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Research Article

The Effects of Mindfulness-Based Stress Reduction on Overall Quality of Life and Its Components in Head and Neck Cancer: Finding Answers in a Randomized Controlled Trial

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Objective: This multicenter randomized controlled trial compared the changes in the degree of quality of life (QOL) and its components between mindfulness-based stress reduction (MBSR) and treatment-as-usual (TAU) groups over 3 points of time (T_0 = preintervention baseline assessment; T_1 = postintervention, which was right after the intervention completed or 6 weeks after the intervention began; and T_2 = follow-up, which was 12 weeks after the intervention ended) in head and neck cancer (HNC) survivors.
Methods: A total of 120 HNC patients were randomized into MBSR ($n = 60$) and TAU ($n = 60$) groups and administered the demographic and clinical data questionnaire and the Malay version of the Functional Assessment for Cancer Therapy-General and Head and Neck module (FACT-General and FACT-HN; to assess the QOL) across the three time points (T_0, T_1, and T_2).
Results: In the MBSR group, the main effect of the interaction between group and time for total FACT-General [$F(2, 232) = 24.7$, $p < 0.001$], social relationship [$F(2, 227) = 21.7$, $p < 0.001$], and emotion-related QOL [$F(2, 230) = 35.1$, $p < 0.001$] was significant after adjusting for confounding factors (such as age of participants, marital status, types of HNC, and stage of cancer). The total FACT-General and social relationship-related QOL scores of participants significantly increased from T_0 to T_1 and from T_1 to T_2, while the emotion-related QOL score significantly increased from T_1 to T_2. However, MBSR exhibited only a small effect on the physical health, functional, and the HN-related QOL scores in the MBSR group across the three time points.
Conclusion: MBSR enhances the overall QOL by enhancing the social and emotional components of QOL across time when compared with TAU. Hence, MBSR may be considered as part of the treatment regime for HNC, but its effect on QOL among HNC patients should be confirmed in the future study with longer follow-up assessments.

Trial Registration: ClinicalTrials.gov identifier: NCT04800419

Keywords: head and neck cancer; mindfulness-based stress reduction; quality of life; randomized controlled trial; treatment-as-usual

1. Introduction

Head and neck cancer (HNC) is the 5th most common cancer among males and the 12th most common among females, making it the seventh most prevalent cancer globally [1]. In 2018, HNC accounted for approximately 888,000 new cases and 453,000 deaths [2]. Over recent decades, population-based analyses have shown a gradual improvement in survival for HNC with overall—5-year relative survival increased substantially between historical

periods, with marked gains for oropharyngeal sites (tonsil, tongue) attributed in part to changing etiology and treatment advances [3]. Even though patients now survive longer, HNC survivors frequently experience persistent physical and psychosocial complications—including facial disfigurement, difficulties with speech and swallowing, pain, fatigue, depression, and anxiety—which can substantially impair quality of life (QOL) and overall well-being [4].

With improvements in HNC survival rates over the years, many patients continue to experience persistent functional disabilities resulting from the cancer itself or its treatment. These functional disabilities often include swallowing difficulties, changes in voice, persistent pain in the neck or throat, weight loss, and visible facial disfigurement, which are particularly common among HNC patients. Such impairments are key determinants of QOL, which serves as an essential indicator of cancer patients' well-being. Assessing QOL is crucial for guiding clinical decision-making and resource allocation for HNC patients. Notably, the QOL of HNC patients is significantly lower than that of the general population due to these persistent functional impairments [4, 5]. Therefore, further investigation into effective psychosocial interventions aimed at improving QOL among HNC patients is warranted.

MBSR has been shown to effectively improve QOL in patients with breast and lung cancer [6, 7]. However, its impact on QOL among HNC patients remains largely unexplored. The psychological benefits of mindfulness are explained by the monitor and acceptance theory (MAT) of mindfulness [8]. This theory posits that mindfulness training, such as mindfulness-based interventions (MBIs), fosters two distinct components: attention monitoring and acceptance. Enhanced attention monitoring, gained through MBI training, increases the awareness of present-moment experiences and improves cognitive function under neutral conditions. However, it may also heighten affective reactivity to experiences, potentially leading to difficulties in emotional regulation and, consequently, impairing psychological well-being. Conversely, when acceptance is cultivated, it facilitates better emotional regulation, reduces affective reactivity, and ultimately enhances psychological well-being [8].

QOL is a critical prognostic factor in cancer survival. Longitudinal changes in QOL from the time of cancer diagnosis serve as a significant predictor of survival outcomes, with declines in QOL associated with lower survival rates over time [9]. Given the lack of data on the effects of MBSR on QOL in HNC patients, this study aimed to address this research gap by comparing changes in overall QOL and its specific components between MBSR and TAU groups over three different points in time: baseline assessment (T_0, preintervention), postintervention assessment (T_1, immediately after the completion of the 6-week intervention), and follow-up assessment (T_2, 12 weeks postintervention).

2. Methods

2.1. Study Design and Site. This study was a multicenter, two-arm, parallel, double-blind, randomized controlled trial conducted between January and December 2023. The trial was carried out at the Oncology and Otorhinolaryngology units of Pusat Perubatan Universiti Sains Malaysia Bertam, Hospital Universiti Sains Malaysia, and Pusat Perubatan Universiti Kebangsaan Malaysia. These three tertiary referral centers for oncology patients and ear, nose, and throat diseases are located in the central and northern east and west coast regions of Peninsular Malaysia. Each center manages an estimated 300–500 HNC patients on average, and they received HNC referrals from the vicinity such as the states of Perlis, Kedah, Pulau Pinang, Perak, Kelantan, Terengganu, Kuala Lumpur, Putrajaya, Selangor, and Negeri Sembilan, covering almost all the states in Peninsular Malaysia.

