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# Association of COVID-19 impact with outcomes of an integrated obesity and depression intervention: Posthoc analysis of an RCT

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# ABSTRACT

*Objective:* To examine the association between COVID-19 impact and clinical outcomes of an integrated collaborative care intervention for adults with obesity and comorbid depression. *Methods:* Latent class analysis identified clusters of self-reported COVID-19 impact. Cluster characteristics were examined using Fishers' least significant difference method and canonical discriminant analysis. Intervention vs.

usual care effects on primary (body mass index [BMI], depressive symptoms) and secondary (anxiety symptoms and other psychosocial) outcomes stratified by cluster were examined using linear mixed models. *Results:* Three clusters were identified: mental health and sleep impact (cluster 1, n = 37), economic impact (cluster 2, n = 18), and less overall impact (cluster 3, n = 20). Clusters differed in age, income, diet, and baseline coping skills. The intervention led to improvements across several health outcomes compared with usual care, with medium to large effects on functional impairments (standardized mean difference, -0.7 [95% CI: -1.3, -0.1]) in cluster 1, depressive symptoms (-1.1 [95% CI: -2.0, -0.1]) and obesity-related problems (-1.6 [95%

CI: -2.8, -0.4]) in cluster 2, and anxiety (-1.1 [95% CI: -1.9, -0.3]) in cluster 3. *Conclusions:* People with obesity and comorbid depression may have varied intervention responses based on

COVID-19 impact. Interventions tailored to specific COVID-19 impact clusters may restore post-pandemic health.

#### 1. Introduction

During the COVID-19 pandemic, stay-at-home orders and social distancing impacted health behaviors, including physical activity and eating habits, and exacerbated the widespread obesity pandemic. Global estimates suggest that 12.8–48.6% of community-dwelling adults reported weight gain associated with lifestyle changes during the COVID-19 pandemic, with higher odds of weight gain among those with elevated baseline BMI [1]. Furthermore, the global prevalence of depression, which commonly co-occurs with obesity [2], grew from 4%

in 2017 [3] to 28% in 2021 [4]. Simultaneous growth of the prevalence of obesity and depression during the COVID-19 pandemic heightened the risk for future health consequences and highlighted the urgent need for effective interventions that support people with this comorbid pattern.

The effectiveness of interventions that leverage lifestyle modification to treat people with obesity and comorbid depression during the post-COVID-19 era may be impacted by societal shifts that occurred during the pandemic. Disparate influences of the COVID-19 pandemic on daily and instrumental activities (e.g., childcare, healthcare access) [5,6],

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stress [7], and health behaviors (i.e., physical activity, diet, sleep) [8] may impede lifestyle modification efforts, especially among individuals with comorbid depression. Investigating the impact of the COVID-19 pandemic on the effectiveness of behavioral interventions for people with obesity and comorbid depression is important as this may inform tailoring of interventions that address the different needs of people among this high-risk population during the ongoing pandemic.

We leveraged data from a pilot randomized clinical trial (RCT) that took place during the COVID-19 stay-at-home order in Illinois [9]. The objectives of this posthoc analysis were to: identify clusters of pilot RCT participants who reported common patterns of COVID-19 pandemic impact, examine associations between cluster membership and baseline characteristics, and examine intervention effects on 6-month clinical outcomes stratified by cluster. Our hypothesis was that the intervention effects would be smaller among clusters of participants that experienced more negative impacts of COVID-19 relative to those who experienced fewer negative impacts.

# 2. Methods and Materials

#### 2.1. Study design

Data were collected between March 7, 2019 and August 19, 2020. The trial aimed to elucidate neurobiological mechanisms of behavior change associated with an integrated collaborative care intervention for comorbid obesity and depression (ClinicalTrials.gov NCT03841682). Participants (N = 106) were randomized (2:1 ratio) to receive an integrated collaborative care intervention (I-CARE2) or usual care over 6 months.

#### 2.2. Participants

Adults ( $\geq$ 18 years) with obesity (body mass index [BMI]  $\geq$ 30.0, or  $\geq$ 27.0 if Asian) and clinically significant depressive symptoms (Patient Health Questionnaire-9 [PHQ-9] score  $\geq$ 10) were included. People with significant comorbid physical or mental health conditions (including pre-existing cardiovascular disease, diabetes, cancer, psychotic or bipolar disorders) or circumstances that would preclude completion of the study procedures were excluded. The inclusion and exclusion criteria were described in detail in the trial protocol [9]. All 105 out of 106 participants who remained enrolled in the trial in March 2020 were invited to complete the COVID-19 Impact Survey, and 75 participants (71%) who completed the survey were included in this posthoc study.

# 2.3. I-CARE2 intervention and usual care control

The I-CARE2 intervention integrates the Diabetes Prevention Program-based Group Lifestyle Balance<sup>TM</sup> (GLB) video program for weight loss [10] and Problem-Solving Therapy (PST) as first-line, plus antidepressant medications as needed for depression care management [11]. A trained health coach delivered 6 one-on-one in-person PST sessions over 2 months followed by 3 PST sessions and 11 home-viewed GLB videos over 4 months. Participants who demonstrated signs of poor engagement or progress toward depression and weight outcomes at sessions 4 and 7, respectively, received a focused or motivational interviewing-enhanced PST session to address barriers. Participants self-monitored their weight and diet and synchronized their activity tracker data via the Fitbit application throughout the intervention. Participants in the usual care control group received information about behavioral health and weight management services available at UI Health and a Fitbit Alta HR (Fitbit, Inc, San Francisco, CA). The full intervention protocol was previously published [9].

