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 trial compared a culturally adapted Mindfulness-Based Health Promotion (MBHP) program to an active psychoeducational control. In intention-to-treat analyses, both groups showed improvements in quality of life from baseline; however, between-group differences in WHOQOL-BREF domains were not statistically significant after adjusting for baseline. Exploratory secondary analyses, corrected for multiplicity via false-discovery-rate control, showed that MBHP conferred significantly greater improvement than the active control on three of seven QASCI caregiver-burden subdomains (Emotional Overload, Personal Life Impact, and Family Support), while the QASCI total score and remaining subdomains did not differ significantly between groups. The intervention was feasible and acceptable, with no adverse events reported. Findings support the pragmatic delivery of MBHP within rehabilitation services while highlighting the need for longer follow-up and replication with enhanced allocation concealment.

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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. Problem-solving training has been identified as a useful strategy to encourage active coping and foster more adaptive caregiving responses[4], and psychoeducational programs more broadly have shown benefits for coping and burden across caregiving populations; however, sustained engagement remains a persistent barrier to these approaches in routine services[5]. In recent years, mindfulness-based interventions (MBIs) have gained attention as a complementary approach that targets acceptance, attentional regulation, and emotional processing rather than problem-focused coping alone. 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[6].

Mindfulness-based programs have been implemented across a range of clinical and non-clinical populations, including caregivers of people with chronic illnesses. A recent systematic review of digital psychological well-being interventions for family carers of people with intellectual and developmental disabilities identified mindfulness, relaxation, and acceptance-based approaches among the most common intervention categories, while noting that rigorous, adequately powered evaluations specific to this population remain scarce[7]. Reviews of MBIs in dementia caregiving—a population facing comparably sustained emotional and physical demands—report consistent, moderate improvements in quality of life, perceived well-being, and caregiver burden[8][9][10][11][12], providing indirect support for extending MBIs to caregivers of people with intellectual disability. Evidence specific to Spanish-speaking and Latin American populations remains limited. A waitlist-controlled trial adapting MBSR for parents of children with developmental delays found the program similarly efficacious for Latino and non-Latino families in the United States, improving parenting stress, depressive symptomatology, and life satisfaction[13], and a controlled trial of a structured mindfulness-based program for women caring for older relatives in Spain demonstrated reductions in caregiver burden and psychological distress[14]. Trials specifically involving caregivers of people with intellectual disability nonetheless remain scarce and

heterogeneous in design, outcome selection, and cultural adaptation. The present pragmatic RCT addresses these gaps by testing a culturally adapted mindfulness protocol against an active, structured comparator within a large Brazilian rehabilitation center.

We specifically evaluated the Mindfulness-Based Health Promotion (MBHP) program, a structured adaptation of MBSR designed for feasibility in public health and rehabilitation settings in Brazil (shorter sessions, simplified language, scheduling aligned with routine service visits). MBHP was selected over the standard 8-week, 2.5-hour MBSR protocol precisely because these adaptations were designed to improve feasibility within public health and rehabilitation services operating under significant time and staffing constraints—features not present in the original MBSR format and considered essential for uptake among caregivers with heavy, inflexible care schedules[15]. We hypothesized improvements in quality of life (primary outcome) and caregiver burden (secondary outcome) relative to an active psychoeducational control. In Brazil, family members—predominantly women, mothers, and often of advanced age and limited formal education—provide long-term unpaid care for relatives with intellectual disability with limited formal support, frequently reporting work overload, fatigue, and social isolation[16], underscoring the need for scalable, low-cost psychosocial interventions delivered within routine institutional workflows.

Methods

This study followed the CONSORT (Consolidated Standards of Reporting Trials) guidelines[17] for reporting randomized controlled trials transparently and comprehensively. We applied the CONSORT 2010 framework, supplemented by the extension for pragmatic trials[18]. Protocol elements (registration, eligibility criteria, outcomes, sample size calculation, randomization and blinding procedures) are reported in accordance with the SPIRIT 2013 statement[19], and both interventions are described below following the TIDieR checklist[20], covering rationale, materials, procedures, providers, delivery mode, setting, dose, tailoring, and fidelity monitoring.

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. Information lectures described two stress-management group programs (mindfulness and problem-solving) in neutral terms, without framing one as superior. To reduce expectancy bias, program labels were de-emphasized and outcome assessors remained blinded. To encourage participation and reduce drop-out, sessions were scheduled during routine wait times at the institution. Audio recordings were available via 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. The trial was registered at ClinicalTrials.gov (NCT03756441), specifying quality of life (WHOQOL-BREF) as the primary outcome and caregiver burden as secondary. A planned 6-month follow-up was registered but not conducted due to service scheduling constraints; this deviation is now explicitly acknowledged. No other deviations affecting primary or secondary endpoints occurred.

