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Research Article

Mindfulness-Based Intervention Improves Quality of Life and Reduces Burden in Family Caregivers of People with Intellectual Disabilities: A Pragmatic Randomized Trial with an Active Control

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This pragmatic randomized controlled trial evaluated the effectiveness of a culturally adapted mindfulness-based intervention (MBI) for improving quality of life and reducing caregiver burden among family caregivers of individuals with intellectual disabilities. Participants (n=100) were randomly assigned to either an MBI group or an active control group involving psychoeducational content. The intervention followed the Mindfulness-Based Health Promotion (MBHP) protocol, delivered over eight weekly sessions, with assessments conducted at baseline and post-intervention. Results showed statistically significant improvements in the MBI group in quality of life, psychological well-being, and reductions in subjective caregiver burden compared to the control group. Exploratory analyses also revealed associations between increased mindfulness levels and improved functional and psychological outcomes. The intervention was rated as feasible and acceptable by participants, with high adherence and satisfaction rates. These findings support the use of mindfulness-based interventions as a promising strategy for promoting mental health and reducing caregiver strain in populations caring for individuals with intellectual disabilities. The results have implications for scalable mental health promotion efforts in public health and rehabilitation contexts.

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Introduction

Family caregiving can be both rewarding and highly demanding, requiring significant time, effort, and adaptation to new roles and responsibilities[1][2]. People who assume this unpaid role are often exposed to elevated levels of stress, physical strain, and financial hardship[3]. These challenges are particularly pronounced among family members caring for people with intellectual disabilities, who frequently face long-term caregiving demands with limited external support.

Various interventions have been proposed to mitigate caregiver burden and promote psychological well-being. Among them, problem-solving training has been identified as a useful strategy to encourage active coping and foster more adaptive caregiving responses[4]. In recent years, mindfulness-based interventions have gained attention as a promising approach for supporting caregivers. Mindfulness practice—commonly used for stress reduction and health promotion—has been associated with improvements in both physical and mental health, as well as cognitive functioning[5].

Mindfulness-based programs have been implemented across a range of clinical and non-clinical populations, including caregivers of people with chronic illnesses. Evidence suggests that mindfulness-based stress reduction (MBSR) may alleviate psychological symptoms in caregivers[6]. However, most existing studies lack methodological rigor, and randomized controlled trials targeting caregivers of people with intellectual disabilities remain scarce.

No prior study has evaluated the effects of a structured Mindfulness-Based Health Promotion (MBHP) program on caregiver burden and quality of life among family members of people with moderate intellectual disabilities. This study addresses this gap by assessing the impact of a mindfulness intervention delivered in a real-world institutional setting.

Methods

This study followed the CONSORT (Consolidated Standards of Reporting Trials) guidelines[7] for reporting randomized controlled trials transparently and comprehensively. We applied the CONSORT 2010 framework, supplemented by the extension for pragmatic trials[8].

Type of Study

This pragmatic randomized controlled trial used pre- and post-intervention measures to assess the effects of mindfulness and active control interventions on family caregivers of people with moderate intellectual disabilities in São Paulo, Brazil.

Setting

The study was conducted from March to June 2019 in São Paulo, at the Teaching and Research Institute of the Jô Clemente Institute (formerly APAE São Paulo, at the time of the study). The Jô Clemente Institute is a nationally recognized nonprofit center for intellectual and developmental disabilities in Brazil, offering free multidisciplinary services. Interventions were conducted in 20–30 m^2 rooms equipped to minimize audiovisual distractions.

Pragmatic approach

Four informational lectures were delivered during family meetings, allowing all caregivers to learn about the study. To encourage participation and reduce dropout, sessions were scheduled during routine wait times at the institution. Audio recordings were available via a mobile app or CD for those without app access.

Ethics

This study was approved by the Human Research Ethics Committee of the Federal University of São Paulo (process no. 2.581.806, April 5, 2018). All participants gave written informed consent. It was registered at ClinicalTrials.gov (NCT03756441).

Participants

The participants were family caregivers of adolescents and adults (aged 14 to 34 years) with a moderate intellectual disability who attended a specialized institution two to three times per week for structured activities promoting cognitive, social, and adaptive skills. All participants were ambulatory (non–wheelchair users) and diagnosed at the institution based on DSM-5 criteria through multidisciplinary assessments. When indicated, the Wechsler Abbreviated Scale of Intelligence (WASI) and the Adaptive Behavior Assessment System, Second Edition (ABAS-II), were administered using age-appropriate versions (5–21 or 16–89 years).

Participants were enrolled in the sector designated for the most complex cases in terms of functional impairment. Their caregivers—predominantly older adults—had been engaged with the institution and caregiving responsibilities for several years, leading to a cumulative burden associated with prolonged care.

In terms of etiology, 55% of caregivers supported people with Down syndrome, 36% with an intellectual disability of unknown origin, and 4% with Fragile X syndrome. Myelomeningocele, Prader-Willi syndrome, and autism spectrum disorder each accounted for 1% of cases.

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Eligibility criteria

Inclusion criteria: female family caregivers aged ≥18, who cared for an adolescent or adult with a moderate intellectual disability attending the APAE São Paulo Rehabilitation Service and provided informed consent.

Exclusion criteria: self-reported acute-phase psychiatric condition during the interview and prior or current engagement in meditation or mindfulness practices.

Sample size calculation

The sample size was estimated a priori using G*Power version 3.1 software[9], based on a multivariate profile analysis model. The analysis indicated that 128 participants (64 per group) would be required to detect statistically significant group differences with 80% power and a 5% significance level (α = .05).

Recruitment, Randomization and Blinding

All female family caregivers of people attending the Rehabilitation Service at APAE São Paulo were invited to participate; the female gender was chosen to ensure sample homogeneity, as it predominates in this population.

Randomization was conducted using the software www.random.org by one of the authors (PP). Family caregivers were randomly assigned to one of two experimental groups: the mindfulness intervention group (MBHP) or an active control group (problem-solving training).

Randomization followed two strategies based on institutional constraints: individual randomization in larger classes and block randomization in two smaller classes, with one assigned to the intervention group and the other to the control group. This approach ensured feasibility within predefined institutional scheduling.

Of the 100 caregivers enrolled in the final sample, 51 were allocated to the intervention group and 49 to the active control group through a block randomization procedure designed to form balanced subgroups over time. Participants were distributed across five intervention groups and five control groups (approximately 10 participants per group), allowing for sequential delivery of the sessions in accordance with logistical constraints. Following the 8-week intervention period, participants in the control groups were offered the opportunity to take part in a subsequent cycle of MBHP training (see Figure 1).

