



Unwinding Anxiety for Migraine: A Pilot Randomized Clinical Trial of a Mindfulness Intervention for People with Migraine and Anxiety

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BACKGROUND

- Migraine and anxiety are comorbid¹.
- Anxiety is associated with higher levels of migraine disability¹.
- The Unwinding Anxiety (UA) intervention is an evidence-based mobile health app that has demonstrated efficacy to reduce generalized anxiety disorder symptoms².

Objective

- This study evaluated the feasibility and acceptability of an app-based mindfulness training for a population of people with migraine and anxiety recruited through Miles for Migraine.
- We evaluated preliminary clinical signals for headache disability, anxiety, and psychological distress compared to a waitlist control.

METHODS

Study Design

- Two-group randomized controlled trial with a waitlist control group.

Participants & Procedures

- 38 participants (100% women; M age = 47, SD = 13) were recruited from the Miles for Migraine website and listserv.
- After an online prescreen and phone screen, participants were randomized to receive either Unwinding Anxiety (UA) immediately, or after a 6-week waitlist period.
- During the treatment, participants received the UA mobile health app, and also attended 6 weekly group sessions designed to facilitate inquiry with trained mindfulness facilitators who also experience migraine.
- Primary outcomes were feasibility (session attendance) and acceptability (Credibility Score from Credibility Expectancy Questionnaire); these outcomes were obtained from both the UA and Waitlist groups after they received treatment.
- Clinical outcomes were assessed at Week 0, Week 6, and Week 12 (waitlist group only): the one-month Migraine Disability Assessment (MIDAS), monthly headache days, average monthly pain intensity, anxiety symptoms (GAD-7 and PDSS), depressive symptoms (PHQ-9), pain catastrophizing (PCS), headache acceptance (HAQ) and mindfulness/interoceptive awareness (MAIA).

Data Analysis

- Mixed models for repeated measures evaluated the change in clinical outcomes in the UA vs. Waitlist groups (Week 0 vs. Week 6) and across both groups pre-intervention (Week 0 for UA, Week 6 for Waitlist) to post-intervention (Week 6 for UA, Week 12 for Waitlist).

RESULTS

- The UA (M CEQ = 20.4, SD = 5.9) and Waitlist (M CEQ = 21.7, SD = 4.7) groups met criteria for acceptability.
- Only the Waitlist group (M session attendance = 5/6, SD = 0.9) met criteria for feasibility; the UA group (M session attendance = 4.3/6, SD = 5.9) approached feasibility criteria but did not surpass the a priori threshold.
- When evaluating UA vs. Waitlist while Waitlist was serving as the control (Table 2), we observed significant increases in mindfulness/interoceptive awareness in the UA vs. Waitlist group from baseline to Week 6 (estimate = 23.7, 95% CI = 14.0, 33.4).
- While evaluating pre- to post-treatment across all study participants, we observed significant reductions in psychiatric symptoms, and putative psychological mechanisms, but not migraine symptoms or disability (Table 2).