Participants

The participants were family caregivers of adolescents and adults (aged 14 to 34 years) with moderate intellectual disability, who attended a specialized institution two to three times per week for structured activities promoting cognitive, social, and adaptive skills. All individuals with intellectual disability were ambulatory (non–wheelchair users) and had diagnoses established at the institution according to DSM-5 criteria, based on multidisciplinary clinical assessments that considered both cognitive functioning and adaptive behavior. When indicated, standardized psychometric instruments—including the Wechsler

Abbreviated Scale of Intelligence (WASI) and the Adaptive Behavior Assessment System, Second Edition (ABAS-II)—were administered using the appropriate age-specific 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 cumulative burden associated with prolonged care.

In terms of etiology, 55% of caregivers supported people with Down syndrome, 36% with 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.

Eligibility criteria

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

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

Sample size calculation

Sample size was estimated a priori using G*Power version 3.1 software[21], 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 individuals attending the Rehabilitation Service at APAE São Paulo were invited to participate. The inclusion of only women was based on the predominance of female caregivers in this population and aimed to ensure sample homogeneity. Recruitment occurred during institutional family meetings through oral announcements, distribution of printed flyers, and direct contact during routine service visits. Caregivers were informed about the voluntary nature of participation and provided written informed consent. A total of 161 mothers of individuals attending the Rehabilitation Service were assessed for eligibility (164 people with intellectual disability were enrolled in the sector, but 3 mothers each accompanied two children). Of these, 61 (37.9%) did not participate in any phase of the study; the

most common reason was that another family member routinely accompanied the person with intellectual disability to the institution (n = 31), followed by inability to establish contact after repeated attempts (n = 14), personal preference (n = 9), health conditions (n = 4), non-attendance after invitation (n = 2), and logistical difficulties (n = 1). The remaining 100 caregivers were randomized (51 to MBHP, 49 to control). This shortfall relative to the a priori target of 128 reflects the constraints of a fixed enrollment window (March–June 2019) within a single institution, an inherent limitation of the pragmatic design (see Figure 1).

An independent researcher (PP) generated the random sequence using random.org (accessed April 2019) with permuted blocks of variable sizes (4–6). Allocation occurred after baseline assessment. For larger classes, individual randomization was used; in two smaller classes, class-level block randomization assigned one class to MBHP and the other to control to meet fixed schedules. We acknowledge that full allocation concealment was not feasible for the two class-level allocations; to minimize bias, baseline assessments preceded allocation and outcome assessors were blinded. Family caregivers were randomly assigned to one of two experimental groups: 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.