#### 2.4. Measures

Participant characteristics and health outcomes measured at baseline

and 6 months were utilized in this study. On March 16, 2020, the state of Illinois instituted stay-at-home orders in response to the COVID-19 pandemic. All participants completed baseline data collection before this date. Outcome data collection continued until August 31, 2020. An ad hoc assessment, the COVID-19 Impact Survey, was sent to participants to complete during follow-up between May and August in 2020.

### 2.4.1. COVID impact

The COVID-19 Impact Survey was adapted from the Epidemic-Pandemic Impacts Inventory (EPII) [12]. A total of 54 of the original 92 items from the EPII were used to assess impacts on work and employment (6 items), education and training (1 item), home life (7 items), social activities (7 items), economic (4 items), emotional health and well-being (6 items), physical health problems (6 items), physical distancing and quarantine combined with COVID-19 infection history (5 items), and positive changes experienced during or as a result of the pandemic (12 items). Specific items are listed the Supplementary Material Table S1. Participants indicated if each item was true in their life (yes/no).

#### 2.4.2. Baseline characteristics

Self-reported sociodemographic variables included age, sex, race/ ethnicity, education, and income. Diet was assessed by interview using multiple multi-pass 24-hour recalls (2 on weekdays and 1 on weekend) to determine adherence to the DASH (Dietary Approach to Stop Hypertension) diet, fruit and vegetable intake, total fat intake, and total calorie intake [13]. Physical activity was assessed using the 7-Day Physical Activity Recall interview to determine metabolic equivalent task (MET) minutes per week of leisure-time moderate-intensity activity and average energy expenditure in kilocalories per kilogram per day [14]. The 25-item Social Problem Solving Inventory-Revised: Short Form was used to generate an overall problem solving ability score and scores on 5 subscales: positive problem orientation (PPO), negative problem orientation (NPO), rational problem solving (RPS), impulsive/careless style (ICS), and avoidance style (AS) [15]. The Coping Orientation to Problems Experienced (COPE) Inventory characterized the use of 14 cognitive coping strategies [16]. The Emotional Regulation Questionnaire characterized emotional regulation strategies [17]. The 15-item Brief Risk-Resilience Index for Screening (BRISC) characterized negativity bias, emotional resilience, and coping skills [18]. Baseline health variables included blood pressure and the health outcomes below.

### 2.4.3. Changes in health outcomes

Changes in BMI and SCL-20 scores at 6 months were the primary outcomes. Changes in GAD-7 scores and other health measures at 6 months were secondary outcomes. Trained research staff measured height (baseline only) and body weight following standard protocols. BMI was computed as weight (kg) divided by height squared  $(m^2)$  [19]. Depressive symptoms were measured using the 20-item Symptom Checklist Depression Scale (SCL-20), with possible scores between 0 (best) and 4 (worst) [20]. Anxiety was measured using the 7-item Generalized Anxiety Disorder questionnaire (GAD-7), with possible scores between 0 (best) and 21 (worst) [21]. Sleep was measured using the PROMIS 8-item Sleep Disturbance and Sleep-Related Impairment questionnaires, with higher T scores indicating more sleep disturbance and impairment [22]. Psychosocial problems related to weight were measured using the Obesity-Related Problems Scale [23], with higher scores indicating more obesity-related psychosocial problems. Functional impairments in work/school, social, and family life was measured using the Sheehan Disability Scale [24], with higher scores indicating more functional impairments. Health-related quality of life was measured using the Medical Outcomes Survey Short Form 8-item questionnaire (SF-8) [25], with higher scores indicating higher physical or mental quality of life.

### 2.5. Statistical analyses

We conducted 3 analyses to (1) identify clusters of participants by COVID-19 Impact; (2) examine the association between baseline characteristics and COVID-19 Impact clusters; and (3) explore the intervention effects stratified by COVID-19 Impact clusters.

Clusters of participants who reported common patterns of impact on the COVID-19 Impact Scale were identified using Latent Class Analysis (LCA). This model-based approach uses participant responses on a set of indicators to identify profiles based on an underlying categorical latent variable. Similar COVID-19 Impact Survey items were combined resulting in 28 items (Supplementary Table S1). The final model was selected based on the model fit (e.g., Log Likelihood, AIC, BIC, CAIC, Adjusted BIC, entropy), relative cluster size, and utility of the clusters [26].

Percentages and means (standard deviations [SD]) were used to describe baseline characteristics among participants who did and did not complete the COVID-19 Impact Survey, and by cluster. We examined the bivariate associations between identified clusters and baseline characteristics using the 2-step Fisher's least significant difference method. After comparing baseline characteristics across clusters (analvsis of variance, Chi-square), we examined pairwise comparisons (Student's t, Chi-square) for variables significant at  $\alpha < 0.05$ . We then used canonical discriminant analysis to identify dimensions representing linear combinations of baseline characteristics that significantly differentiate the COVID-19 impact clusters by including baseline characteristics with P values  $\leq$  0.10 from the bivariate analyses [27]. Canonical discriminant analysis is a multivariate dimension-reduction technique that derives linear combinations of explanatory variables that have the highest possible multiple correlation, the canonical correlation, with the groups of a classification variable. Dimensions defined by each linear combination are considered canonical dimensions. Standardized canonical coefficients measured the strength and direction of correlation of each dimension with the characteristics. Participant scores on each canonical dimension were calculated as a sum of the products of canonical coefficients and the participant's individual values for the characteristics. These scores were compared among the 3 COVID-19 impact clusters using analysis of variance.