2.2. Sample Size. The estimated sample size was determined using a sample size calculator for a mixed linear model (MLM) in R, with a type I error of 0.05, a study power of 0.8, and an effect size of 0.3 (based on a previous two-arm randomized controlled trial, which investigated the effects of MBSR on the QOL in breast cancer patients [10]). Hence, an estimation of 100 subjects was needed for the study, and with the inclusion of a 20% dropout rate, a total of 120 subjects were required, with 60 participants per group.

2.3. Study Participants. The participants in this study were partially drawn from a randomized controlled trial, which investigated the effect of MBSR on positive psychological traits and experiential avoidance among HNC survivors [11]. The study population comprised HNC patients registered for treatment at the three designated centers. Recruitment was facilitated through advertisements in the form of flyers and posters displayed on the notice boards of the oncology units in these centers. A trained research assistant (RA), who was not involved in the study, conducted subject recruitment using consecutive sampling. The research assistant is a bachelor in psychology graduate who was trained by the research team on subject recruitment in this study, randomization of participants, and data collection (learned about the meaning of all items in the questionnaires used in the study) through role play prior to conduct of the study, and followed the study procedures according to the research protocol. Potential participants were approached by the research assistant and provided with a detailed explanation of the study, including its objectives, procedures, duration, potential risks and benefits, and their right to withdraw at any time without consequences, ensuring that their data would be discarded upon withdrawal. Participants were also assured of the anonymity and confidentiality of their personal information. Interested individuals underwent eligibility screening based on the following inclusion and exclusion criteria: (1) those diagnosed with HNC as a primary tumor with confirmation from their histopathological report regardless of the cancer stage, (2) patients who currently received chemotherapy, (3) age 18 years and above, and (4) literate in the Malay language; while the exclusion criteria were (1) those with comorbid medical illnesses that affect QOL (screened by a clinical doctor not involved in the

study), (2) those with other types of cancer as primary tumor, and (3) those who were pregnant. Following eligibility screening, only participants fulfilling all inclusion criteria and not meeting any exclusion criteria were invited to provide written informed consent prior to enrollment.

2.4. Randomization. Randomization was carried out by a trained research assistant who was not part of the research team and who was blinded to its objectives. A stratified blocked randomization approach was employed, in which participants were stratified based on age (18–29 years, 30–45 years, 46–60 years, and > 60 years) and marital status (married vs. single/divorced/widowed). Participants were then randomly assigned to either the MBSR or TAU control group in a 1:1 ratio. Randomization was performed using computer-generated random sequential numbers, which were sealed in opaque envelopes. Each participant received an envelope containing allocation instructions, ensuring assignment to the appropriate intervention group while maintaining allocation concealment.

2.5. Ethical Considerations. This study received approval from the Human Research Ethics Committee of the targeted centers (codes: USM/JEPeM/21040321 and UKM/PPI/111/8/JEP-2021-753) and complied with the ethical standard set by the Declaration of Helsinki 1964 and its subsequent amendments. The study was also conducted according to the CONSORT guideline, in which the CONSORT checklist is presented as Supporting File 1.

2.6. Intervention. MBSR was selected over other MBIs as the intervention to be tested in this study due to the following reasons: (1) MBSR was more extensively studied with more evidence-based effectiveness of MBSR for enhancing QOL and other psychological variables in other types of cancer compared with other MBIs, (2) MBSR has a well-defined structure, and its multimodal design provides cancer patients with more benefits to cope with physical and emotional issues related to cancer, (3) MBSR can be conducted in group sessions, giving cancer patients the opportunity to widen their social network, share experiences, and sense of belonging, and (4) MBSR is more physical activity-oriented and yet modest, which makes it easier for cancer patients to follow, compare with mindfulness-based cognitive therapy, which require patients to learn cognitive restructuring, and which may be more difficult to follow, particularly cancer patients with cognitive impairment.

Participants in the MBSR group received a structured MBSR program, consisting of a 1-h session per week for 6 weeks, with an additional 50-min home assignment after each session. Similarly, participants in the TAU control group attended nontherapeutic sessions of equal duration (1 h per week for 6 weeks). All sessions were conducted in a group format, with 10 participants per group. The structure of the MBSR sessions followed the well-established therapy sessions by Kabat-Zinn [12].

Summary of the MBSR sessions is described as follows:

1. The MBSR session in this study was administered according to the MBSR exercises recommended by Kabat-Zin (1990) [13]:
   a. Session 1: Demonstration and awareness of "automatic pilot," which regulates our thoughts; learning body scan to be aware of the present moment; our thoughts, feelings, and bodily sensations; home assignment of practicing body scan and "10-finger gratitude practice."
   b. Session 2: Learning and practicing mindfulness breathing; practice of metaphorical awareness of thoughts and its effects onto feelings, behavioral impulses and bodily sensations; learning and practicing "50–50 attention" to be aware of the present moment can overcome "automatic pilot"; home assignments with pleasure experiences calendar and practice of "50–50 attention" and body scan.
   c. Session 3: Practice of a 5-min mindfulness breathing and keep mindfulness of the body movement with some yoga and mindful stretching; engage in a "3-step breathing space" to enhance awareness and focus on the present moment; home assignment of mindfulness movement, "3-step breathing space" and filling in calendar of experiences with this time focus on unpleasant experiences.
   d. Session 4: Learning and engage in sit and observing thoughts and reactivities with metaphors such as observing leaves in the river or observing thoughts and reactivities as in a cinema; learn to accept exposure to unpleasant thoughts and emotions via "The Vicious Flower"; review of mindfulness theory learned and suggest for participants to practice as home assignments.
   e. Session 5: Repractice observing thoughts and reactivities and a "3-step breathing space"; awareness of thoughts are not facts through two metaphors; practicing watching and allow thoughts to arrive and leave with openness and without being judgmental.
   f. Session 6: Summarizing the mindfulness exercises learned and engage in the kindness exercise of imagining sending well-wishes to three types of people: someone we like, someone we dislike and ourselves and learn further on awareness to accept and openness on any situations we experience without being judgmental; to illiterate on focus on nourishing activities in life instead of dwelling into depleting activities.
2. Nontherapeutic sessions in the TAU control group: In the TAU control group, all the participants were engaged in nontherapeutic sessions such as deep breathing exercise, self-ventilation, and reassurance from the same therapists who ran the MBSR sessions. They received the same amount of attention and sessions as that of the MBSR group.