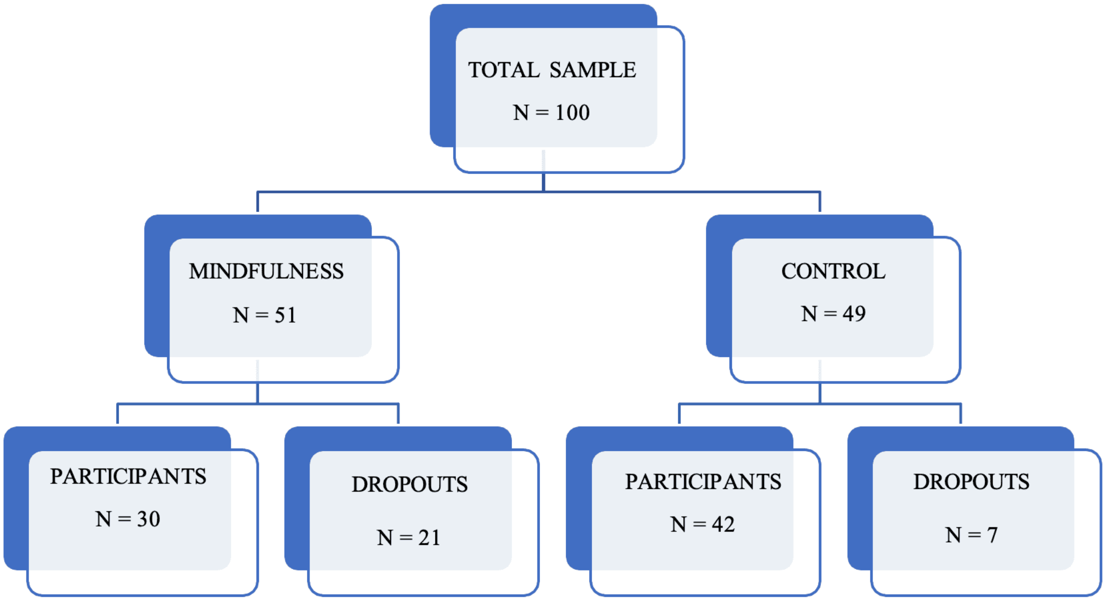

Figure 1. Participation flow

Although participants and facilitators could not be blinded due to the nature of the intervention, outcome assessors were blinded to group allocation during the data collection and analysis phases. This approach aimed to minimize potential measurement bias and ensure the objectivity of outcome evaluations. Additionally, several procedures were implemented to reduce potential biases. To minimize selection bias, random allocation was performed after baseline assessments. Detection bias was addressed by blinding outcome assessors. Performance bias was partially mitigated by using an active control group that received structured mental health-related educational content, thus ensuring participant engagement across both arms of the study.

Final Sample

The final sample comprised 100 family caregivers: 94 mothers, 5 aunts, and 1 grandmother. Four caregivers each supported two people with intellectual disabilities—two in the control group and two in the intervention group.

With respect to caregiver health, 66 participants reported the daily use of at least one medication, 8 reported no medication use, and 26 did not provide this information. Seventeen caregivers had private health insurance, while 79 did not, and 4 declined to respond. Regarding the people with intellectual disabilities, 61 required medications administered by a caregiver, 29 did not, and 10 responses were missing. Additionally, four caregivers reported engaging in yoga practice, evenly distributed between the two groups (n = 2 per group).

Moreover, baseline sociodemographic characteristics did not differ significantly between the control and intervention groups (see Table 1).

Variable	Measure	MBHP		Control group		CI 95%	p-value
		n	Value	n	Value		
Mother's age *Mean ± SD*	Years	51	56.98±10.56	49	56.29±9.16	−3.24, 4.62	.73[a]
Patient's age *Mean ± SD*	Years	51	24.75±6.46	49	23.47±5.31	-1.07, 3.63	.28[a]
Amount of time dedicated to patient care *Mean ± SD*	Hours/day	41	21.12±7.11	38	21.95±5.52	−3.69, 2.04	.84[b]
	Days/week	43	6.70±1.06	38	6.76±0.85	−0.49, 0.36	.91[b]
Menopause (mother) *n (%)*	Yes	48	29 (60.42)	47	36 (76.60)		.12[c]
Academic background (mother) *n (%)*	Elementary school High school Higher education Postgraduate studies	48	27 (56.25) 19 (39.58) 2 (4.17) 0	48	29 (60.42) 15 (31.25) 3 (6.25) 1 (2.08)		.63[d]
Marital status (mother) *n (%)*	Never married Currently married Separated Divorced Widowed Cohabiting with a partner	50	3 (6.00) 17 (34.00) 10 (20.00) 2 (4.00) 13 (26.00) 5 (10.00)	49	7 (14.29) 14 (28.57) 11 (22.45) 3 (6.12) 8 (16.33) 6 (12.24)		.64[d]
Religion (mother) *n (%)*	None Catholic Evangelical Umbanda Other		0 25 18 1 5		4 30 8 1 4		.08[d]

Table 1. Baseline comparative analysis of participants' characteristics

All numbers are absolute, except numbers in parentheses, which represent percentages.

SD = standard deviation

95% CI = 95% confidence interval

[a] *Evaluated using an unpaired t-test (two-tailed)*

[b] *Evaluated using the Mann-Whitney U test (two-tailed)*

[c] *Evaluated using Fisher's exact test (two-tailed)*

[d] *Evaluated using the chi-square test*

Interventions

Mindfulness-Based Health Promotion (MBHP)

MBHP is adapted from the original Mindfulness-Based Stress Reduction (MBSR) model by Jon Kabat-Zinn[10], tailored by our research group for primary health care and health promotion contexts. The MBHP model features shorter sessions than MBSR, making it more feasible for implementation in health services, with a didactic sequence to enhance patient learning[11].

The structured program runs over eight weeks, with one 1.5-hour session per week in which participants practice mindfulness techniques[12]. Additional informal practices, lasting 15–20 minutes (up to 45 minutes, depending on participant pace), encourage the integration of mindfulness into daily activities.

Formal practices with audio-guided exercises focused on breathing, body awareness, and movement (light intensity) were conducted, suitable for varying physical capabilities. Group dynamics and a silence session were also included, as outlined in the MBHP program[12].