STUDY FLOW DIAGRAM

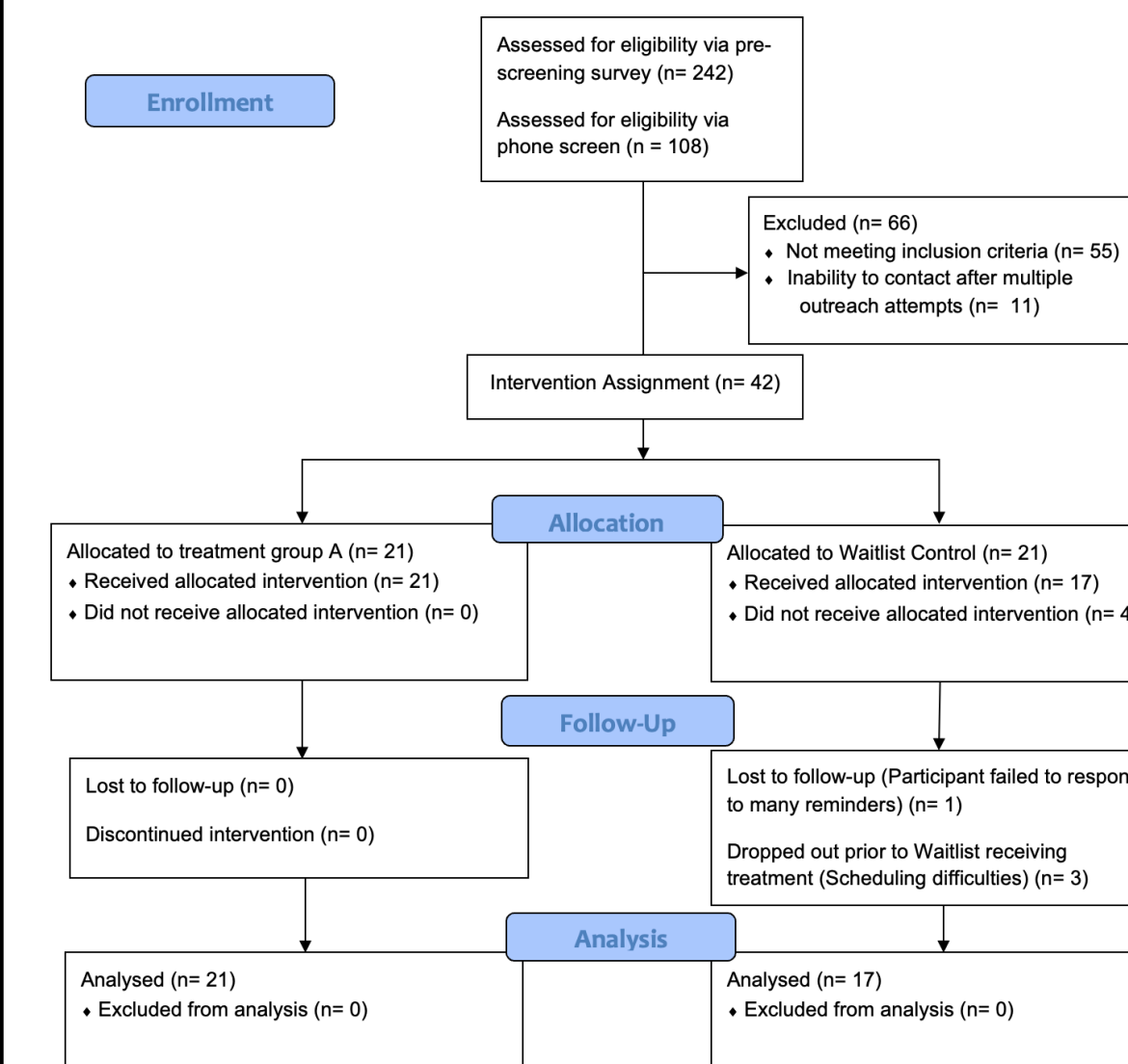


TABLE 2

Variable	Total M(SD)	Group A M(SD) or N (%)	Group B M(SD) or N (%)
GAD-7			
Pre-Intervention	11.37 (5.15)	12.48 (5.52)	10.76 (4.74)
Post-Intervention	7.68 (3.62)	8.67 (3.95)	6.47 (2.81)
Change Score	4.03 (4.63)	3.81 (5.17)	4.29 (4.0)
PDSS			
Pre-Intervention	7.84 (6.91)	10.29 (6.68)	5.24 (7.07)
Post-Intervention	5.82 (5.46)	7.14 (5.96)	4.18 (4.43)
Change Score	2.21 (5.33)	3.14 (5.29)	1.06 (5.31)
MIDAS			
Pre-Intervention	45.72 (33.75)	47.38 (31.06)	34.35 (30.44)
Post-Intervention	37.47 (28.68)	47.52 (31.49)	25.06 (19.15)
Change Score	4.08 (27.17)	-0.14 (27.40)	9.29 (26.77)
HAQ			
Pre-Intervention	20.4 (5.23)	20.24 (5.32)	21.21 (5.23)
Post-Intervention	23.53 (4.71)	22.76 (4.66)	24.47 (4.74)
Change Score	-2.76 (4.5)	-2.52 (4.47)	-3.06 (4.66)
MAIA			
Pre-Intervention	75.42 (21.4)	73.57 (20.08)	72.94 (23.65)
Post-Intervention	98.34 (20.15)	94.76 (21.53)	102.76 (17.94)
Change Score	-25.05 (24.51)	-21.19 (15.41)	-29.82 (32.39)

Note. Change Scores defined as Pre-Score – Post-Score.

TABLE 3

Variable	Estimates and 95% CI		
	Group	Time	Group * Time
Primary Headache Outcomes			
MIDAS	13.0 (-6.3 – 32.3)	-7.3 (-19.1 – 4.5)	7.4 (-8.3 – 23.1)
MIDAS A	7.0 (-4 – 13.6)	-1.9 (-4.1 – .4)	.76 (-2.3 – 3.8)
MIDAS B	-.079 (-1.2 – 1.1)	-.175 (-1.0 – .7)	.423 (-.7 – 1.6)
Psychiatric Variables			
GAD	1.7 (-1.4 – 4.8)	-1.0 (-3.3 – 1.2)	-2.8 (-5.8 – .24)
PHQ	2.9 (-.42 – 6.1)	-1.3 (-2.8 – .29)	-1.8 (-3.9 – .23)
PDSS	5.1 (.9 – 9.2)	-.595 (.9 – 9.2)	-2.5 (-5.7 – .63)
Putative Psychological Mechanisms			
HAQ	-1.2 (-4.3 – 2.0)	.842 (-1.2 – 2.9)	1.7 (-1.0 – 4.4)
MAIA	.63 (-13.1 – 14.3)	-2.5 (-9.8 – 4.8)	23.67 (14.0 – 33.4)
PCS	.303 (-5.6 – 6.2)	-2.7 (-6.5 – 1.1)	-3.8 (-8.8 – 1.3)

CONCLUSION

- The Unwinding Anxiety for Migraine intervention was acceptable to all participants, with mixed feasibility across groups.**
- We observed reductions in psychiatric symptoms and changes in putative psychological mechanisms pre- to post-treatment across all study participants.**
- We observed a specific treatment effect in mindfulness/interoceptive awareness.**

REFERENCES & FUNDING

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