2.7. Treatment Fidelity. There were four therapists who carried out the interventions in the MBSR and TAU groups. The background of the therapists was carefully considered such as they were psychology postgraduate students with 2 years or longer experience in delivering psychotherapy. They were not part of the research team and blinded to the objectives of this study. Initially, all four therapists attended a 2-day intensive workshop on MBSR delivered by the principal investigator. Subsequently, each therapist participated in 12 supervised MBSR sessions over a 3-month period, during which they practiced as cotherapists under direct supervision. Only after the completion of these supervised sessions were they permitted to independently deliver the MBSR intervention in the study. Then, 15% of audiovisual recording of the MBSR sessions in the early, mid, and late MBSR sessions from each therapist were selected randomly and assessed by the principal investigator (a psychiatrist) and a clinical psychologist, both trained in MBSR by using the MBIs: Teaching Assessment Criteria (MBI-TAC) [14]. The inter-rater reliability was measured, which was 0.78. In addition, any therapist with some issues while conducting the MBSR sessions discussed the issues they experienced with the principal investigator in order to resolve the issues.

2.8. Blinding. The researchers were blinded in this study as the recruitment of subjects, their randomization into groups, and collection of data in this study were carried out by RAs who were not involved in the study. The data analysis was also carried out by statisticians who were not involved in the study and blinded on the study objectives according to the preplan statistical manual. Hence, the data analyst was also blinded. The researchers were only unblind after data collection and analysis were completed, and the data were then unlocked.

The allocation of group for the participants was also concealed as they were randomized according to the sequential number enclosed in an opaque envelope to their respective intervention group. Then, the intervention sessions in the MBSR and TAU groups were carried out with equal amount of attention and number of sessions in groups of 10 participants by the same therapists.

2.9. Data Collection. Assessments were conducted at three time points (T_0 = preintervention baseline assessment; T_1 = postintervention, immediately after completion of intervention at 6 weeks after intervention commenced; and T_2 = follow-up, 12 weeks after completion of intervention). At each time point, participants completed the questionnaires either in paper-based form during clinic visits or electronically through Google form, depending on their preference. At T_0, all participants in the MBSR and TAU groups completed a demographic and clinical data questionnaire, along with the Malay version of the Functional Assessment of Cancer Therapy-General and Head and Neck Module (FACT-General and FACT-HN), which were administered to all participants. At T_1 and T_2, the FACT-General and FACT-HN were readministered to assess changes in QOL. To minimize attrition, participants received reminder messages or phone calls 3 days before their scheduled assessment. Those who missed their appointments were contacted by research assistants to reschedule at the earliest possible date.

2.10. Measures

2.10.1. Primary Outcome

2.10.1.1. QOL. The Functional Assessment of Cancer Therapy-General and Head and Neck Module (FACT-HN) is a self-administered instrument to measure the degree of QOL among HNC patients. It comprises 39 items distributed across five domains: physical health-related QOL (7 items), social relationship-related QOL (7 items), emotion-related QOL (6 items), functional-related QOL (7 items), and head and neck module for HNC (12 items). Each item is rated on a 5-point Likert scale, ranging from 0 (not at all) to 4 (very much). Higher scores in each domain indicate a better QOL in the respective component. The FACT-General and FACT-HN have demonstrated excellent psychometric properties [15]. The Malay version of FACT-General and FACT-HN was validated in the Malaysian cancer population, exhibiting acceptable internal consistency, with Cronbach's α ranging from 0.65 to 0.87 across all subscales [16].

2.10.2. Demographic and Clinical Data Questionnaire. The sociodemographic characteristic data collected from the participants included age, gender, and marital status. Meanwhile, the clinical data recorded encompassed HNC type, time since diagnosis, and cancer stage.

2.10.3. Data Analysis. All data analysis was performed using the Statistical Package for Social Sciences version 28 (SPSS 28). Descriptive statistics were computed for the sociodemographic and clinical characteristics of participants, presented as frequencies and percentages. Differences in sociodemographic and clinical characteristics between the MBSR and TAU groups were assessed using Pearson's chi-squared test or Fisher's exact test (for variables with cell counts < 5).

To achieve objectives (1) and (2), a MLM was employed as it accounts for missing data more effectively than the last observation carried forward (LOCF) method, ensuring a more accurate analysis. The analysis followed the intention-to-treat principle. The main effects of the groups, points of time, the groups and points of time interaction for the total FACT-HN, and all its domain scores were measured while controlling for confounding factors such as age of participants, monthly household income, marital status, employment status, mode of treatment received, types of HNC, and stages of cancer [17–19]. Then, post hoc analysis to compute the mean difference between the MBSR and TAU groups in each point of time (the between group mean difference) and post hoc analysis to evaluate the mean difference across the three time points (T_0, T_1, and T_2) within

the MBSR and TAU groups (within group mean difference) were carried out. The effect size for mean difference, which was statistically significant ($p < 0.05$), was assessed with Cohen's d. Cohen's $d = 0.2$ (small effect size), Cohen's $d = 0.5$ (moderate effect size), while Cohen's $d = 0.8$ (large effect size).

