (SD)	p-value	Difference	Cohen's d
Depression[a]							
Hispanic, Black or female	29	30	9.3 (5.6)	12.7 (7.4)	0.05	26.8%	0.52
Income ≤ $50k/yr	59	55	11.0 (6.0)	13.5 (7.3)	0.04	18.5%	0.38
Obesity, diabetes, or COPD	42	47	11.2 (5.9)	13.8 (7.0)	0.06	18.8%	0.40
Anxiety[b]							
Hispanic, Black or female	29	30	4.4 (4.8)	6.9 (5.1)	0.06	36.2%	0.49
Income ≤ $50k/yr	59	55	5.4 (4.7)	7.4 (5.1)	0.03	27.0%	0.42
Obesity, diabetes, or COPD	42	47	5.2 (4.1)	7.4 (4.9)	0.03	29.7%	0.47

[a] Measured using the CES-D-10, which ranges from 0-30 with higher scores indicating more severe depression.

[b] Measured using the GAD-7, which ranges from 1-21, with higher scores indicating more severe anxiety.

Conference on Retroviruses and Opportunistic Infections; March 6-10, 2021; Virtual

Berko et al. CROI 2021; Virtual. Session Oral-04, SubSession ID 3018

13

CONCLUSION

Conclusion

- In this randomized controlled trial that included 214 adults, online mindfulness lessons produced significant reductions in depression, anxiety, and daily loneliness.

- For many patients, this intervention may offer emotional relief even in the face of the COVID-19 pandemic.

- This intervention holds promise as a way to supplement strained existing mental health resources, without the need for face-to-face interaction and with minimal disruption to provider workflow.

Conference on Retroviruses and Opportunistic Infections; March 6-10, 2021; Virtual

Berko et al. CROI 2021; Virtual. Session Oral-04, SubSession ID 3018

15