Mindfulness instructors were recruited via social media flyers, followed by CV screening and interviews. Four instructors led the MBHP program, all certified by Mente Aberta Mindfulness Brazil (UNIFESP), with at least 1.5 years of training and prior group facilitation experience. All staff were blinded to the study objectives and received training to ensure protocol alignment.

Problem-Solving Training

The active control group participated in a standardized problem-solving training protocol, delivered over the same 8-week period as the intervention group, with one 1.5-hour session per week, conducted concurrently to minimize temporal confounding. Grounded in a cognitive-behavioral framework, this approach conceptualizes problem-solving as a learned skill essential to effective coping with everyday challenges[13][14]. The training targets five core components: problem orientation, problem definition, generation of alternatives, decision-making, and solution implementation with verification. It also addresses emotional factors—such as anxiety or depression—that may interfere with the application of learned skills. Previous studies have demonstrated its effectiveness in improving adaptive functioning and reducing caregiver psychological distress, with effects maintained over time[15].

Psychologists were recruited via social media flyers, followed by CV screening and interviews. Four female psychologists, with an average of 10 years of professional experience, facilitated the control group, all with group therapy experience. Two recently graduated psychologists (6 months of experience), with prior health-related internships, assisted with data collection and participant follow-up, including tracking absences (after two consecutive unexplained absences or withdrawal). All staff were blinded to the study objectives and received training to ensure protocol alignment.

Outcomes

The primary outcome was the family caregiver's quality of life, assessed at baseline and post-intervention in both the mindfulness and control groups.

Secondary outcomes included caregiver burden, mindfulness (attention and awareness), anxiety, depression, and functionality, all measured at both time points.

Explanatory variables

Anxiety, depression, functionality, and level of mindfulness were considered explanatory variables for the outcomes of quality of life and caregiver burden, based on prior evidence of their associations with caregiver outcomes in the context of intellectual disability[16][17].

Instruments

Sociodemographic questionnaire: A structured instrument with 16 closed-ended items to outline the sample profile, plus 11 open-ended questions to explore caregiving experiences and probe the perceived effects of the interventions.

Quality of Life Scale (WHOQOL-Brief): A widely used 26-item measure assessing perceived quality of life across four domains: physical health, psychological well-being, social relationships, and environment. It has been previously used in studies involving family caregivers of people with intellectual disabilities in Brazil.

Items are rated on a 5-point Likert scale, with higher scores indicating better quality of life. Internal consistency coefficients range from 0.66 to 0.84 across domains. The instrument has demonstrated good construct validity and factorial structure in Brazilian samples[18].

Informal Caregiver Burden Assessment Questionnaire (QASCI): A 32-item questionnaire specifically developed to assess caregiver burden among informal caregivers of people with functional dependence, including those with intellectual disabilities. It has been applied in Brazilian studies with this population. Items are scored on a 5-point Likert scale ranging from 1 (never) to 5 (always). The instrument exhibits excellent internal consistency ($\alpha = 0.95$ overall; domain-specific α ranging from 0.70 to 0.94). Factorial analyses support its content and construct validity[19].

Disability Assessment Scale (WHODAS 2.0 short version): Developed by the World Health Organization, this is a standardized instrument designed to assess levels of functioning across six life domains defined by the International Classification of Functioning, Disability and Health (ICF): cognition, mobility, self-care, getting along with others, life activities, and participation in society. While primarily applied to people with disabilities, it has been used in caregiver-related contexts to evaluate perceived impact and support needs. The short version includes 12 items rated on a 5-point Likert scale (1 = no difficulty to 5 = extreme difficulty/cannot do). In Brazilian samples, internal consistency coefficients exceed 0.80, and the instrument has shown good construct and concurrent validity[20].

Hospital Anxiety and Depression Scale (HADS): This scale consists of 14 items assessing symptoms of anxiety and depression, divided into two subscales. It has been extensively used in Brazilian studies with caregivers of people with intellectual and developmental disabilities. Responses are scored on a 4-point Likert-type scale with item-specific descriptors. The Brazilian version demonstrates high internal consistency ($\alpha > 0.80$) for both subscales and has shown solid construct and criterion validity[21].

Mindful Attention Awareness Scale (MAAS): A 15-item instrument designed to assess mindfulness. Although not specifically developed for or widely used with caregivers of people with intellectual disabilities, it has been applied in related caregiver populations to explore coping and emotional regulation. Items are rated on a 6-point Likert scale (1 = almost always to 6 = almost never), with higher scores indicating greater mindfulness. The Brazilian adaptation has demonstrated good internal consistency ($\alpha > 0.80$) and validity based on exploratory and confirmatory factor analysis[22].

The questionnaire scales were randomized to avoid differences in motivation or fatigue responses, and the questionnaires were administered only after the focus group was performed so that the eight caregivers did not have access to the principles of what we were seeking to know. The intention was to reduce bias in the content.

Statistical analysis

Data were analyzed following both intention-to-treat and per-protocol principles. Microsoft Excel 2010 was used for data entry, and IBM SPSS Statistics for Windows, Version 23.0[23], was used for statistical analyses.

Data normality was tested using the Kolmogorov–Smirnov test. Most variables were normally distributed; however, non-normal distributions were observed in some WHODAS and QASCI scale items. Group comparisons at baseline were conducted using independent-samples t-tests or Mann–Whitney U tests for continuous variables and chi-square or Fisher's exact tests for categorical variables, as appropriate.

Post-intervention, intra- and inter-group comparisons were performed for the HADS, WHOQOL-BREF, QASCI, MAAS, and WHODAS instruments. Paired and independent t-tests were used for normally distributed variables, and Mann–Whitney U tests for those not normally distributed. Mean changes (Δ) from baseline to follow-up were calculated, and group differences were assessed accordingly.

Where relevant, clinical impact was assessed by calculating the number needed to treat (NNT) or number needed to harm (NNH). Pearson or Spearman correlation coefficients were used to explore relationships among outcome measures. Multiple linear regression analyses were conducted to examine the influence of study variables within the intervention group. Statistical significance was set at $p < .05$ for all tests.

Qualitative approach

To complement quantitative data and better understand participants' subjective experiences[24], focus groups were conducted to explore participants' expectations and experiences. In the pre-intervention phase, one focus group was held with eight randomized caregivers (four from each group), with audio recordings collected. Pre-intervention questionnaires were then administered by a researcher blinded to the study objectives. The focus group was intentionally held prior to questionnaire completion to avoid biasing responses.