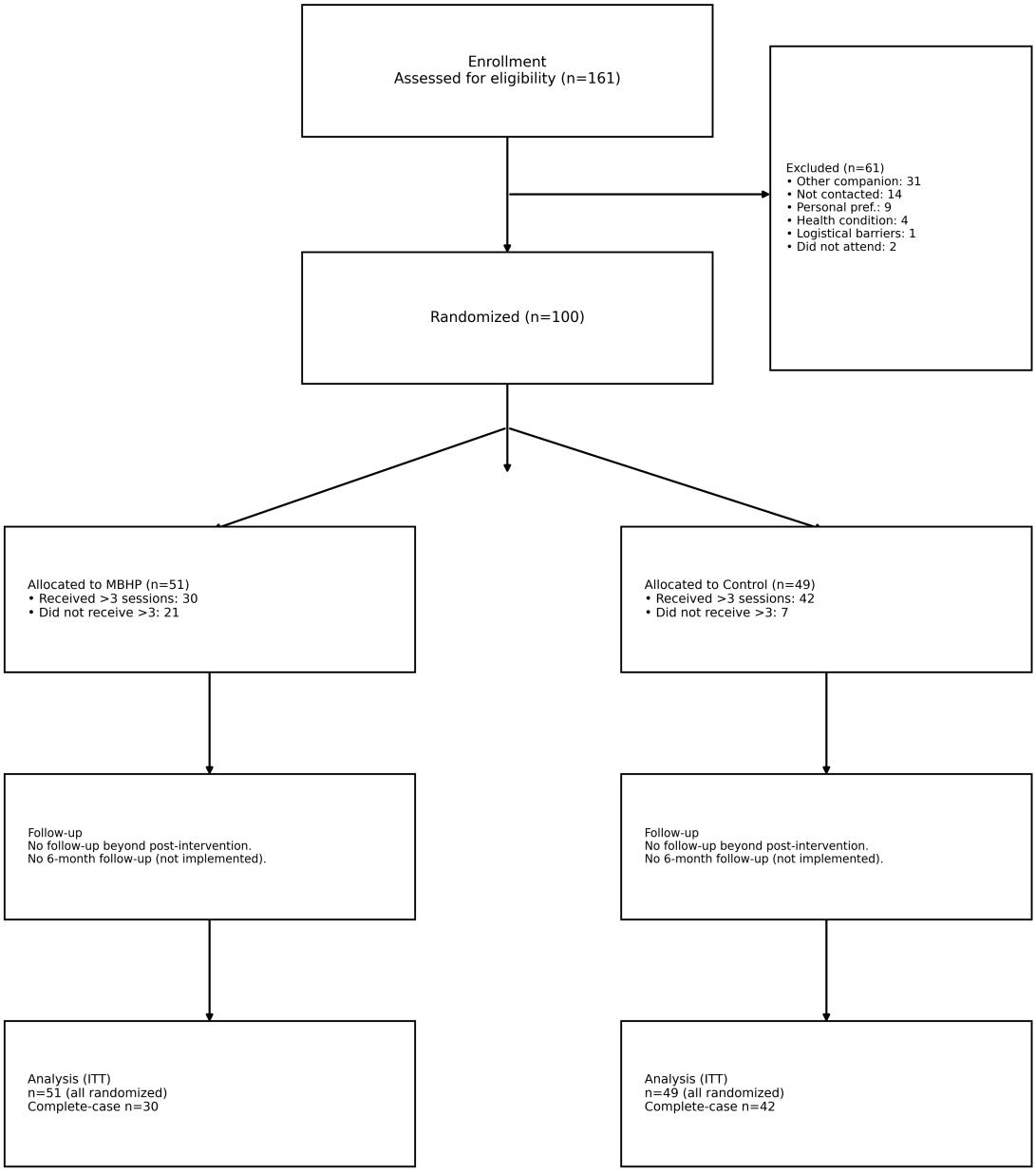


Figure 1. CONSORT 2010 flow diagram detailing screening, eligibility, randomization, follow-up, and analysis with reasons for dropout per group.

Although participants and facilitators could not be blinded due to the nature of the intervention, outcome assessors were blinded to group allocation during data collection and analysis phases. This approach aimed to minimize potential measurement bias and ensure the objectivity of outcome evaluations. Also,

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 supported two people with intellectual disability each—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 significantly differ between the control and intervention groups (see Table 1).

Variable	Measure	MBHP		Control group		CI 95%	Value-p
		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 patient *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 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 got married Currently married Separate Divorced Widow Cohabitates 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 (%)*	There is not Catholic Evangelical Umbanda Another		0 25 18 1 5		4 30 8 1 4		.08[d]

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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 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)

The MBHP program is a structured mindfulness-based intervention adapted from the original Mindfulness-Based Stress Reduction (MBSR) model by Jon Kabat-Zinn[22]. Developed by our research group for Primary Health Care and Health Promotion settings in Brazil, it incorporates cultural and logistical adaptations to enhance feasibility in real-world services. These adaptations include shorter sessions, simplified language, and a didactic sequence aimed at improving participant understanding and engagement[15].

The structured program runs over eight weeks, with one 1.5-hour session per week in which participants practice mindfulness techniques[23]. Additional informal practices, lasting 15–20 minutes (up to 45 minutes depending on participant pace), encourage 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. Dynamics and a silence session were also included, as outlined in the MBHP program[23].

Mindfulness instructors were recruited via social media flyers, followed by CV screening and interviews. Four instructors led the MBHP program, all formally certified to deliver the MBHP protocol by Mente Aberta – Mindfulness Brazil (UNIFESP), with at least 1.5 years of structured training and prior experience facilitating mindfulness groups. All staff were blinded to study objectives and received training to ensure protocol alignment as the planned fidelity strategy; no formal session-by-session fidelity audit was

conducted, and this is acknowledged as a limitation. Sessions were delivered face-to-face in closed groups (approximately 10 participants per group) at the study site described above (Setting). Materials comprised the MBHP facilitator manual[23] and audio-guided practice recordings, provided via mobile app or CD for home use. No modifications to the manualized MBHP protocol were made during the trial.

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[24][25]. 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[5].

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 clinical training and prior experience in cognitive-behavioral interventions and group therapy. Two recently graduated psychologists (6 months of experience), with prior health-related internships, assisted with data collection and participant follow-up, including tracking absences. All staff were blinded to study objectives and received training to ensure protocol alignment as the planned fidelity strategy; as with MBHP, no formal session-by-session fidelity audit was conducted. Sessions were delivered face-to-face in closed groups at the same institutional site, following a structured facilitator protocol[24][25] with session-specific worksheets for each of the five problem-solving components. No modifications to the manualized protocol were made during the trial.

Monitoring and Safety Procedures

All sessions were conducted in group format within the facilities of the participating institution. Instructors were trained to observe participants for any signs of psychological distress and were instructed to notify the research team if any adverse reactions occurred. Participants were also informed that they could withdraw or report discomfort at any time without consequences. The environment was

designed to be supportive and flexible, with facilitators maintaining open communication before and after each session. No clinical incidents requiring intervention occurred throughout the study.

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[26][27].

Instruments

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

Quality of Life Scale (WHOQOL-Brief): is 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[28];

Informal Caregiver Burden Assessment Questionnaire (QASCI): is 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 (α = 0.95 overall; domain-specific α ranging from 0.70 to 0.94). Factorial analyses support its content and construct validity[29];

Disability Assessment Scale (WHODAS 2.0 short version): Developed by the World Health Organization, 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[30];

Hospital Anxiety and Depression Scale (HADS): 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 (α > 0.80) for both subscales and has shown solid construct and criterion validity[31];

Mindful Attention Awareness Scale (MAAS): is 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 (α > 0.80) and validity based on exploratory and confirmatory factor analysis[32].