Finally, sensitivity analysis was also performed, where the MLM analysis was repeated for the FACT-HN total score and all its domain scores by employing the last observation carry forward (LOCF) analysis (missing data of the time point replaced by the last observed data from the previous time points). Then, the findings of the MLM obtained between ITT and LOCF were compared and if there was no significant difference, it indicates that the findings from ITT were reliable.

3. Results

3.1. Study Participants. Initially, in the subject recruitment chronology, a total of 200 HNC patients were identified from the three targeted centers for subject recruitment. Fifty patients were excluded due to the lack of interest to participate in the study (35 patients) and other reasons (such as residing in a location far from the site of data collection, physically unfit to participate, and nobody to bring them to the site of data collection). Hence, 150 patients were screened for the eligibility criteria for the study, but another 25 patients were excluded due to failure to fulfill all the inclusion criteria and/or presence of exclusion criteria and another 5 patients refused to participate without citing a reason. Hence, a total of 120 participants were enrolled in the study.

Subsequently, only 57 participants completed the T_2 assessment in each of the MBSR and TAU groups, as three participants dropped out from the MBSR group (one drop-out at T_1 and two drop-out at T_2) and three participants dropped out from the TAU group (two drop-out at T_1 and one drop-out at T_2). The chronology of subject recruitment, response, and attrition rate are illustrated in Figure 1. There was no harm or adverse effects documented in this study.

In terms of the sociodemographic and clinical characteristics of the participants, there were no difference in the proportion of participants between the MBSR and TAU groups. The sociodemographic and clinical characteristics among the participants in this study are presented in Table 1.

3.2. The Effect of MBSR on the QOL and Its Components According to the Intention-to-Treat Analysis Among HNC Patients. Based on the MLM of the FACT-General total score among the HNC participants in this study according to the ITT analysis, the main effects of points of time [$F(2, 231) = 37.842$, $p < 0.001$] and the groups and points of time interaction [$F(2, 231) = 24.846$, $p < 0.001$] were statistically significant after controlling for the confounding factors (such as age of participants, monthly household income, marital status, employment status, mode of treatment received, types of HNC, and stages of cancer), whereas the group main effect was not statistically significant ($p = 0.056$). In the context of the components of QOL, the MLM for the social relationship-related QOL indicated that the group main effect [$F(1, 123) = 12.737$, $p < 0.001$], points of time [$F(2, 227) = 20.267$, $p < 0.001$], and the group and points of time interaction [$F(2, 227) = 21.907$, $p < 0.001$] were statistically significant after controlling for the confounding factors. While for emotion-related QOL, the main effects of time [$F(2, 229) = 50.403$, $p < 0.001$] and the interaction between groups and time [$F(2, 229) = 35.132$, $p < 0.001$] were statistically significant after controlling for the confounding factors, whereas the group main effect was not statistically significant ($p = 0.486$). As for the physical-related QOL, only the main effect of time [$F(2, 137) = 9.778$, $p < 0.001$] was significant after controlling for the confounding factors, while the main effects of group ($p = 0.083$) and the interaction between groups and time ($p = 0.092$) were not statistically significant. As for functional-related QOL, only the main effect of groups [$F(1, 121) = 4.826$, $p = 0.030$] was significant after controlling for the confounding factors, while the main effects of points of time ($p = 0.086$) and the group and points of time interaction ($p = 0.166$) were not statistically significant. While for the FACT-HN module, the main effects of groups [$F(1, 124) = 9.772$, $p = 0.002$] and points of time [$F(2, 231) = 3.194$, $p = 0.043$] were statistically significant upon controlling for the confounding factors, while the main effect of the interaction between groups and time was not significant ($p = 0.131$).

The post hoc analysis reporting the mean difference in the total FACT-General, social relationship-related QOL, and emotion-related QOL scores between the MBSR and TAU groups at the points of time (between group mean difference) in the context of the ITT analysis is summarized in Table 2. The post hoc analysis presenting the mean difference in the total FACT-General, social relationship-related QOL, and emotion-related QOL scores across the three time points (T_0, T_1 and T_2) within the MBSR and TAU group, respectively (within group mean difference), and the effect size (EF) for significant mean difference while performing the ITT analysis are presented in Table 3. In terms of the between group comparison, initially, there is no statistically significant difference in the FACT-General total score between the two groups (MBSR vs. TAU) at T_0 ($p = 0.278$). Then, at T_1, the total FACT-General score increases in the MBSR group, whereby the score was significantly higher in the MBSR group compared with that of the TAU group (mean difference = 6.983, 95% CI = 2.437–11.130, SE = 2.202, $p = 0.002$). Further increment in the FACT-General total score in the active intervention group (MBSR) at T_2 leads to a greater mean difference in the score between the two groups (mean difference = 7.347, 95% CI = 2.967–11.728, SE = 2.219, $p = 0.001$). To confirm the elevation of the FACT-General total score in the MBSR group across time points, the within subject comparison was computed. According to the within subject adjusted mean differences in the MBSR group, there was a significant increase in the total FACT-General score from T_0 to T_1 (at postintervention; mean difference = 9.553, 95% CI = 7.312–11.795, $t = 8.961$, SE = 1.06, $p < 0.001$) and from T_1 to T_2 (at follow-up; mean difference = 2.626, 95% CI = 0.348–4.903, $t = 2.385$, SE = 0.944, $p = 0.018$), resulting in the maintenance of the total FACT-General score from baseline to follow-up (T_0 to T_2, mean difference = 12.179, 95%