At the end of the intervention, two separate focus groups were conducted: one with participants from the mindfulness group and another with those from the control group. Group assignments were randomized. Post-intervention questionnaires were subsequently administered to all eligible participants.

Qualitative Data Analysis

Qualitative data were collected through pre- and post-intervention focus groups and semi-structured questions embedded within the sociodemographic questionnaire. These data were analyzed using NVivo 11[25] and IRaMuTeQ version 0.7 alpha 2[26].

To explore participants' expectations, lexical frequency analysis was conducted using the pre-intervention responses. The 15 most frequently occurring words were identified to provide insight into dominant themes prior to the intervention.

Post-intervention focus group transcripts were used to assess perceived outcomes of the intervention. Transcripts were coded and organized into thematic categories, which were subsequently analyzed through hierarchical similarity analysis (multilevel clustering). This analysis employed Pearson's correlation coefficient to calculate the Similarity Index among clusters. Associations were interpreted as follows: strong ($\geq$ 0.7), moderate (0.5–0.6), and weak (< 0.5).

Results

Although the target sample size was not reached, a post hoc power analysis was performed based on the observed effect size for the primary outcome (quality of life, WHOQOL-BREF total score). Using G*Power software (version 3.1), with an observed effect size (Cohen's d) of 0.65, $\alpha = 0.05$, and a total sample size of 100 (approximately 50 per group), the estimated statistical power to detect between-group differences using an independent t-test was 96%. This high power suggests that the study was adequately powered to detect moderate effects, reinforcing the reliability of the findings.

Feasibility

Participants who attended at least five of the eight scheduled sessions were included in the study. Based on this criterion, 28 participants (21 in the intervention group and 7 in the control group) were classified as dropouts. All were contacted to determine the reasons for discontinuation.

Among dropouts in the intervention group, reported reasons included personal preference (n = 11), health problems (n = 3), repeated absence of the caregiver at the scheduled session times (n = 3), logistical difficulties (n = 1), and, in one case, discontinuation following the death of the person with an intellectual disability. In two cases, despite up to three phone call attempts on different days and at different times, contact could not be established. In the control group, the reasons cited were health problems (n = 3), personal preference (n = 2), and logistical difficulties (n = 2).

Primary and Secondary Outcomes

Results demonstrated statistically significant improvements in quality of life and psychological well-being within the MBHP group, as well as greater reductions in subjective caregiver burden in the MBHP group compared to the active control group (see Table 2).

Variable	**MBHP**		**Control Group**		**CI 95%**	**p-Value**
	n	**Δ** *Mean ± SD*	**n**	**Δ** *Mean ± SD*		
HADS						
Anxiety	27	-1.48±2.41	44	-1.00±3.31	-1.94, 0.98	.51[a]
Depression	28	-2.96±5.85	41	-1.44±5.32	−4.24, 1.18	.27[a]
WHOQOL-BREF						
Physical domain	28	1.69±3.01	44	0.78±2.47	−0.38, 2.21	.16[a]
Psychological domain	28	1.57±2.90	44	0.65±2.11	−0.26, 2.10	.12[a]
Social relationships	27	1.63±3.59	44	0.45±3.14	−0.44, 2.79	.15[a]
Environment	28	1.47±2.95	44	0.53±1.68	−0.15, 2.02	.09[a]
QASCI						
Emotional overload	31	-2.48±2.95	44	-1.45±3.34	-2.52, 0.46	.09[b]
Implications for personal life	31	−4.94±6.09	44	-1.43±6.84	−6.56, −0.45	**.0253**[a]
Financial overload	31	0.10±2.23	44	−0.11±2.29	−0.85, 1.27	.99[b]
Reactions to requirements	31	-1.13±3.85	44	0.09±3.06	-2.81, 0.37	.13[a]
Perception of Efficiency and Control Mechanisms	31	1.19±3.16	44	0.11±5.08	-0.97, 3.13	.33[b]
Family Support	31	1.13±3.06	44	−0.27±3.72	−0.22, 3.02	.12[b]
Satisfaction with Role and Family	31	1.03±3.94	44	−0.25±5.79	-1.11, 3.67	.97[b]
General‡	31	-12.03±12.00	44	-2.43±14.81	-16.02, -3.19	**.0039**[a]
MAAS						
General	28	0.60±0.84	43	0.38±0.94	−0.22, 0.65	.32[a]

Variable	MBHP		Control Group		CI 95%	p-Value
	n	Δ *Mean ± SD*	n	Δ *Mean ± SD*		
WHODAS						
General	26	-2.50±5.39	44	-3.16±8.22	-2.95, 4.27	.72[a]
H1 (days)	22	-1.55±8.91	44	-2.10±12.71	-5.57, 6.67	.71[b]
H2 (days)	22	-1.95±6.64	42	-1.12±3.68	-3.41, 1.74	.39[b]
H3 (days)	22	-2.27±6.76	42	-1.02±7.94	-5.23, 2.73	.94[b]

Table 2. Comparative analysis of pre- and post-intervention mean scores (Δ) in HADS, WHOQOL-BREF, QASCI, MAAS, and WHODAS

All figures are absolute.

SD = standard deviation

95% CI = 95% confidence interval

[a] *Evaluated using the unpaired t-test (two-tailed)*

[b] *Evaluated using the Mann-Whitney U test (two-tailed)*

Number Needed to Treat (NNT) and Number Needed to Harm (NNH)

The lowest NNT was 3 for overall caregiver burden (QASCI), with WHOQOL-BREF domains of quality of life indicating values between 5 and 7. NNH values were high, and confidence intervals for increased absolute risk crossed zero in all cases, suggesting a low probability of the intervention causing harm (see Table 3).