Repeated-measures mixed-effects linear modeling was used to explore the intervention versus usual care effects on health outcomes over the 6-month trial stratified by COVID-19 impact clusters. The fixed effects of each model included baseline value of the outcome, randomization covariates (age, sex, race/ethnicity, education, BMI, SCL-20 score, current use of antidepressant medication), a dichotomous COVID lockdown indicator (dummy variable indicating whether the outcome was collected before or after 3/16/2020), group, time-point (2 or 6 months), group-by-time interaction, the main effect of the COVID-19 impact cluster, and its interaction with group. The random effects accounted for repeated measures with an unstructured covariance matrix. Model-based point estimates of adjusted between-group differences in means are reported with 95% confidence intervals (CIs). Standardized mean differences on outcomes were computed using the baseline standard deviations and interpreted using Cohen's d conventions for small (d=0.2), medium (d=0.5), and large (d=0.8) effect sizes. Given the exploratory nature of this study, we focused on the magnitude and precision (95% CIs) of intervention versus control effects within each COVID-19 impact cluster instead of the statistical significance of the interaction term of the COVID-19 impact cluster with group, and no multiple comparison corrections were made. Analyses used all available data for each outcome, and missing data were handled directly through maximum-likelihood estimation via mixed modeling. In the case of missing study-measured weight, the closest electronic health record (EHR) weight within 3 months of the due date of a missed study visit or self-reported weight (if no EHR weight) was used. All analyses were conducted in SAS version 9.4 (SAS Institute Inc., Cary, North Carolina).

#### 3. Results

#### 3.1. Participant characteristic

Demographic and baseline health outcomes did not significantly differ between participants who did (n = 75) and did not (n = 31) respond to the COVID-19 Impact Survey (Table 1). Responding participants were primarily females (76.0%) with a mean (SD) age of 47.8 (12.4) years. Notably, this sample consisted of a high proportion of underrepresented groups across race/ethnicity (54.7% African-American, 19.8% Hispanic), education (48.0% some college or less), and income (32% less than \$35,000). Participants met criteria for obesity (mean [SD] BMI, 37.5 [6.6]) and reported mild to moderate depressive symptoms (mean [SD] PHQ-9, 12.7 [2.8]; SCL-20, 1.2 [0.6]).

#### 3.2. COVID-19 impact clusters

The 3-class model provided the best overall fit relative to the 4- and 5-class models indicated by the lowest information criterion values (see Electronic Supplementary, Table S2). Although the 2-class model had lower information criterion values, the 3-class model was selected due to its domain usefulness and lower log likelihood. Additionally, the entropy index (0.92) indicated good classification relative to the 2-class model and the smallest cluster contained over 5% of the sample [26].

Participant cha	racteristics
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	All	Responders	Nonresponders	
	N = 106	n = 75	n = 31	
Intervention, n	71	50	21	_
Control, n	35	25	10	Р
				value
Age, year	$47.0~\pm$	$\textbf{47.8} \pm \textbf{12.4}$	$\textbf{44.8} \pm \textbf{10.4}$	0.23
	11.9			
Female, %	76.4	76.0	77.4	0.88
Race/Ethnicity, %				0.20
Non-Hispanic White	17.9	16.0	22.6	
African American	54.7	50.7	64.5	
Hispanic	19.8	24.0	9.7	
Other	7.5	9.3	3.2	
Education				0.21
High school/GED or less	13.2	13.3	12.9	
College - 1 year to 3 years	40.6	34.7	54.8	
College - 4 years or more	27.4	29.3	22.6	
Post college	18.9	22.7	9.7	
Income				0.58
< \$35,000	32.1	32.0	32.3	
\$35,000- < \$55,000	24.5	28.0	16.1	
\$55,000- < \$75,000	14.2	13.3	16.1	
≥ <b>\$75,000</b>	29.2	26.7	35.5	
Taking antidepressant	17.9	20.0	12.9	0.39
medication, %				
BMI, kg/m2	37.1 $\pm$	$37.5\pm6.6$	$\textbf{36.2} \pm \textbf{4.4}$	0.32
	6.0			
SCL-20	$1.2\pm0.7$	$1.2\pm0.6$	$1.2\pm0.8$	0.66
PHQ-9	12.8 $\pm$	$12.7\pm2.8$	$13.2\pm2.7$	0.37
	2.8			
GAD-7	$\textbf{6.9} \pm \textbf{4.8}$	$\textbf{6.4} \pm \textbf{4.4}$	$\textbf{8.2} \pm \textbf{5.4}$	0.08
Weight, kg	101.5 $\pm$	102.2 $\pm$	$99.6 \pm 11.9$	0.42
0.0	15.2	16.4		
SF8-Physical Component	45.8 $\pm$	$\textbf{45.4} \pm \textbf{8.6}$	$\textbf{46.9} \pm \textbf{8.1}$	0.40
	8.5			
SF8-Mental Component	40.9 $\pm$	$41.0\pm9.9$	$40.8 \pm 12.0$	0.94
L.	10.5			
PROMIS Sleep	57.9 ±	$57.7 \pm 7.6$	$58.5 \pm 10.3$	0.65
Disturbance, T-score	8.4			
PROMIS Sleep	55.8 ±	$54.9 \pm 8.1$	$\textbf{58.2} \pm \textbf{10.9}$	0.09
Impairments, T-score	9.1			
£				