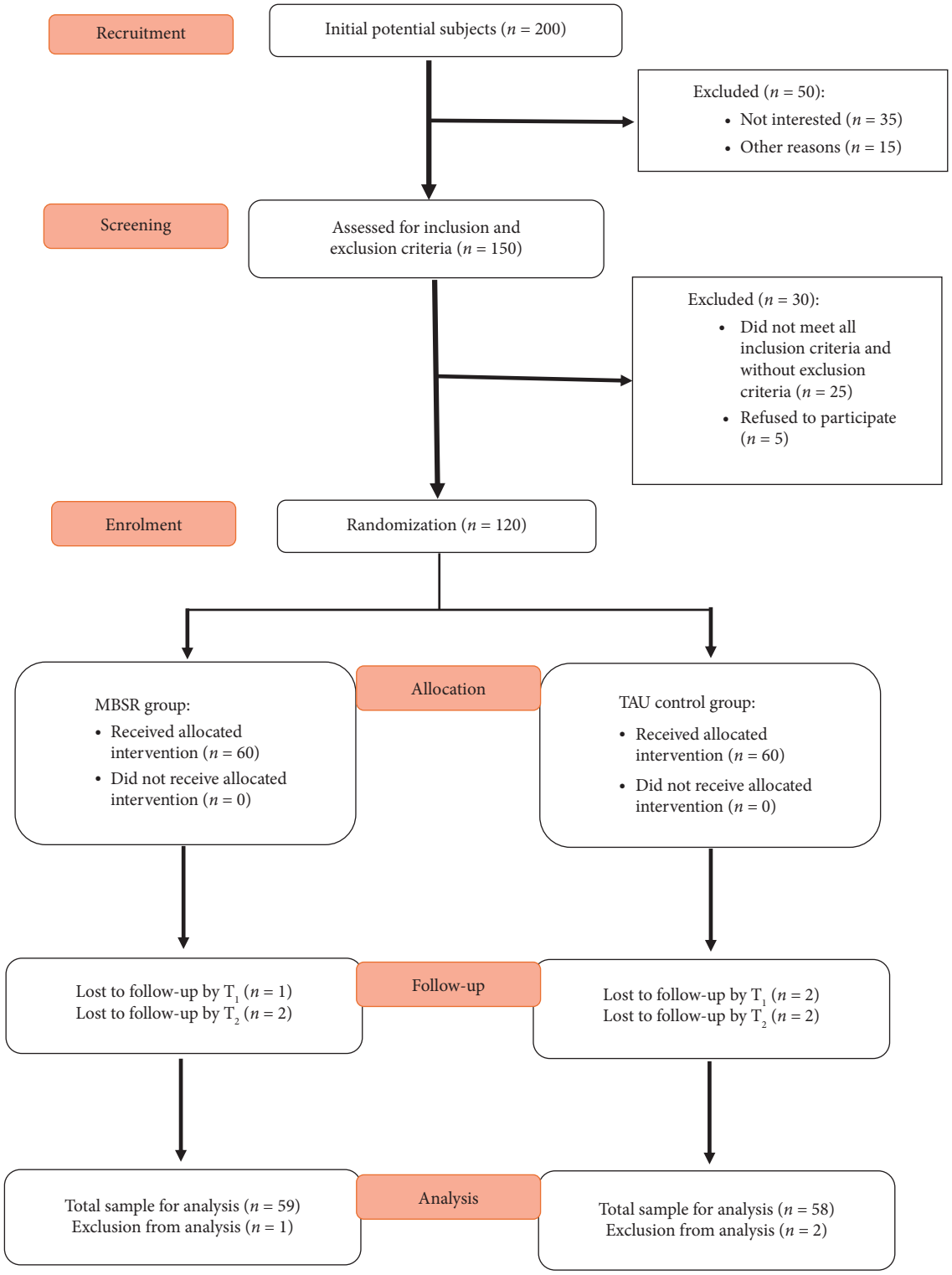

Figure 1: The flowchart on the chronology of subject recruitment, drop-out, and attrition in this study.

CI = 9.166–15.193, $t = 8.453$, SE = 1.251, $p < 0.001$) with a large EF (Cohen's $d = 0.967$). As a comparison, the TAU group exhibited only a statistically significant increment in the FACT-General total score from T_1 to T_2, with an overall maintenance of the total FACT-General score from baseline to follow-up (T_0 to T_2) with small EF (Cohen's $d = 0.233$), while no significant change was documented in the FACT-General total score from T_0 to T_1.

Referring to the findings of the FACT domains, between subjects comparison revealed that initially at T_0, there was no significant difference in the social relationship-related QOL score between the MBSR and TAU groups ($p = 0.792$).

Table 1: The sociodemographic and clinical characteristics of all the participants.

Variables	Number of participants (n)		Percentage (%)		p value
	MBSR group	Control group	MBSR group	Control group	
Age					
18–25 years	1	3	1.6	5.0	
26–45 years	22	24	36.7	40.0	
46–59 years	34	28	56.7	46.7	
≥ 60 years	3	5	5.0	8.3	0.254
Gender					
Male	34	32	56.7	53.3	
Female	26	28	43.3	46.7	0.855
Marital status					
Married	50	50	81.8	83.6	
Nonmarried	10	10	18.2	16.4	1.000
Monthly household income:					
< RM 4500	41	45	68.3	75.0	
RM 4500–RM 11,000	16	11	26.7	18.3	
> RM 11,000	3	4	5.0	6.7	0.151
Employment status					
Employed	19	15	31.7	25.0	
Unemployed/retired	41	45	68.3	75.0	0.198
Types of head and neck cancer					
NPC	31	24	51.7	40.0	
Tongue cancer	12	14	20.0	23.3	
Oral cancer	13	15	21.6	25.0	
Others	4	7	6.7	11.7	0.599
Stage of cancer					
Stage 1	3	8	5.0	13.3	
Stage 2	12	16	20.0	26.7	
Stage 3	20	18	33.3	30.0	
Stage 4	25	18	41.7	30.0	0.073
Time since diagnosis					
New case	21	22	35.0	36.7	
1–6 months	39	38	65.0	63.3	1.000
Mode of treatment received					
Surgery + chemotherapy	18	28	30.0	46.7	
Chemotherapy alone	21	20	35.0	33.3	
Chemotherapy + radiotherapy	12	4	20.0	6.7	
Surgery + chemotherapy + radiotherapy	9	8	15.0	13.3	< 0.001*

Note: The significance of "*" is at $p < 0.05$.