Variable	Adverse outcome (%)		ARR (%)	IAR (%)	CI 95%	NNT	NNH
	Intervention	Control					
HADS							
Anxiety	40.74	43.18	2.44		-21.17, 26.06	41	
Depression	28.57	41.46	12.89		-9.63, 35.42	8	
WHOQOL-BREF							
Physical domain	39.29	54.55	15.26		-8.06, 38.58	7	
Psychological domain	21.43	40.91	19.48		-1.54, 40.51	6	
Social relationships	48.15	54.55	6.40		-17.51, 30.31	16	
Environment	25.00	45.45	20.45		-1.31, 42.22	5	
QASCI							
Emotional overload	35.48	50.00	14.52		-7.89, 36.92	7	
Implications for personal life	32.26	47.73	15.47		-6.64, 37.57	7	
Financial overload	67.74	70.45	2.71		-18.56, 23.99	37	
Reactions to requirements	38.71	61.36	22.65		0.27, 45.04	5	
Perception of Efficiency and Control Mechanisms	54.84	63.64	8.80		-13.76, 31.36	12	
Family Support	48.39	63.64	15.25		-7.37, 37.87	7	
Satisfaction with Role and Family	64.52	63.64		0.88	-21.16, 22.92		114
General ‡	16.13	50.00	33.87		14.23, 53.52	3	

Variable	Adverse outcome (%)		ARR (%)	IAR (%)	CI 95%	NNT	NNH
	Intervention	Control					
MAAS							
General	25.00	44.19	19.19		-2.67, 41.04	6	
WHODAS							
General	38.46	38.64	0.17		-23.42, 23.77	573	
H1 (days)	68.18	62.50		5.68	-18.89, 30.26		18
H2 (days)	72.73	80.95	8.23		-13.85, 30.30	13	
H3 (days)	77.27	66.67		10.61	-11.98, 33.19		10

Table 3. Comparative analysis of NNT and NNH from HADS, WHOQOL-BREF, QASCI, MAAS, and WHODAS outcomes

Adverse outcome = participants did not show improvement in scores

ARR = absolute risk reduction

IAR = increased absolute risk

CI = 95% confidence interval

NNT = number needed to treat

NNH = number needed to harm

Linear regression analysis

Linear regression analyses were conducted to examine the associations between anxiety, depression, mindfulness, and functional disability with quality of life and caregiver burden (Tables 4–9).

	HADS - Anxiety					
Variable	**R**	**R^2**	**R^2 adjusted**	**SD**	**F**	**p**
WHOQOL-BREF						
Physical domain	.517	.268	.241	1.98	9.870	**.004**
Psychological domain	.337	.114	.081	2.87	3.458	.074
Social relationships	.128	.016	-.020	3.44	0.453	.507
Environment	.361	.130	.098	2.03	4.051	.054
	HADS – Depression					
Variable	R	R^2	R^2 adjusted	SD	F	p
WHOQOL-BREF						
Physical domain	.338	.114	.081	2.18	3.473	.073
Psychological domain	.477	.228	.199	2.68	7.958	**.009**
Social relationships	.510	.260	.232	2.99	9.480	**.005**
Environment	.532	.283	.257	1.84	10.673	**.003**

Table 4. Linear regression analysis between HADS and WHOQOL-BREF scores at the end of the MBHP program

SD = standard deviation

	HADS - Anxiety					
Variable	**R**	**R^2**	**R^2 adjusted**	**SD**	**F**	**p**
QASCI						
Emotional overload	.424	.180	.150	2.31	5.927	**.022**
Implications for personal life	.237	.056	.021	3.77	1.605	.216
Financial overload	.037	.001	-.036	2.24	0.036	.851
Reactions to requirements	.362	.131	.099	3.30	4.067	.054
Perception of Efficiency and Control Mechanisms	.131	.017	-.019	1.24	0.471	.498
Family Support	.052	.003	-.034	2.11	0.072	.790
Satisfaction with Role and Family	.434	.188	.158	1.66	6.255	**.019**
General‡	.376	.141	.109	10.98	4.441	**.045**
	HADS - Depression					
Variable	R	R^2	R^2 adjusted	SD	F	p
QASCI						
Emotional overload	.213	.045	.010	2.49	1.283	.267
Implications for personal life	.136	.018	-.018	3.85	0.506	.483
Financial overload	.053	.003	-.034	2.23	0.077	.783
Reactions to requirements	.129	.017	-.020	3.51	0.458	.504
Perception of Efficiency and Control Mechanisms	.081	.006	-.030	1.25	0.176	.678
Family Support	.061	.004	-.033	2.11	0.102	.751
Satisfaction with Role and Family	.032	.001	-.036	1.84	0.028	.869
General‡	.158	.025	-.011	11.70	0.692	.413

Table 5. Linear regression analysis between HADS and QASCI scores at the end of the MBHP program

SD = standard deviation

	MAAS					
Variable	**R**	**R^2**	**R^2 adjusted**	**SD**	**F**	**p**
WHOQOL-BREF						
Physical domain	.647	.419	.394	1.85	17.280	**<.0001**
Psychological domain	.446	.199	.165	2.86	5.945	**.023**
Social relationships	.408	.166	.132	3.24	4.787	**.039**
Environment	.566	.320	.292	1.87	11.302	**.003**

Table 6. Linear regression analysis between MAAS and WHOQOL-BREF scores at the end of the MBHP program

SD = standard deviation

	MAAS					
Variable	**R**	**R^2**	**R^2 adjusted**	**SD**	**F**	**p**
QASCI						
Emotional overload	.663	.440	.418	1.84	20.397	**<.0001**
Implications for personal life	.519	.270	.242	3.23	9.600	**.005**
Financial overload	.076	.006	-.032	2.17	0.153	.699
Reactions to requirements	.499	.249	.221	2.88	8.643	**.007**
Perception of Efficiency and Control Mechanisms	.340	.115	.081	1.21	3.391	.077
Family Support	.330	.109	.075	1.91	3.176	.086
Satisfaction with Role and Family	.586	.343	.318	1.52	13.568	**.001**
General	.643	.414	.391	8.50	18.351	**<.0001**

Table 7. Linear regression analysis between MAAS and QASCI scores at the end of the MBHP program

SD = standard deviation

	WHODAS-Total Score					
Variable	**R**	**R^2**	**R^2 adjusted**	**SD**	**F**	**p**
WHOQOL-BREF						
Physical domain	.547	.299	.270	1.76	10.240	**.004**
Psychological domain	.045	.002	-.040	2.69	0.049	.826
Social relationships	.019	.000	-.041	3.08	0.009	.927
Environment	.252	.063	.024	2.11	1.626	.215
	WHODAS-H1					
Variable	R	R^2	R^2 adjusted	SD	F	p
WHOQOL-BREF						
Physical domain	.111	.012	-.037	2.21	0.250	.622
Psychological domain	.034	.001	-.049	2.39	0.024	.879
Social relationships	.352	.124	.080	2.70	2.829	.108
Environment	.254	.065	.018	2.26	1.385	.253
	WHODAS-H2					
Variable	R	R^2	R^2 adjusted	SD	F	p
WHOQOL-BREF						
Physical domain	.210	.044	-.004	2.17	0.923	.348
Psychological domain	.128	.016	-.033	2.37	0.331	.571
Social relationships	.103	.011	-.039	2.87	0.213	.649
Environment	.151	.023	-.026	2.31	0.469	.501
	WHODAS-H3					
Variable	R	R^2	R^2 adjusted	SD	F	p
WHOQOL-BREF						
Physical domain	.028	.001	-.049	2.22	0.016	.902
Psychological domain	.144	.021	-.028	2.37	0.423	.523
Social relationships	.078	.006	-.044	2.88	0.122	.731