Note. Values are Mean  $\pm$  Standard Deviation or Percent

Abbreviations: BMI=Body-Mass Index; SCL-20 =Symptom Checklist-20; GAD=Generalized Anxiety Disorder Scale; SF8 =Short Form 8-item Health Survey Members of all 3 clusters had a high probability of reporting social separation and cancelled activities including family events, travel, and religious or spiritual activities (see Electronic Supplementary Material, Fig. S1). Members of all 3 clusters were also likely to report engagement in fewer enjoyable activities, worse health behaviors, and less medical care. Members of Cluster 1 (*mental health and sleep impacts*, n = 37, 49.3%) were more likely to report negative mental health and sleep health impacts than members of clusters 2 and 3. Members of Cluster 2 (*economic impacts*, n = 18, 24.0%) were more likely to report negative impacts on meeting basic needs (e.g., getting enough food or healthy food, paying important bills like rent or utilities, and getting needed medications) and transportation than members of clusters 1 and 3. Members of Cluster 3 (*less overall impacts*, n = 20, 26.7%) were the least likely to report overall negative impacts of the other 2 clusters.

# 3.3. Associations between COVID-19 impact clusters and baseline characteristics

# 3.3.1. Bivariate analysis

Significant bivariate associations were observed between clusters and age, systolic blood pressure, and a subset of coping strategies (i.e., acceptance and religion) (P < 0.05) (Table 2). Participants in cluster 1 were significantly younger (mean [SD], 43.5 [9.8]), had lower systolic blood pressure (116.6 [12.7] mm Hg), and had lower scores for acceptance (4.7 [1.7]) and religion (4.5 [2.3]) relative to clusters 2 and 3.

#### 3.3.2. Multivariate analysis

Canonical discriminant analysis identified 2 orthogonal dimensions representing statistically significant combinations of baseline characteristics. The canonical variates of dimensions 1 and 2 explained 40% and 26%, respectively, of the total variance of the 3 clusters. Participants in clusters 1 and 2 were characterized by the most extreme mean scores (-0.81 vs. 1.00, P < 0.001) on dimension 1 (Fig. 1). Participants in clusters 2 and 3 had the most extreme mean scores (-0.73 vs. 0.86, P < 0.001) on dimension 2 (Fig. 1). According to characteristics with the highest positive or negative correlation coefficients (Table 3), participants with lower systolic blood pressure, lower calorie intake, lower acceptance coping score, lower self-blame coping score and more obesity-related problems had a higher probability to be in cluster 1 versus cluster 2. Participants who were younger, had lower income, more obesity-related problems, higher religion coping score, lower selfblame coping score, and lower avoidance problem solving style score had a higher probability to be in cluster 2 versus cluster 3.

# 3.4. Intervention effects on health outcomes over 6 months stratified by COVID-19 impact cluster

Standardized mean differences (95% CI) between the intervention and control groups on health outcomes over 6 months stratified by COVID-19 impact cluster are depicted in Fig. 2. Compared with the usual care control group, the intervention had medium mean effects on reduced depressive symptoms (standardized mean difference, -0.6 [95% CI: -1.0, -0.3]), anxiety (-0.7 [-1.1, -0.3]), obesity-related problems (-0.7 [-1.2, -0.2]), functional impairments (-0.7 [-1.1, -0.3]), and improved mental health quality of life (0.7 [0.3, 1.2]) among participants across the 3 clusters. However, the results were null for BMI, sleep disturbance, sleep-related impairment, and physical health quality of life. Compared with the control group, the intervention had medium mean effects on reduced functional impairments (standardized mean difference, -0.7 [95% CI: -1.3, -0.1]) in cluster 1; large mean effects on reduced depressive symptoms (-1.1 [95% CI: -2.0, -0.1]) and obesity-related problems (-1.6 [95% CI: -2.8, -0.4]) in cluster 2; and large mean effects on reduced anxiety (-1.1 [95% CI: -1.9, -0.3]) in cluster 3. Adjusted mean differences (unstandardized) and 95% CIs on all outcomes stratified by cluster are reported in the Table 2

Bivariate analyses of COVID-19 Impact clusters and baseline characteristics.