The increase in the social relationship-related QOL score at T_1 resulted in a significantly higher score in the MBSR group compared with that of the TAU group (mean difference = 2.859, 95% CI = 1.511–4.206, SE = 0.683, $p < 0.001$). Similarly, further increase in the social relationship-related QOL score in the MBSR group at T_2 documented a further widening of the mean difference in the score between the two groups (mean difference = 3.942, 95% CI = 2.402–5.125, SE = 0.690, $p < 0.001$). The within group comparison indicated that the MBSR group also demonstrated a statistically significant increment in the social relationship-related QOL score from T_0 to T_1 (at postintervention; mean difference = 2.797, 95% CI = 1.937–3.657, $t = 6.723$, SE = 0.357, $p < 0.001$) and from T_1 to T_2 (at follow-up; mean difference = 1.219, 95% CI = 0.346–2.092, $t = 2.878$, SE = 0.362, $p = 0.003$), resulting in the maintenance of the social relationship-related QOL score from baseline to follow-up (T_0 to T_2; mean difference = 4.016, 95% CI = 2.897–5.135, $t = 7.619$, SE = 0.465, $p < 0.001$) with a large effect size (Cohen's $d = 1.092$).

Regarding the emotion-related QOL score, the between subject comparison initially documented a significantly lower score in the MBSR compared with the TAU group at T_0 (mean difference = −2.142, 95% CI = −4.044 to −0.440, SE = 0.912, $p = 0.015$). Elevation of the emotion-related QOL score in the MBSR group at T_1 contributed to a significantly higher score in the MBSR group compared with that of the TAU group (mean difference = 1.935, 95% CI = 0.127–3.743, SE = 0.916, $p = 0.036$). However, there was no further increase in the emotion-related QOL score in the MBSR group at T_2, leading to an almost similar mean difference between the scores of the two groups (mean difference = 2.000, 95% CI = 0.279–3.920, SE = 0.922, $p = 0.024$). The within group comparison verified that the emotion-related QOL score was significantly elevated from T_0 to T_1 in the MBSR group (at postintervention; mean difference = 4.562, 95% CI = 3.709–5.416, $t = 11.373$,

Table 2: The post hoc cmparison of the FACT-HN-total and its domain scores (MBSR vs. TAU groups) in each of the three time points (T_0, T_1, and T_2) after controlling for confounding factors (age, monthly household income, marital status, employment status, mode of treatment received, types of HNC, and stages of cancer) and following intention-to-treat analysis.

Time point	Mean FACT-HN-total score in MBSR (SD), sample size (*n*)	Mean FACT-HN-total score in TAU (SD), sample size (*n*)	Mean difference (95% CI)	SE	*p* value	Effect size (Cohen's *d*)
T_0	87.9 (11.3), 60	90.4 (9.5), 60	−2.388 (−6.715 to 1.940)	2.192	0.278	−0.239
T_1	97.7 (14.0), 59	90.7 (8.6), 58	6.983 (2.437–11.130)	2.202	0.002*	0.603
T_2	100.8 (15.1), 59	92.5 (8.5), 58	7.347 (2.967–11.728)	2.219	0.001*	0.677
Time point	**Mean physical health-related QOL score in MBSR (SD), sample size (*n*)**	**Mean physical health-related QOL score in TAU (SD), sample size (*n*)**	**Mean difference**	**SE**	***p* value**	**Effect size (Cohen's *d*)**
T_0	14.3 (7.0), 60	17.3 (7.7), 60	−2.926 (−5.763 to −0.089)	1.435	0.043*	−0.408
T_1	15.8 (7.1), 59	17.5 (8.4), 58	−1.653 (−4.498 to 1.192)	1.439	0.253	−0.219
T_2	16.3 (7.1), 59	19.0 (7.4), 58	−2.637 (−5.495 to 0.221)	1.446	0.070	−0.372
Time point	**Mean social relationship-related QOL score in MBSR (SD), sample size (*n*)**	**Mean social relationship-related QOL score in TAU (SD), sample size (*n*)**	**Mean difference**	**SE**	***p* value**	**Effect size (Cohen's *d*)**
T_0	20.8 (4.4), 60	21.1 (3.6), 60	−0.279 (−1.518 to 1.159)	0.679	0.792	−0.075
T_1	23.7 (3.3), 59	20.8 (3.5), 58	2.859 (1.511–4.206)	0.683	< 0.001*	0.853
T_2	25.0 (3.2), 59	21.1 (3.4), 58	3.942 (2.402–5.125)	0.690	< 0.001*	1.181
Time point	**Mean emotion-related QOL score in MBSR (SD), sample size (*n*)**	**Mean emotion-related QOL score in TAU (SD), sample size (*n*)**	**Mean difference**	**SE**	***p* value**	**Effect size (Cohen's *d*)**
T_0	11.8 (4.5), 60	13.9 (4.6), 60	−2.142 (−4.044 to −0.440)	0.912	0.015*	−0.462
T_1	16.2 (4.1), 59	14.3 (5.0), 58	1.935 (0.127–3.743)	0.916	0.036*	0.416
T_2	16.5 (4.8), 59	14.5 (5.1), 58	2.000 (0.279–3.920)	0.922	0.024*	0.404
Time point	**Mean functional-related QOL score in MBSR (SD), sample size (*n*)**	**Mean functional-related QOL score in TAU (SD), sample size (*n*)**	**Mean difference**	**SE**	***p* value**	**Effect size (Cohen's *d*)**
T_0	19.1 (5.2), 60	17.8 (5.4), 60	1.344 (−0.518 to 3.806)	1.094	0.135	0.245
T_1	20.2 (4.6), 59	18.0 (6.5), 58	2.231 (0.163–4.499)	1.097	0.035*	0.391
T_2	20.6 (4.9), 59	17.8 (6.3), 58	2.829 (0.751–5.107)	1.102	0.009*	0.496
Time point	**Mean H&N-related QOL score in MBSR (SD), sample size (*n*)**	**Mean H & N-related QOL score in TAU (SD), sample size (*n*)**	**Mean difference**	**SE**	***p* value**	**Effect size (Cohen's *d*)**
T_0	22.4 (4.9), 60	20.4 (4.0), 60	2.000 (0.087–3.437)	0.848	0.039*	0.447
T_1	23.1 (4.9), 59	20.2 (4.5), 58	2.924 (0.842–4.206)	0.852	0.003*	0.616
T_2	23.9 (4.3), 59	20.4 (4.3), 58	3.508 (1.413–4.802)	0.858	< 0.001*	0.814