The questionnaire scales were randomized to avoid differences in motivation for fatigue responses, and the questionnaires were applied only after the focus group was performed so that the 8 caregivers did not have access to the principles of what we were seeking to know. The intention was to reduce the bias in the content.

Statistical analysis

Primary analyses followed the intention-to-treat (ITT) principle including all randomized participants. Between-group differences in change from baseline to post-intervention were tested using ANCOVA with baseline scores as covariates and group as the fixed factor, reporting adjusted mean differences with 95% confidence intervals (CIs). Within-group changes used paired t-tests or Wilcoxon signed-rank tests as appropriate. To address multiplicity across secondary endpoints, we controlled the false discovery rate at 5% using the Benjamini–Hochberg procedure, reporting adjusted q-values. Missing post-intervention

data were handled via multiple imputation (m=20) under a Missing At Random assumption; complete-case analyses were conducted as sensitivity checks. A per-protocol analysis (attendance >3/8 sessions, i.e., excluding the 28 participants classified as dropouts) is presented as supplementary.

Clinical significance

For responder analyses, a clinically meaningful improvement was defined as ≥0.5 SD from baseline for each scale; Number Needed to Treat (NNT) / Harm (NNH) and 95% CIs were computed accordingly. These metrics are reported as secondary/exploratory.

Qualitative approach

Qualitative methods followed COREQ recommendations: the coding team comprised two researchers with training in psychology and qualitative methods (co-authors), supervised by a senior clinical researcher (M.D.); the team's relationship with participants was limited to their designated study roles (facilitation, data collection, or analysis), with no prior therapeutic or personal relationship (L.S.O. and V.S.J). We used a semi-structured guide (Supplementary File S1) addressing expectations, coping, perceived benefits, and barriers. Condensed results with illustrative lexical findings are reported below (Qualitative Findings) alongside word-cloud and cluster analyses (Figures 2–4). Focus groups were audio-recorded, transcribed verbatim, and anonymized. Two coders independently conducted thematic analysis with iterative codebook development (L.S.O. and V.S.J); discrepancies were resolved by consensus with a third reviewer (M.D.). Data sufficiency was assessed for thematic adequacy rather than statistical saturation.

Results

Primary and Secondary Outcomes

In ITT ANCOVA models (n=100; missing post-intervention data handled via MICE multiple imputation, m=20; adjusted mean differences pooled using Rubin's rules), between-group differences in WHOQOL-BREF domains were not statistically significant after Benjamini–Hochberg correction (physical: q=.226; psychological: q=.294; social: q=.294; environment: q=.226; see Table 2). Within-group paired tests (complete-case, paired t-test or Wilcoxon signed-rank as appropriate) showed significant improvement from baseline in the MBHP group across all four WHOQOL-BREF domains (physical, psychological,

social, environment; all p<.05), and in the control group for the physical domain (p=.028); psychological and environment domains showed borderline within-group improvement in control (p=.042–.046) that did not reach significance in the social domain (p=.34). Complete-case (available-case, n=72) ANCOVA yielded directionally consistent results, with nominally lower p-values (physical p=.025, environment p=.046) that likewise did not survive FDR correction (q≥.092). In contrast, ITT-ANCOVA analysis of QASCI subdomains (secondary/exploratory, FDR-corrected within a 12-test secondary family comprising QASCI total and its 7 subdomains, HADS anxiety and depression, MAAS, and WHODAS) showed that MBHP conferred significantly greater reductions than control on three subdomains after FDR correction: Emotional Overload (adjusted difference −8.18, 95% CI −14.30 to −2.07, q=.035), Personal Life Impact (−9.46, 95% CI −15.51 to −3.41, q=.027), and Family Support (−18.14, 95% CI −31.56 to −4.72, q=.035; note this domain is reverse-scored so a greater decrease indicates greater improvement in perceived family support). Efficacy/Control Perception showed a similar direction but did not survive correction (q=.066). QASCI Total, Financial Overload, Reactions to Demands, and Role Satisfaction were not significant (all q>.18). Within-group tests showed significant improvement from baseline in MBHP for Emotional Overload, Personal Life Impact, Reactions to Demands, Efficacy/Control Perception, and Family Support (all p<.05), whereas the control group improved significantly only in Emotional Overload; notably, the control group′s Family Support score worsened numerically over the study period (mean change +5.8) while MBHP′s improved (mean change −17.4).