	All	Cluster 1	Cluster 2	Cluster 3	P value
	n = 75	n = 37	n = 18	n = 20	
Intervention, %	66.7	56.8	83.3	70.0	0.14
Age, year	47.8 ±	43.5 ±	52.4 ±	51.7 ±	* 0.01
Esmals 0/	12.4 76.0	9.8 a	13.0 b	14.0 b	0.76
Female, % Race/Ethnicity, %	76.0	78.4	77.8	70.0	0.76 <b>0.10</b>
Non-Hispanic	16.0	18.9	5.6	20.0	0.10
White					
African American	50.7	45.9	72.2	40.0	
Hispanic	24.0	32.4	11.1	20.0	
Other	9.3	2.7	11.1	20.0	
Education	10.0	10.0	167	0.0	0.24
High school/GED or less	13.3	18.9	16.7	0.0	
College - 1 year to	34.7	32.4	38.9	35.0	
3 years	0 117	0211	0015	0010	
College - 4 years or	29.3	29.7	33.3	25.0	
more					
Post college	22.7	18.9	11.1	40.0	
Income					0.08
< \$35,000	32.0	24.3	61.1	20.0	
\$35,000- <	28.0	29.7	22.2	30.0	
\$55,000 \$55,000- <	13.3	18.9	5.6	10.0	
\$75,000	15.5	10.9	5.0	10.0	
≥ \$75,000	26.7	27.0	11.1	40.0	
Takes	20.0	13.5	16.7	35.0	0.14
antidepressant					
medication					
BMI, kg/m2	37.5 $\pm$	37.4 $\pm$	$\textbf{38.9} \pm$	$\textbf{36.4} \pm$	0.49
	6.6	6.3	7.3	6.5	
SCL-20	$1.2 \pm 0.6$	$1.2 \pm 0.6$	$1.2 \pm 0.7$	$1.3 \pm 0.6$	0.83
GAD-7 Weight kg	$6.4 \pm 4.4$ 102.2 $\pm$	$6.5 \pm 4.5 \\ 102.5 \pm$	$6.6 \pm 5.0 \\ 106.1 \pm$	$6.3 \pm 3.9 \\ 98.2 \pm$	0.98
Weight, kg	$102.2 \pm 16.4$	$102.5 \pm 16.7$	100.1 ± 17.6	$98.2 \pm 14.6$	0.33
SBP, mmHg	$121.2 \pm$	$116.6 \pm$	$128.4 \pm$	$123.3 \pm$	* 0.01
021, 111118	14.3	12.7 a	15.0 b	13.9 ab	0101
DBP, mmHg	75.7 $\pm$	74.4 $\pm$	75.1 $\pm$	78.7 $\pm$	0.23
	9.1	8.6	8.3	10.2	
PTSD	33.6 $\pm$	33.3 $\pm$	37.1 $\pm$	$31.1 \pm$	0.42
	12.8	11.7	15.3	12.8	
Obesity-Related	49.8 ±	56.6 ±	$\begin{array}{c} 44.4 \pm \\ 22.0 \end{array}$	41.9 ±	0.09
Problems Scale SF8-Physical	$\begin{array}{c} 26.8 \\ 45.4 \pm \end{array}$	$\begin{array}{c} 26.6 \\ 46.0 \pm \end{array}$	$43.1 \pm$	$\begin{array}{c} 28.9 \\ 46.1 \ \pm \end{array}$	0.45
Component	8.6	7.6	10.8	8.2	0.10
SF8 Mental	41.0 ±	40.8 ±	43.0 ±	39.4 ±	0.53
Component	9.9	8.9	8.7	12.5	
Sheehan Disability	10.4 $\pm$	10.0 $\pm$	11.5 $\pm$	10.0 $\pm$	0.82
Scale	8.6	8.7	8.9	8.7	
PROMIS Sleep	57.7 ±	58.7 ±	56.7 ±	56.6 ±	0.53
Disturbance	7.6	7.2	7.4	8.6	0.05
PROMIS Sleep Impairment	$54.9 \pm 8.1$	$56.2 \pm 7.2$	$\begin{array}{c} 52.3 \pm \\ 8.8 \end{array}$	$\begin{array}{c} 54.6 \pm \\ 9.0 \end{array}$	0.25
DASH score	$1.6 \pm 1.0$	$1.6 \pm 0.9$	$1.3 \pm 1.2$	$1.7 \pm 1.1$	0.55
Fruits and	$3.0 \pm 2.0$	$3.0 \pm 2.0$	$2.9 \pm 1.6$	$3.1 \pm 2.5$	0.95
Vegetables,					
Servings					
Total Fat	73.4 $\pm$	$\textbf{68.2} \pm$	84.2 $\pm$	73.4 $\pm$	0.21
	31.6	26.2	41.0	30.5	
Energy intake,	1714.9	1552.9	1972.9	1782.3	0.08
kilocalories 7D-PAR LTPA	$\pm$ 667.6 671.2 $\pm$	$\pm$ 539.9 548.1 $\pm$	$\pm$ 883.8 531.1 $\pm$	$\pm$ 604.7 1025.1	0.14
/D-FAR LIFA	925.3	650.0	451.4	$\pm 1473.8$	0.14
7D-PAR Energy	33.4 ±	$33.3 \pm$	32.8 ±	34.1 ±	0.27
Expenditure	2.3	1.8	1.2	3.7	
SPSI-R:S Total	13.1 $\pm$	13.3 $\pm$	13.6 $\pm$	12.3 $\pm$	0.24
	2.5	2.2	2.5	2.8	
SPSI-PPO subscale	$11.2 \pm$	10.9 ±	12.3 ±	10.7 ±	0.42
CDCL NDC - 1 1	4.3	4.1	4.0	4.8	0.07
SPSI-NPO subscale SPSI-RPS subscale	$6.1 \pm 4.1 \\ 10.6 \pm$	$\begin{array}{c} \textbf{6.1} \pm \textbf{4.0} \\ \textbf{10.9} \pm \end{array}$	$\begin{array}{c} 5.8\pm4.3\\ 11.2\pm\end{array}$	$\begin{array}{c} \textbf{6.6} \pm \textbf{4.1} \\ \textbf{9.5} \pm \textbf{3.2} \end{array}$	0.86
or or into subscale	10.6 ± 4.1	10.9 ± 4.4	11.2 ± 4.3	9.3 ± 3.2	0.36
SPSI-ICS subscale	$4.4 \pm 3.6$	$3.9 \pm 3.2$	$5.1 \pm 3.4$	$4.7\pm4.3$	0.49
SPSI-AS subscale	$5.6 \pm 4.2$	$5.2 \pm 3.5$	$4.7\pm3.4$	$7.3 \pm 5.4$	0.10
				(continued on	
				,	Page)