Note: T_0 = baseline assessment prior to intervention, T_1 = postintervention, which was right after the intervention completed or 6 weeks after the intervention began; and T_2 = follow-up, which was 12 weeks after the intervention ended.

Abbreviations: MBSR, mindfulness-based stress reduction; TAU, treatment-as-usual.

*$p < 0.05$ denotes statistical significance.

Table 3: Post hoc comparison of the changes in the FACT-HN-total and its domain scores over the three time points in the MBSR and the TAU groups after controlling for confounding factors (age, monthly household income, marital status, employment status, mode of treatment received, types of HNC, and stages of cancer) and following intention-to-treat analysis.

Intervention group	Adjusted mean difference between time points (95% CI)	*t*	Standard error	*p* value	Effect size (Cohen's *d*)
FACT-HN-total					
	T_0 to T_1: 9.553 (7.312–11.795)	8.961	0.930	< 0.001*	0.770
MBSR	T_1 to T_2: 2.626 (0.348–4.903)	2.385	0.944	0.018*	0.213
	T_0 to T_2: 12.179 (9.166–15.193)	8.453	1.251	< 0.001*	0.967
	T_0 to T_1: 0.383 (−1.877 to 2.642)	0.472	0.937	1.000	0.033
TAU	T_1 to T_2: 2.062 (−0.217 to 4.341)	2.628	0.945	0.090	0.211
	T_0 to T_2: 2.444 (−0.579 to 5.468)	2.345	1.255	0.158	0.233
Social relationship-related QOL					
	T_0 to T_1: 2.797 (1.937–3.657)	6.723	0.357	< 0.001*	0.746
MBSR	T_1 to T_2: 1.219 (0.346–2.092)	2.878	0.362	0.003*	0.400
	T_0 to T_2: 4.016 (2.897–5.135)	7.619	0.465	< 0.001*	1.092
	T_0 to T_1: 0.241 (−1.108 to 0.625)	−0.813	0.359	1.000	−0.084
TAU	T_1 to T_2: 0.33 (−0.560 to 1.188)	1.135	0.362	1.000	0.087
	T_0 to T_2: 0.073 (−1.049 to 1.195)	0.258	0.465	1.000	0.000
Emotion-related QOL					
	T_0 to T_1: 4.562 (3.709–5.416)	11.373	0.354	< 0.001*	1.022
MBSR	T_1 to T_2: 0.351 (−0.516 to 1.219)	0.879	0.360	0.989	0.067
	T_0 to T_2: 4.914 (3.755–6.072)	9.225	0.481	< 0.001*	1.010
	T_0 to T_1: 0.385 (−0.475 to 1.246)	1.247	0.357	0.844	0.083
TAU	T_1 to T_2: 0.186 (−0.681 to 1.054)	0.588	0.360	1.000	0.040
	T_0 to T_2: 0.556 (−0.45 to 1.55)	1.334	0.41	0.185	0.124
Physical health-related QOL					
	T_0 to T_1: 1.488 (0.347–2.630)	2.657	0.473	0.006*	0.213
MBSR	T_1 to T_2: 0.569 (−0.591 to 1.729)	1.182	0.481	0.715	0.070
	T_0 to T_2: 2.057 (0.568–3.546)	3.358	0.613	0.003*	0.284
	T_0 to T_1: 0.215 (−0.936 to 1.366)	0.765	0.477	1.000	0.025
TAU	T_1 to T_2: 1.553 (0.392–2.714)	2.786	0.481	0.004*	0.189
	T_0 to T_2: 1.768 (0.274–3.262)	2.986	0.615	0.014*	0.225
Functional-related QOL					
	T_0 to T_1: 0.880 (0.026–1.734)	1.768	0.354	0.041*	0.224
MBSR	T_1 to T_2: 0.410 (−0.458 to 1.278)	1.139	0.360	0.768	0.084
	T_0 to T_2: 1.290 (0.132–2.448)	2.707	0.477	0.024*	0.297
	T_0 to T_1: 0.193 (−0.668 to 1.054)	0.676	0.357	1.000	0.033
TAU	T_1 to T_2: −0.188 (−1.057 to 0.680)	−0.655	0.360	1.000	−0.031
	T_0 to T_2: 0.005 (−1.157 to 1.167)	0.078	0.478	1.000	0.000
H & N-related QOL					
	T_0 to T_1: 0.641 (−0.203 to 1.486)	1.890	0.350	0.205	0.143
MBSR	T_1 to T_2: 0.840 (−0.018 to 1.699)	2.361	0.356	0.057	0.174
	T_0 to T_2: 1.482 (0.342–2.621)	3.133	0.473	0.006*	0.325
	T_0 to T_1: −0.121 (−0.973 to 0.731)	−0.564	0.353	1.000	−0.047
TAU	T_1 to T_2: 0.257 (−0.602 to 1.116)	0.898	0.356	1.000	0.045
	T_0 to T_2: 0.136 (−1.007 to 1.279)	0.657	0.475	1.000	0.000

Note: T_0 = baseline assessment prior to intervention, T_1 = postintervention, which was right after the intervention completed or 6 weeks after the intervention began; and T_2 = follow-up, which was 12 weeks after the intervention ended.
Abbreviations: MBSR, mindfulness-based stress reduction; TAU, treatment-as-usual.
*$p < 0.05$ denotes statistical significance.