Outcome	n (MBHP/Control)	Adjusted mean difference*	95% CI	p	q (FDR)
Primary outcome: WHOQOL-BREF domains					
Physical	51/49	5.32	-1.11 to 11.75	0.105	0.226
Psychological	51/49	3.09	-2.69 to 8.87	0.294	0.294
Social	51/49	5.09	-3.55 to 13.73	0.247	0.294
Environment	51/49	4.14	-0.98 to 9.25	0.113	0.226
Secondary/exploratory outcomes					
QASCI Total	51/49	-2.70	-7.87 to 2.47	0.307	0.460
QASCI Emotional Overload	51/49	-8.18	-14.30 to -2.07	0.009	0.035
QASCI Personal Life Impact	51/49	-9.46	-15.51 to -3.41	0.002	0.027
QASCI Financial Overload	51/49	-4.38	-15.68 to 6.92	0.447	0.517
QASCI Reactions to Demands	51/49	-3.53	-11.01 to 3.94	0.353	0.471
QASCI Efficacy/Control Perception	51/49	-11.64	-21.60 to -1.68	0.022	0.066
QASCI Family Support	51/49	-18.14	-31.56 to -4.72	0.008	0.035
QASCI Role Satisfaction	51/49	-6.92	-14.61 to 0.77	0.078	0.184
HADS Anxiety	51/49	-0.99	-2.13 to 0.16	0.092	0.184
HADS Depression	51/49	-0.26	-1.77 to 1.25	0.732	0.732
MAAS Total	51/49	0.25	-0.12 to 0.62	0.185	0.318
WHODAS Total	51/49	-0.91	-3.40 to 1.59	0.474	0.517

Table 2. Intention-to-treat ANCOVA analysis (multiple imputation, m=20), adjusted for baseline, with false discovery rate (FDR) correction

*n = randomized sample (intention-to-treat). *Adjusted mean difference (MBHP – Control) in post-intervention score, adjusting for baseline score (ANCOVA), pooled across m=20 multiply-imputed datasets using Rubin's rules. WHOQOL-BREF and MAAS: positive values favor MBHP. QASCI, HADS, WHODAS: negative values favor MBHP (lower burden/symptom scores). q = Benjamini–Hochberg FDR-adjusted p-value, computed separately within the primary (WHOQOL-BREF, 4 tests) and secondary (12 tests) families.*

For descriptive purposes, we also report the original per-protocol comparison of change scores (Δ; unpaired t-tests or Mann-Whitney U tests as appropriate, without baseline-covariate adjustment or correction for multiplicity). In this unadjusted analysis, the MBHP group showed significantly greater improvement than control only in QASCI Personal Life Impact ($p = .025$) and the QASCI general/total burden score ($p = .004$); no other domain, including WHOQOL-BREF physical ($p = .16$) or QASCI Emotional Overload ($p = .09$), reached significance at $p < .05$ (see Table 3). We present this analysis transparently for continuity with the original dataset. Notably, the ITT-ANCOVA model above, despite its more conservative FDR correction, identified a broader and partly non-overlapping set of significant secondary findings (Emotional Overload, Personal Life Impact, and Family Support), underscoring the value of baseline adjustment and multiple imputation over the simpler unadjusted comparison; the ITT-ANCOVA model is therefore the primary basis for our conclusions.

Variable	MBHP		Control group		CI 95%	Value-p
	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]
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]

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Variable	MBHP		Control group		CI 95%	Value-p
	n	Δ *Mean ± SD*	n	Δ *Mean ± SD*		
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 3. 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)*

Although the target sample size was not eventually 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.

No adverse effects were reported during the intervention period. None of the participants expressed distress requiring clinical intervention, and overall satisfaction with the sessions was high across both groups.

Feasibility

Feasibility was examined descriptively using four applicable domains from Bowen et al.'s[33] framework: acceptability, demand, implementation, and practicality. Acceptability was supported by high self-reported satisfaction in both arms and the absence of adverse events (see Results above). Demand was reflected in the recruitment yield: 100 of 161 eligible caregivers (62%) were ultimately randomized, with

non-participation attributable mainly to competing caregiving arrangements rather than disinterest in the programs themselves (Figure 1). Implementation and practicality are detailed below through session attendance, dropout, and reasons for discontinuation.

Among the 72 participants engaged with their assigned program (attendance >3/8 sessions; session distribution: 4 sessions, n=10; 5, n=12; 6, n=15; 7, n=22; 8, n=13), median attendance was 6/8 sessions in MBHP and 7/8 in control. Engagement rates differed between arms: 30/51 (58.8%) of MBHP participants and 42/49 (85.7%) of control participants met the >3/8 engagement threshold.

Conversely, 28 participants (21 in the intervention group and 7 in the control group) were classified as dropouts (attendance ≤3/8 sessions). All were contacted to determine 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, the discontinuation occurred following the death of the people with intellectual disability. In two cases, despite up to three phone call attempts on different days and times, contact could not be established. In the control group, reasons cited were health problems (n = 3), personal preference (n = 2), and logistical difficulties (n = 2).

Number needed to treat (NNT) and Number needed to harm (NNH)

Using a ≥0.5 SD responder definition (available-case sample), NNTs were 5.1 (WHOQOL physical), 7.2 (psychological), 6.8 (social), and 4.2 (environment) domains. For QASCI subdomains, NNTs were 5.5 (Emotional Overload), 5.0 (Personal Life Impact), 5.8 (Financial Overload), 17.7 (Reactions to Demands), and 7.9 (Family Support); Efficacy/Control Perception and Role Satisfaction showed risk differences favoring control numerically (NNT not estimable in the direction hypothesized). Corresponding 95% CIs for the underlying risk differences crossed zero for all domains except WHOQOL environment (risk difference 0.011–0.469), consistent with imprecise estimates overall, though the point estimates for Emotional Overload, Personal Life Impact, and Family Support are directionally consistent with the FDR-significant ITT-ANCOVA findings reported above; see Table 4.