#### Table 2 (continued)

	$\begin{array}{l} All\\ n=75 \end{array}$	Cluster 1 $n = 37$	$\begin{array}{l} Cluster \ 2 \\ n = 18 \end{array}$	$\begin{array}{l} Cluster \; 3 \\ n = 20 \end{array}$	P value
COPE					
Self-Distraction	$\textbf{4.8} \pm \textbf{1.5}$	$4.6\pm1.5$	$5.2\pm1.4$	$\textbf{4.7} \pm \textbf{1.6}$	0.35
Active Coping	$4.9\pm1.8$	$4.6\pm1.6$	$5.7\pm1.9$	$\textbf{4.9} \pm \textbf{1.8}$	0.09
Denial	$2.8 \pm 1.1$	$2.8\pm1.2$	$2.8 \pm 1.3$	$2.7\pm1.0$	0.86
Substance Use	$\textbf{2.4} \pm \textbf{0.9}$	$\textbf{2.4} \pm \textbf{0.9}$	$\textbf{2.3} \pm \textbf{0.8}$	$\textbf{2.5}\pm\textbf{0.9}$	0.81
Use of Emotional Support	$\textbf{3.9} \pm \textbf{2.0}$	$\textbf{4.1}\pm\textbf{1.9}$	$\textbf{4.2}\pm\textbf{2.3}$	$\textbf{3.4}\pm\textbf{1.7}$	0.34
Use of Instrumental	$\textbf{3.8} \pm \textbf{1.7}$	$\textbf{4.1} \pm \textbf{1.8}$	$\textbf{4.0} \pm \textbf{2.0}$	$\textbf{3.2}\pm\textbf{1.0}$	0.13
Support					
Behavioral Disengagement	$2.7\pm1.2$	$2.6 \pm 1.3$	$2.8\pm1.2$	$2.6\pm1.0$	0.76
Venting	$3.8 \pm 1.6$	$3.5\pm1.4$	$4.0\pm1.6$	$4.3\pm1.7$	0.24
Positive Reframing	$4.6\pm1.9$	$4.4\pm2.0$	$4.9\pm2.0$	$\textbf{4.7} \pm \textbf{1.7}$	0.64
Planning	$5.4 \pm 1.8$	$5.2\pm1.9$	$5.6\pm1.9$	$5.6 \pm 1.8$	0.69
Humor	$\textbf{3.7} \pm \textbf{2.1}$	$3.5\pm2.0$	$\textbf{3.4} \pm \textbf{1.9}$	$\textbf{4.4} \pm \textbf{2.2}$	0.26
Acceptance	$\textbf{5.2} \pm \textbf{1.7}$	$4.7 \pm 1.7$ a	$5.8\pm1.7$ b	$5.6 \pm 1.4$ ab	* 0.04
Religion	$\textbf{4.9} \pm \textbf{2.2}$	4.5 ± 2.3 a	$6.2 \pm 2.0$	$4.3 \pm 2.0$	* 0.01
Self-Blame	$\textbf{4.5} \pm \textbf{1.8}$	a 4.1 ± 1.6	4.8 ± 2.0	$5.2 \pm 1.8$	0.07
ERQ					
Cognitive	$29.7~\pm$	$\textbf{29.9} \pm$	$29.6~\pm$	29.6 $\pm$	0.99
Reappraisal Score	8.2	6.9	9.1	9.8	
Expressive	15.1 $\pm$	15.5 $\pm$	15.7 $\pm$	$13.9 \pm$	0.53
Suppression Score BRISC	5.7	5.7	5.1	6.3	
Negativity Bias	$8.9 \pm 4.7$	$9.1 \pm 4.3$	$7.9 \pm 5.3$	$9.3 \pm 5.0$	0.61
Emotional	$8.3 \pm 2.9$	$9.1 \pm 4.5$ $8.7 \pm 2.6$	$7.9 \pm 3.3$ 8.4 ± 2.7	$7.5 \pm 3.4$	0.32
Resilience	0.0 ± 2.9	0.7 ± 2.0	0.1 ± 2.7	7.0 ± 0.1	0.02
Social Skills	13.4 $\pm$	$13.5 \pm$	13.6 $\pm$	$13.3 \pm$	0.97
oociai olalio	3.2	3.0	2.5	4.0	0157
Canonical		-0.81 a	1.00 b	0.57 b	*
Dimension 1					< 0.001
Canonical		-0.11 a	-0.73 b	0.86c	* 0.03
Dimension 2					

Note: Values are mean  $\pm$  standard deviation or percent; \*P < 0.05; Bolded P-values indicate P < 0.10 and were included in canonical discriminant analysis Cluster 1 = Mental Health and Sleep Impact; Cluster 2 = Economic Impact; Cluster 3 = Less Overall Impact

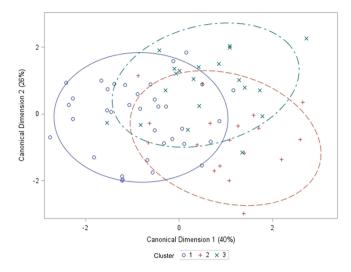
a, b, c indicate groups which differed from each other when between-group differences were statistically significant