	WHODAS-Total Score					
Variable	R	R^2	R^2 adjusted	SD	F	p
Environment	.056	.003	-.047	2.34	0.063	.804

Table 8. Linear regression analysis between WHODAS and WHOQOL-BREF scores at the end of the MBHP program

SD = standard deviation

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	WHODAS-Total Score					
Variable	**R**	**R^2**	**R^2 adjusted**	**SD**	**F**	**p**
QASCI						
Emotional overload	.283	.080	.041	2.42	2.082	.162
Implications for personal life	.368	.135	.099	3.63	3.760	.064
Financial overload	.051	.003	-.039	2.16	0.063	.803
Reactions to requirements	.386	.149	.113	3.21	4.200	.051
Perception of Efficiency and Control Mechanisms	.136	.018	-.022	1.28	0.452	.508
Family Support	.128	.017	-.024	2.13	0.403	.532
Satisfaction with Role and Family	.479	.230	.197	1.70	7.150	**.013**
General	.442	.196	.162	10.45	5.843	**.024**
	WHODAS-H1					
Variable	R	R^2	R^2 adjusted	SD	F	p
QASCI						
Emotional overload	.122	.015	-.034	2.64	0.301	.590
Implications for personal life	.001	.000	-.050	4.13	0.000	.996
Financial overload	.186	.035	-.014	2.26	0.719	.406
Reactions to requirements	.065	.004	-.046	3.61	0.085	.773
Perception of Efficiency and Control Mechanisms	.134	.018	-.031	1.32	0.365	.553
Family Support	.093	.009	-.041	1.91	0.175	.680
Satisfaction with Role and Family	.255	.065	.018	2.00	1.386	.253
General	.096	.009	-.040	12.13	0.187	.670
	WHODAS-H2					
Variable	R	R^2	R^2 adjusted	SD	F	p
QASCI						
Emotional overload	.081	.007	-.043	2.65	0.132	.720
Implications for personal life	.312	.097	.052	3.93	2.153	.158

	WHODAS-Total Score					
Variable	**R**	**R^2**	**R^2 adjusted**	**SD**	**F**	**p**
Financial overload	.072	.005	-.045	2.29	0.105	.749
Reactions to requirements	.251	.063	.016	3.50	1.343	.260
Perception of Efficiency and Control Mechanisms	.122	.015	-.034	1.32	0.303	.588
Family Support	.131	.017	-.032	1.90	0.351	.560
Satisfaction with Role and Family	.119	.014	-.035	2.06	0.285	.599
General	.282	.080	.034	11.69	1.731	.203
	WHODAS-H3					
Variable	R	R^2	R^2 adjusted	SD	F	p
QASCI						
Emotional overload	.017	.000	-.050	2.66	0.006	.941
Implications for personal life	.212	.045	-.003	4.04	0.941	.344
Financial overload	.170	.029	-.020	2.26	0.593	.450
Reactions to requirements	.093	.009	-.041	3.60	0.176	.680
Perception of Efficiency and Control Mechanisms	.076	.006	-.044	1.33	0.116	.737
Family Support	.216	.047	-.001	1.88	0.983	.333
Satisfaction with Role and Family	.165	.027	-.022	2.04	0.556	.464
General	.027	.001	-.049	12.18	0.014	.906

Table 9. Linear regression analysis between WHODAS and QASCI scores at the end of the MBHP program

SD = standard deviation

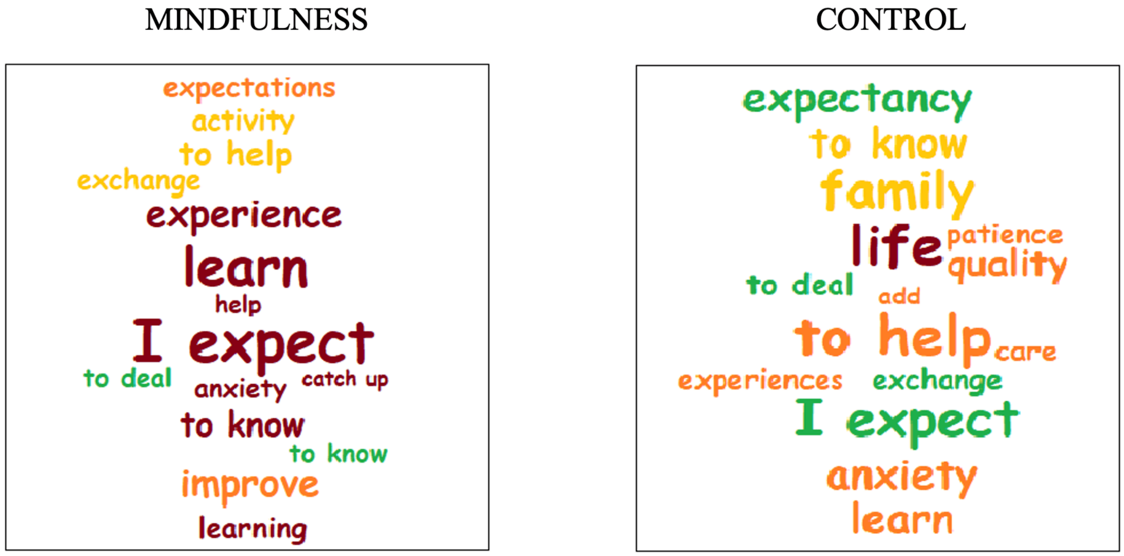
Higher anxiety symptoms were significantly associated with lower scores in the physical domain of quality of life (p = .004) and greater caregiver burden, particularly increased emotional overload (p = .022), reduced satisfaction with caregiving and the care recipient (p = .019), and higher overall burden (p = .045). Depressive symptoms were associated with lower psychological (p = .009), social (p = .005), and environmental (p = .003) quality of life but showed no significant associations with caregiver burden.