Outcome	n MBHP	Responder % MBHP	n Control	Responder % Control	Risk difference (95% CI)	NNT
WHOQOL-BREF domains						
Physical	28	53.6	44	34.1	19.5 (-3.7 to 42.7)	5.1
Psychological	28	57.1	44	43.2	14.0 (-9.5 to 37.4)	7.2
Social	28	46.4	44	31.8	14.6 (-8.4 to 37.6)	6.8
Environment	28	53.6	44	29.5	24.0 (1.2 to 46.9)	4.2
QASCI (total and subdomains)						
Total	26	46.2	30	33.3	12.8 (-12.7 to 38.4)	7.8
Emotional Overload	31	45.2	41	26.8	18.3 (-3.8 to 40.5)	5.5
Personal Life Impact	29	48.3	39	28.2	20.1 (-3.0 to 43.1)	5.0
Financial Overload	31	29.0	42	11.9	17.1 (-1.6 to 35.9)	5.8
Reactions to Demands	28	21.4	38	15.8	5.6 (-13.5 to 24.8)	17.7
Efficacy/Control Perception	31	22.6	42	26.2	-3.6 (-23.4 to 16.2)	NA
Family Support	28	35.7	39	23.1	12.6 (-9.5 to 34.8)	7.9
Role Satisfaction	31	22.6	43	30.2	-7.7 (-27.8 to 12.5)	NA

Table 4. Number Needed to Treat (NNT), ≥0.5 SD responder definition (available-case sample)

Responder = post-intervention change meeting or exceeding ±0.5 baseline SD in the direction of improvement (increase for WHOQOL-BREF; decrease for QASCI, given burden-oriented scoring). NNT = 1/risk difference; not estimable (NA) where the point estimate favored control. All risk-difference 95% CIs cross zero except WHOQOL Environment, indicating imprecise estimates for most domains.

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 5–10).

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 ($p = .024$).

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

SD = standard deviation

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

SD = standard deviation

doi.org/10.32388/Q5GB40.2

	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 7. 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 8. 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
Environment	.056	.003	-.047	2.34	0.063	.804

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

SD = standard deviation

	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						

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Emotional overload	.081	.007	-.043	2.65	0.132	.720
Implications for personal life	.312	.097	.052	3.93	2.153	.158
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 10. Linear regression analysis between WHODAS and QASCI scores at the end of the MBHP program

SD = standard deviation

Qualitative Findings

To complement the quantitative results, focus groups were analyzed using lexical frequency and hierarchical similarity clustering[34] (Pearson's correlation coefficient as similarity index, per Methods).

Two word clouds illustrating the fifteen most frequent terms describing participants' expectations prior to the intervention showed that both groups expressed similar expectations at the outset, centered on gaining knowledge, learning, coping, managing anxiety, exchanging experiences, and improving life (Figure 2).

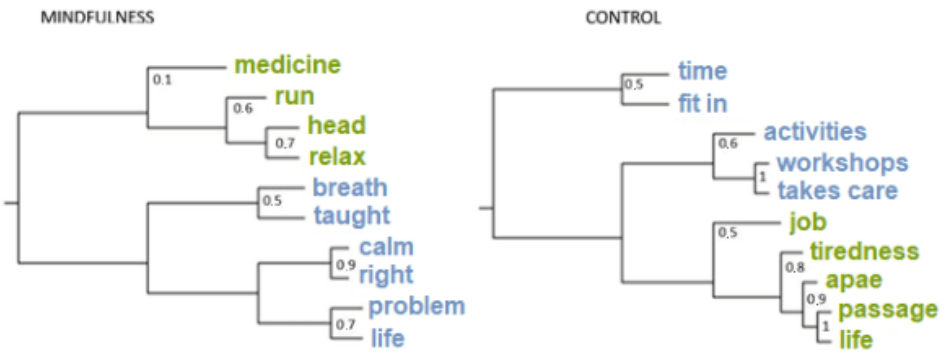


Figure 2. Word cloud showing the frequency of terms in participant reports about expectations prior to the intervention (IRaMuTeQ).

Hierarchical cluster analysis of post-intervention focus group transcripts identified distinct lexical patterns between arms, reflecting differences in thematic focus and vocabulary structure. In the MBHP group, words such as "problem" and "life" frequently co-occurred with "calm," "breathing," and "relaxation," suggesting incorporation of stress-regulation and emotional self-management strategies; in the control group, dominant terms related to daily caregiving and institutional routines, including "APAE," "tiredness," "work," "care," "activities," and "time" (Figure 3). Both groups expressed emotional and physical strain, but MBHP narratives were more self-referential and introspective, emphasizing psychological coping and personal development, whereas control narratives focused on logistical demands and external caregiving contexts.