Abbreviations: BMI=Body Mass Index; SCL-20 =Symptom Checklist-20; GAD-7 =Generalized Anxiety Disorder Scale-7; SBP=Systolic Blood Pressure; DBP=Diastolic Blood Pressure; PTSD=Post-Traumatic Stress Disorder severity score; SF-8 =Short Form 8-item Health Survey; DASH=Dietary Approach to Stop Hypertension; 7D-PAR LTPA= 7-Day Physical Activity Recall Leisure-time physical activity in MET minutes/week of moderate physical activity; 7D-PAR Energy Expenditure= 7-Day Physical Activity Recall average energy expenditure/day; SPSI-R:S=Social Problem Solving Inventory-Revised: Short Form; PPO = Positive Problem Orientation; NPO = Negative Problem Orientation; RPS = Rational Problem Solving; ICS = Impulsivity/Carelessness Style; AS = Avoidance Style; COPE=Coping Orientation to Problems Experienced; ERQ=Emotional Regulation Questionnaire; BRISC=Brief Risk-Resilience Index for Screening

### Electronic Supplementary Materials, Table S3.

#### 4. Discussion

Adults with obesity and comorbid depression who completed the COVID-19 Impact Survey during the first part of the COVID-19 pandemic were characterized by 3 clusters, highlighting mental health and sleep impact, economic impact, and less overall impact. differed in age, income, diet, and baseline coping skills. The intervention led to improvements across several health outcomes compared with usual care, specifically with medium to large effects on functional impairments in cluster 1, on depressive symptoms and obesity-related



**Fig. 1.** Discriminant analysis of COVID-19 Impact Clusters. Canonical discriminant analysis results of baseline characteristics for participants' COVID-19 impact clusters. This figure represents the distribution of participants' dimension scores according to the 3 clusters. Each symbol represents an individual participant. Individual symbols (participants) of one shape belong to the ellipse of the same shape denoting each cluster: circle, cluster 1 (mental health and sleep impacts, n = 37); cross, cluster 2 (economic impacts, n = 18); multiplication, cluster 3 (less overall impacts, n = 20). Each ellipse indicates an 80% confidence ellipse for the mean of each cluster.

### Table 3

Canonical analysis distinguishing COVID impact clusters.

	Standardized Canonical Coefficients		
	<sup>a</sup> Dimension 1	<sup>b</sup> Dimension 2	
Age, year	0.35	0.50	
White (reference: minority)	-0.16	0.08	
Income> =\$35,000 (reference: <\$35,000)	-0.19	0.71	
SBP, mmHg	0.39	-0.31	
Obesity-Related Problems Scale	-0.54	-0.41	
Energy intake, kilocalories	0.42	-0.33	
SPSI-AS subscale	0.03	0.46	
COPE-Active Coping	0.17	0.04	
COPE-Acceptance	0.37	0.09	
COPE-Religion	-0.09	-0.39	
COPE-Self-Blame	0.43	0.39	

Note. Results based on 74 participants who had complete data for all the baseline characteristics used in the Canonical discriminant analysis.

Abbreviations: SBP=systolic blood pressure; SPSI-AS=Social Problem Solving Inventory Avoidance Style; COPE=Coping Orientation to Problems Experienced <sup>a</sup> Dimension 1: Canonical function F(22, 122)= 2.80, P < 0.001; R<sup>2</sup> of the

canonical correlation= 0.40.  $^{b}$  Dimension 2: Canonical function F(10, 62)= 2.17, P = 0.03;  $R^{2}$  of the ca-

nonical correlation= 0.26.

problems in cluster 2, and on anxiety in cluster 3. These exploratory findings may have important implications for the tailoring and implementation of behavioral interventions designed to restore health among adults with comorbid depression and obesity as society navigates the ongoing pandemic.

Participants in cluster 1 were likely to report detrimental impacts on mental health and sleep. These participants were the youngest among all 3 clusters. This aligns with evidence that younger people reported worse mental health during the COVID-19 pandemic [14]. Participants in cluster 1 also had medium effect sizes on functional impairments in the intervention versus the control group. This effect size is similar to that reported in prior PST studies [28], suggesting that PST may be a viable treatment for adults who experienced pandemic-related mental health and sleep impacts. It is also worth noting that although intervention

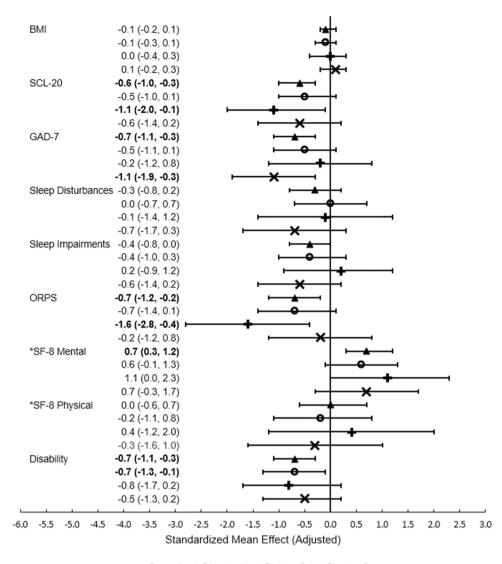


Fig. 2. Standardized mean effects (95% CI) of I-CARE2 intervention on health outcomes at 6 months in the overall sample and by COVID-19 Impact cluster. Forest plot depicting the overall and stratified standardized mean effects of the I-CARE2 intervention on health outcomes. Intervention effects in the overall sample for each outcome are represented by the triangle symbol. Intervention effects within each cluster are represented by: circle, cluster 1 (mental health and sleep impacts); cross, cluster 2 (economic impacts); multiplication, cluster 3 (less overall impacts). Error bars indicate 95% confidence intervals. Bolded text indicates that the 95% confidence interval does not contain null. Asterisk indicates outcomes in which expected direction of improvement is to the right of 0. For all other outcomes, expected direction of improvement is to the left of 0. BMI = BodyMass Index; SCL-20 = Symptom Checklist-20; GAD-7 = Generalized Anxiety Disorder Scale-7; SF-8 = Short Form 8-item Health Survey; ORPS = Obesity-Related Problems Scale.