Mindfulness levels were positively associated with all domains of quality of life, especially the physical (p < .0001) and environmental (p = .003) domains. Higher mindfulness was also related to reduced emotional burden (p < .0001), fewer personal life impacts (p = .005), greater satisfaction with caregiving and the care recipient (p = .001), and lower total burden scores (p < .0001).

Greater functional disability was associated with lower physical quality of life scores (p = .004) and higher caregiver burden, especially reduced satisfaction with caregiving (p = .013) and increased general burden (p = .024).

Presentation of analysis of word clouds and clusters

Two word clouds were generated to illustrate the fifteen most frequently used words describing participants' expectations for each proposed activity. The most prominent terms reflected desires related to gaining knowledge, learning, coping, managing anxiety, exchanging experiences, and improving life. The analysis indicated that both groups expressed similar expectations at the outset of the intervention (Figure 2).



MINDFULNESS

CONTROL

Figure 2. Word cloud showing the frequency of terms in participant reports about expectations prior to the intervention. Source: N-Vivo Software

Word cluster: Hierarchical analysis by similarity (multilevel cluster)

Cluster analysis identified distinct lexical patterns between groups, reflecting differences in thematic focus and vocabulary structure. In the mindfulness group, words such as "problem" and "life" frequently co-occurred with "calm," "breathing," and "relaxation," indicating the incorporation of strategies related to stress regulation and emotional self-management. In the control group, dominant terms related to daily caregiving and institutional routines, including “APAE,” “tiredness,” “work,” “care,” “activities,” and “time” (Figure 3).

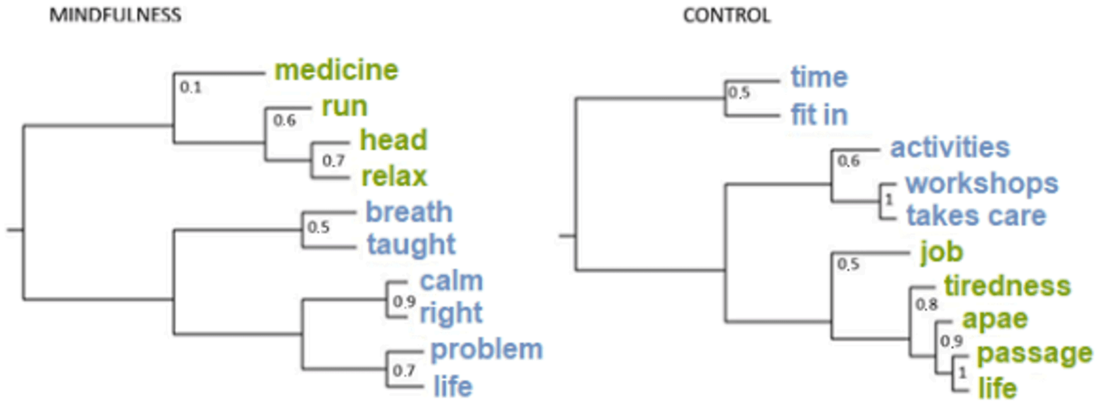


Figure 3. Word cluster from participant reports based on hierarchical similarity analysis using Pearson’s coefficient. Theme: What is the experience of caring for a relative like? Source: IRaMuTeQ software

Both groups expressed emotional and physical strain; however, the mindfulness group presented more self-referential and introspective narratives, emphasizing psychological coping and personal development. The control group focused on logistical demands and external caregiving contexts.

When describing daily emotions and thoughts, mindfulness participants expressed existential concerns—death, illness, future support, and caregiving in isolation—whereas control participants highlighted immediate challenges, such as early waking, transportation, routine management, and institutional schedules (Figure 4).

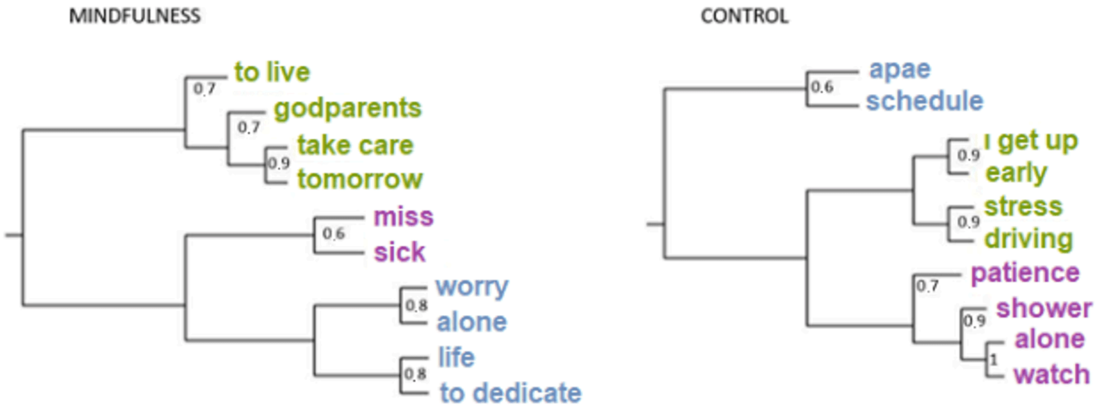


Figure 4. Word cluster from participant reports based on hierarchical similarity analysis using Pearson's coefficient. Theme: Feelings and thoughts most present in daily life. Source: IRaMuTeQ software

Regarding the group experience, mindfulness participants emphasized terms related to "friendship," "learning," and "relaxed body," suggesting perceived individual benefits and self-awareness. Control participants valued mutual exchange and collective identification, using terms such as "mothers," "group," "support," and "APAE," underscoring shared caregiving experiences and social belonging (Figure 5).