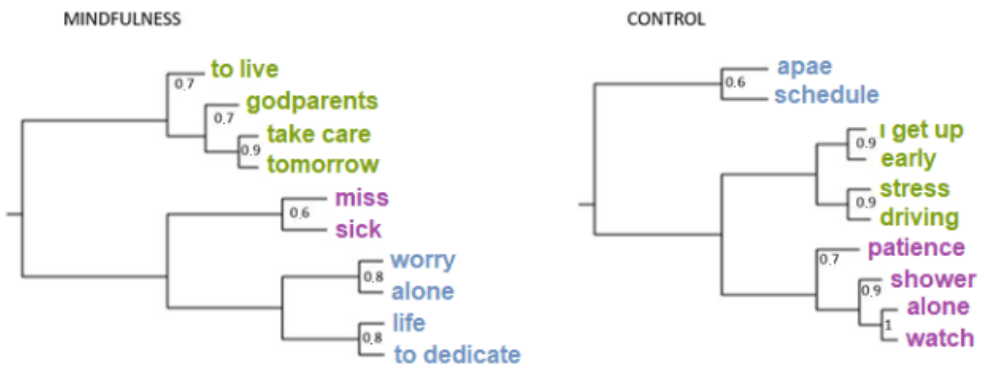


Figure 3. Word cluster from participant reports based on hierarchical similarity analysis (Pearson's coefficient). Theme: experience of caring for a relative.

When describing daily emotions and thoughts, MBHP participants expressed existential concerns—death, illness, future support, and caregiving in isolation—whereas control participants highlighted immediate challenges such as early waking, transport, routine management, and institutional schedules (Figure 4). Regarding the experience of speaking within the group, MBHP participants emphasized terms related to "friendship," "learning," and "relaxed body," suggesting perceived individual benefit and self-awareness; control participants valued mutual exchange and collective identification, using terms such as "mothers," "group," "support," and "APAE," underscoring shared caregiving experience and social belonging.

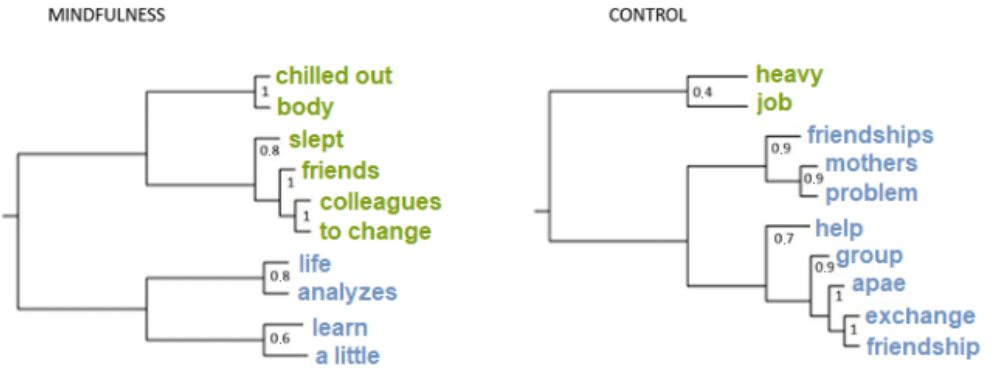


Figure 4. Word cluster from participant reports based on hierarchical similarity analysis (Pearson's coefficient). Theme: feelings and thoughts most present in daily life.

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Taken together, while both arms fostered engagement, the differing content and format of the two programs appeared to shape the orientation of participant narratives, with MBHP participants focusing more on individual psychological resources and control participants on collective caregiving dynamics—a pattern consistent with the FDR-significant quantitative improvements in Family Support and Personal Life Impact reported above.

Discussion

This study is the first to evaluate the impact of a structured mindfulness-based program—the MBHP protocol—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 primary outcome analysis found no statistically significant between-group difference in quality of life after intention-to-treat ANCOVA adjustment for baseline and correction for multiplicity (all WHOQOL-BREF domains, $q \geq .226$); both MBHP and the active psychoeducational control were associated with improvement from baseline. These findings do not support the conclusion that MBHP is more effective than an active control for improving quality of life in this population. Exploratory, FDR-corrected secondary analyses did indicate that MBHP conferred significantly greater benefit than control on three of seven QASCI caregiver-burden subdomains (Emotional Overload, Personal Life Impact, and Family Support), a finding discussed further below.

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[35][36][11]. 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[12][8][9][10][11].