▲Overall OCluster 1 Cluster 2 XCluster 3

effects (95% CI) on depression, anxiety, sleep-related impairments, obesity-related psychosocial problems, and mental health quality of life overlapped the null in cluster 1, the effect was in the expected direction. This may be, in part, related to challenges adhering to behavioral health recommendations reported by adults who experienced mental health impacts during the COVID-19 pandemic [29]. Augmenting PST with additional support or increasing the intensity of intervention may be required to bolster effects on important health outcomes. Further research specifying treatment needs of adults who report mental health and sleep impacts during the pandemic will inform tailoring of behavioral interventions that support this vulnerable group.

Participants in cluster 2 were likely to report difficulty meeting basic needs such as accessing food, medication, transportation, and inability to pay bills. These participants had low income relative to those in the less overall impact cluster. The economic toll of the COVID-19 pandemic was associated with elevated depressive symptoms among people with low income [30]. Participants in cluster 2 also had large effects on obesity-related problems and depression in the intervention versus the control group. PST, which was a key part of the integrated intervention, previously demonstrated efficacy for reducing depressive symptoms and improving mental health among low income populations [31]. The problem solving skills and coping strategies developed during the intervention may have supported participants as they navigated economic problems associated with the pandemic. Enhancing coping strategies may be particularly important for people with obesity and comorbid depression who experienced high economic impact associated with the COVID-19 pandemic. Further research that elucidates the impact of increasing positive coping strategies and reducing negative coping strategies on health outcomes should guide the tailoring of interventions for members of this cluster.

Participants in cluster 3 were least likely to report negative or positive impacts related to the COVID-19 pandemic. These participants were the oldest and had the highest income among all 3 clusters. Interestingly, among all clusters, these participants also had the highest scores on selfblame coping and avoidance problem solving style, which are maladaptive strategies that were associated with worse anxiety, depression, and stress outcomes during the pandemic [32]. However, the demographic characteristics of this cluster are consistent with prior findings that age and income were protective of mental health [33]. This aligns with evidence suggesting that social determinants of health (i.e., access to resources such as income) may play a greater role in health outcomes than individual psychological factors [34]. Members of the less overall impact cluster demonstrated improvements on anxiety, but no other health outcomes. Future studies may investigate whether improving maladaptive coping strategies in this less overall impact cluster may lead to improvements in weight, sleep, and depression

#### outcomes.

#### 4.1. Limitations

This clinical trial was ongoing at the onset of the COVID-19 pandemic. Consequently, it was not prospectively designed or adequately powered to evaluate the impact of COVID-19 on intervention outcomes. Although the small sample size used to conduct LCA was compensated for by the large number of indicators (COVID-19 Impact Survey questions), the clusters should be viewed as exploratory and replicated in larger samples [35]. Additionally, 29% of trial participants did not respond to the COVID-19 Impact survey. Although responders and nonresponders did not differ in baseline characteristics, generalizability of the findings may be limited. Finally, the EPII is a new tool which was designed in tandem with the ongoing COVID-19 pandemic and is currently undergoing validation to establish psychometric properties [12]. The present analysis supports and advances that work.

# 4.2. Conclusions

Despite these limitations, this posthoc study takes an important step toward characterizing the impact of the COVID-19 pandemic on the effectiveness of interventions within a uniquely high-risk and underserved population with obesity and comorbid depression. Participants in 3 distinct COVID-19 impact clusters differed in baseline characteristics (e.g., age, income, diet, and baseline coping skills) and may vary in their response to behavioral interventions. Future research that clarifies the unique needs of patients who experienced substantial mental health, sleep, and economic impacts of the COVID-19 pandemic is required to advance intervention tailoring and implementation to restore health and well-being among at-risk populations as society continues to navigate the pandemic.

### Adherence to ethical standards

This research was conducted in accordance with the Declaration of Helsinki and with the approval and oversight of the University of Illinois at Chicago Institutional Review Board. A copy of the Institutional Review Board documentation and approval is available upon request. All study participants demonstrated adequate understanding and provided written consent prior to completing study procedures.

### Disclosures

Dr. Jun Ma is a paid scientific consultant for Health Mentor, Inc (San Jose, CA). Dr. Leanne M. Williams is on the Scientific Advisory Board for One Mind Psyberguide and the External Advisory Board for the Laureate Institute for Brain Research. Dr. Olusola A. Ajilore is the co-founder of Keywise AI and serves on the advisory boards for Blueprint Health and Embodied Labs. All other authors have no disclosures.

#### **Declaration of Competing Interest**

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Dr. Jun Ma is a paid scientific consultant for Health Mentor, Inc (San Jose, CA). Dr. Leanne M. Williams is on the Scientific Advisory Board for One Mind Psyberguide and the External Advisory Board for the Laureate Institute for Brain Research. Dr. Olusola A. Ajilore is the co-founder of Keywise AI and serves on the advisory boards for Blueprint Health and Embodied Labs. All other authors have no disclosures.

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# Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.orcp.2022.05.005.

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