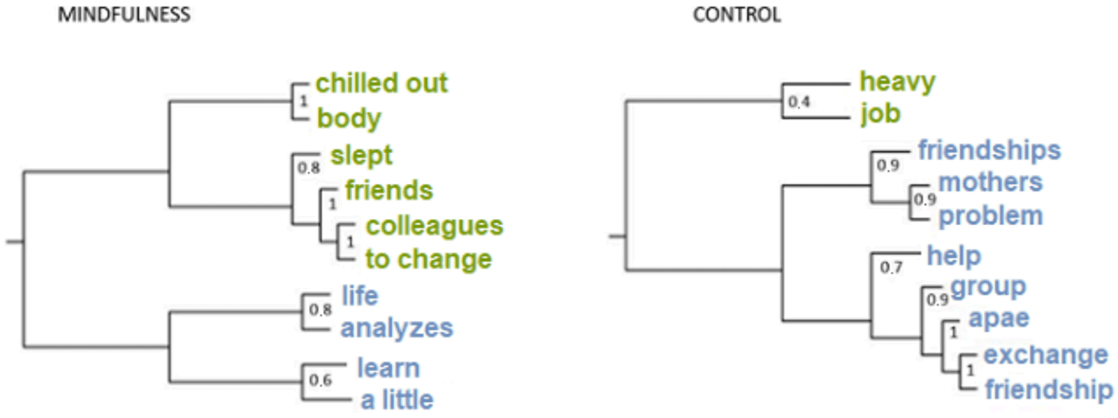


Figure 5. Word cluster from participant reports based on hierarchical similarity analysis using Pearson's coefficient. Theme: Opportunity to speak in the group. Source: IRaMuTeQ software

While both interventions fostered engagement, the differing content and format appeared to influence the orientation of participant narratives, with the mindfulness group focusing more on individual resources and the control group on collective caregiving dynamics.

Discussion

This study is the first to evaluate the impact of a mindfulness-based program on caregiver burden and quality of life among Brazilian family caregivers of people with moderate intellectual disability, conducted within routine public service settings. By involving the entire eligible population of a specialized rehabilitation center and delivering the intervention during routine waiting periods, the study increases ecological validity and contributes to an underexplored area of research in the Latin American context.

The findings reinforce previous evidence on the benefits of mindfulness-based interventions (MBIs) in reducing psychological burden and improving emotional well-being among family caregivers[6][27][28]. Consistent with recent meta-analyses of MBIs for caregivers of individuals with dementia—another group facing sustained emotional and physical demands—statistically significant improvements in quality of life, perceived well-being, and caregiver burden were observed following the intervention[29][30][31][32][28].

The current study adds to the literature by demonstrating these effects in a different caregiving context, involving intellectual disability, a population for which empirical evidence remains limited. As highlighted in prior systematic reviews[33][34], mindfulness interventions may promote resilience, emotion regulation, and adaptive coping mechanisms across various caregiving roles—factors that were also emphasized by participants in the qualitative component of this study.

The inclusion of qualitative data enriched the findings by revealing subjective experiences and perceived benefits, including increased calmness, emotional balance, and improved interpersonal relationships. These elements align with theoretical frameworks such as Acceptance and Commitment Therapy (ACT), which emphasize psychological flexibility and the decentering of unhelpful thoughts as core mechanisms of change[35][36][37].

A notable feature of the current sample is the high level of chronic caregiving demands. The majority of caregivers were older women—primarily mothers—who had been providing care for years, often while facing their own health limitations. This cumulative exposure may explain the high baseline burden and underscores the relevance of interventions targeting stress relief and self-care for this group.

Despite the promising outcomes, several limitations must be acknowledged. The absence of a follow-up period limits the ability to assess the sustainability of observed effects. In addition, the intervention relied on self-report measures, and no waitlist control condition was included, which restricts causal inference. These are common challenges in pragmatic implementation research but highlight the need for future studies with more robust designs and longer-term monitoring.

Attrition rates were moderate, with some participants citing unfamiliarity with mindfulness or logistical barriers such as scheduling conflicts. These findings point to the importance of preparatory activities and flexible delivery models to improve engagement and retention.

Practice Implications

The results of this study support the feasibility and potential impact of MBIs as a strategy to reduce psychological burden and improve emotional well-being among family caregivers of individuals with intellectual disabilities. Real-world integration—such as delivering the intervention during existing service appointments—may enhance reach and acceptability.

To strengthen implementation, future programs should include brief orientation sessions to demystify mindfulness concepts, offer scheduling flexibility, and incorporate tools to support home practice. Considering the demographic profile of caregivers, programs should also address their broader health needs and promote discussions around long-term caregiving sustainability and support networks.

Further research is warranted to confirm these findings, explore mechanisms of change in more depth, and assess long-term outcomes through follow-up assessments and comparison with active controls.

Limitations

As mentioned before, this study has several limitations that should be considered when interpreting the results. First, although randomization was applied, the sample size was relatively small and limited to a single rehabilitation center, which may restrict the generalizability of the findings. Second, due to the pragmatic design, the blinding of participants and facilitators was not feasible, potentially introducing performance bias. While outcome assessors were blinded, self-reported measures were used for all outcomes, increasing the risk of response and social desirability biases.

Third, there was no follow-up assessment, which restricts conclusions about long-term effects. Future studies should include follow-up assessments to evaluate the sustainability of observed benefits. Additionally, although an active control group was used, the study did not include a waitlist or placebo condition, limiting causal inferences about the specific mechanisms of the intervention.

Finally, as this was a real-world study conducted under routine service conditions, adherence to home practices and the influence of unmeasured contextual variables could not be fully controlled. Despite these limitations, the study provides relevant preliminary evidence on the feasibility and potential benefits of mindfulness-based interventions in vulnerable caregiver populations.

Conclusion

This study demonstrated that a mindfulness-based intervention can effectively reduce caregiver burden and enhance coping resources among family members caring for individuals with moderate intellectual disabilities. These effects were achieved even when the intervention was delivered under routine conditions to caregivers—mostly older adults—responsible for the long-term care of highly dependent adolescents and adults.

The findings suggest that MBIs may offer meaningful psychological support by fostering emotional regulation and resilience among family caregivers. Further research is needed to evaluate long-term outcomes, explore implementation models across different service contexts, and confirm the generalizability of these effects in larger and more diverse samples.

Statements and Declarations

Author Contributions

Conceptualization: MD, DO, LSO; Methodology: MD, DO, PP; Formal analysis: DO, PP; Investigation: LSO, PP, DG, VSJ; Data Curation: LSO; Writing – Original Draft: LSO, DO; Writing – Review & Editing: MD, DO, JM, CAK; Supervision: MD, JM; Project Administration: MD; Funding Acquisition: MD. All authors contributed to the intellectual development of this work and the preparation of the manuscript.

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Data Availability

The raw data supporting the conclusions of this article may be made available by the authors upon reasonable request, subject to ethical and privacy considerations related to participant data. Requests should be directed to the corresponding author.

Conflicts of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Declarations

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