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[37][38], 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 qualitative findings offer a plausible explanatory link for two of the quantitative results reported above, rather than merely a parallel narrative. First, MBHP participants' post-intervention lexical clusters centered on "problem," "life," "calm," "breathing," and "relaxation" (Figure 3), consistent with the incorporation of stress-regulation and emotional self-management strategies; this converges with the FDR-significant reductions in QASCI Emotional Overload and Personal Life Impact, suggesting that the specific skills participants described adopting (breath-based calming, decentering from distressing thoughts) may be a plausible mechanism for the burden reductions observed quantitatively in these two subdomains. Second, the divergent Family Support trajectory (improving in MBHP, worsening numerically in control) mirrors a qualitative contrast in how the two groups framed the group experience itself: MBHP participants emphasized individually oriented terms ("friendship," "learning," "relaxed body"), whereas control participants emphasized collective, institution-bound terms ("mothers," "group," "support," "APAE"); it is possible that the problem-solving format's more logistics-focused, institution-anchored framing did less to strengthen participants' sense of support from family members outside the program, while MBHP's individually oriented approach to acceptance and connection may have generalized more readily to family relationships. These convergences should be interpreted as hypothesis-generating rather than confirmatory, given the exploratory nature of both data streams. More broadly, the perceived benefits described by participants—increased calmness, emotional balance, and improved interpersonal relationships—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[39][40][41].

The exploratory regression analyses further support a coherent picture across outcomes: higher self-reported mindfulness was consistently associated with better quality of life and lower caregiver burden across nearly all domains, whereas higher anxiety, depression, and functional disability of the care recipient were associated with worse outcomes on the domains most conceptually related to each predictor (e.g., anxiety with emotional overload; depression with psychological, social, and environmental quality of life; disability with physical quality of life and role satisfaction). This pattern is consistent with mindfulness operating along the hypothesized pathway from attentional and emotional regulation to reduced burden, though the cross-sectional, correlational nature of these analyses precludes causal inference and they should be interpreted as hypothesis-generating. The NNT estimates (Table 4),

while imprecise, were directionally consistent with the FDR-significant ITT-ANCOVA findings, providing a rough index of potential clinical relevance (approximately 5 to 8 caregivers needed to treat for one additional responder on Emotional Overload, Personal Life Impact, or Family Support) that may aid future power calculations and clinical interpretation, notwithstanding the wide confidence intervals.

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 structured mindfulness-based programs, such as MBHP, 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.

As noted above, MBHP performed at least as well as an active psychoeducational control on the primary outcome, while showing FDR-corrected advantages on specific burden subdomains. The divergence in Family Support—improving in MBHP but declining numerically in control over the study period—is particularly notable and merits replication, as it suggests the two programs may affect caregivers' perceived family support differently even though neither produced a detectable change in overall quality of life. These subdomain-level findings should still be interpreted cautiously given the pragmatic design and the absence of long-term follow-up.

Several factors may explain the absence of between-group differences on the primary endpoint: (i) the active control likely conferred meaningful benefits; (ii) heterogeneity in baseline burden and long

caregiving histories may have attenuated incremental effects; (iii) dose and adherence varied under routine conditions; and (iv) measurement immediately post-intervention (without follow-up) may have missed delayed effects.

The feasibility findings, examined through Bowen et al.'s[33] framework, help contextualize point (iii) above. While acceptability appeared high in both arms (high satisfaction, no adverse events) and demand was reasonable (62% of eligible caregivers ultimately randomized), implementation differed markedly between arms: only 58.8% of MBHP participants met the >3/8 session engagement threshold, compared with 85.7% of control participants. This asymmetry suggests that group mindfulness sessions may have been less practical to sustain within this population's routine caregiving schedules than the more directive problem-solving format, potentially diluting the effective intervention dose received in the MBHP arm under intention-to-treat analysis and contributing to the attenuated primary-outcome effect. Strategies to improve MBHP-specific engagement—such as preparatory orientation sessions demystifying mindfulness practice, flexible session formats, or reminder systems—may be particularly relevant for future implementation in similarly time-constrained caregiver populations.

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

Using RoB 2.0, risk of bias was rated as raising some concerns across multiple domains, reflecting pragmatic constraints on allocation concealment and the impossibility of participant and facilitator blinding; performance and response/social-desirability biases cannot be excluded given reliance on self-report outcomes, although detection bias was mitigated by blinding outcome assessors. The sample size was relatively small and drawn from a single rehabilitation center, which may limit generalizability. Attrition and missing data may introduce bias despite the use of ITT analysis with multiple imputation. The study did not include a waitlist or placebo condition, limiting causal inferences about the specific mechanisms of change, and secondary endpoints were exploratory, controlled for multiplicity using FDR.

The planned 6-month follow-up registered at ClinicalTrials.gov was not conducted, restricting conclusions about the durability of observed effects; future studies should incorporate longer-term follow-up. 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 a structured mindfulness-based program (MBHP) for vulnerable caregiver populations.

Conclusion

In a real-world institutional setting, MBHP was comparable to an active psychoeducational control for improving quality of life, and conferred additional, FDR-corrected benefits on specific caregiver-burden subdomains (emotional overload, personal life impact, and family support), suggesting a role in fostering emotional regulation and resilience among family caregivers. Future adequately powered trials with longer follow-up, enhanced allocation concealment, and fidelity monitoring are warranted to confirm these effects and their generalizability across larger and more diverse samples.

Statements and Declarations

Funding

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Potential Competing Interests

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.

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.

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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