SE = 0.354, $p < 0.001$), but no further significant increase in the score from T_1 to T_2 ($p = 0.989$). However, the emotion-related QOL score was maintained from baseline to follow-up (T_0 to T_2; mean difference = 4.914, 95% CI = 3.755–6.072, $t = 9.225$, SE = 0.481, $p < 0.001$) with a large effect size (Cohen's $d = 1.010$). Contrastingly, there was no significant changes in the TAU group's social relationship-related and emotion-related QOL scores across all the three time points.

In the context of the physical health-related QOL, the between group comparison revealed that initially the physical health-related QOL score was significantly lower in the MBSR compared with that of the TAU group at T_0 (mean difference = −2.926, 95% CI = −5.763 to −0.089, SE = 1.435, $p = 0.043$), but then, an increase in the physical health-related QOL score in the MBSR group at T_1 ($p = 0.253$) and T_2 ($p = 0.070$) led to no significant difference in the score between MBSR and TAU groups. The within subject comparison confirmed that the physical health-related QOL score in the MBSR group significantly increased from T_0 to T_1 (mean difference = 1.488, 95% CI = 0.347–2.630, $t = 2.657$, SE = 0.473, $p = 0.006$) but did not increase further from T_1 to T_2 ($p = 0.715$). Hence, the physical health-related QOL score in the MBSR group remained significant from T_0 to T_2 (mean difference = 2.057, 95% CI = 0.568–3.546, $t = 3.358$, SE = 0.613, $p = 0.003$) but only exerted a small effect size (Cohen's $d = 0.284$). Likewise, the TAU group also documented a significant increase in the physical health-related QOL score from T_1 to T_2, resulting in a significantly higher score from T_0 to T_2 (mean difference = 1.768, 95% CI = 0.274–3.262, $t = 2.986$, SE = 0.615, $p = 0.014$) with a small EF (Cohen's $d = 0.225$).

While for the functional-related QOL, based on the between subject comparison, an increase in the functional-related QOL score in the MBSR group at T_1 led to a significantly higher score in the group compared with that of the TAU group, but no further increase was observed in the score at T_2 in the MBSR group, resulting in a mean difference between the group and that of the TAU group (mean difference = 2.829, 95% CI = 0.751–5.107, SE = 1.102, $p = 0.009$) to exhibit only a small effect size (Cohen's $d = 0.496$). The within group comparison in the MBSR group verified that, indicating a significant overall increase in the functional-related QOL score from T_0 to T_2 (mean difference = 1.290, 95% CI = 0.132 to 2.448, $t = 2.707$, SE = 0.477, $p = 0.024$) with a small effect size (Cohen's $d = 0.297$). Contrastingly, the TAU group exhibited no changes in the functional-related QOL score across all three time points.

In the head and neck (H & N)-related QOL score, based on the between group comparison, the H & N-related QOL score was significantly higher in the MBSR group (mean difference = 2.000, 95% CI = 0.087–3.437, SE = 0.848, $p = 0.039$). An increase of the score in the MBSR group at T_1 and T_2 resulted in a larger mean difference in the score between the group and that of the TAU group at T_2 (mean difference = 3.508, 95% CI = 1.413–4.802, SE = 0.858, $p < 0.001$) with a large EF (Cohen's $d = 0.814$). However, the within group comparison in the MBSR group revealed no statistically significant increment in the H & N-related QOL score from T_0 to T_1 ($p = 0.205$) and from T_1 to T_2 ($p = 0.057$), but there was an overall increase in the score from T_0 to T_2 (mean difference = 1.482, 95% CI = 0.342–2.621, $t = 3.133$, SE = 0.473, $p = 0.006$) with only a small EF (Cohen's $d = 0.325$). On the contrary, the TAU group reported no changes in the functional-related QOL score across all three time points.

3.3. Sensitivity Analysis. The MLM of the FACT-HN total score following the LOCF analysis after controlling for the confounding factors (age of participants, monthly household income, marital status, employment status, mode of treatment received, types of HNC, and stages of cancer) indicated a significant main effect for points of time ($p < 0.001$) and the group and points of time interaction ($p < 0.001$), which were similar to the findings that utilized the ITT analysis. Similarly, the main effects of groups ($p < 0.001$), time ($p < 0.001$), and the interaction between groups and time ($p < 0.001$) for the social relationship-related QOL score were statistically significant after controlling for the confounding factors for the LOCF analysis, which was similar to the findings in the ITT analysis. As for the emotion-related QOL score, the main effects for points of time ($p < 0.001$) and the group and points of time interaction ($p < 0.001$) were statistically significant after controlling for the confounding factors for the LOCF analysis but not for groups ($p > 0.05$). These findings were similar to that of the ITT analysis. As for the physical health-related QOL score, only the main effect of points of time was significant ($p < 0.001$) but not the main effects of group and the group and points of time interaction after controlling for the confounding factors, with similar findings documented during the ITT analysis. Then, the main effect of group was statistically significant ($p = 0.031$) for the functional-related QOL score after controlling for the confounding factors but not the main effects of points of time and the group and points of time interaction. Again, this was similar to that of the ITT analysis. Finally, for the H & N-related QOL score, the main effects of groups ($p = 0.002$) and time ($p = 0.048$) were significant after controlling for the confounding factors but not the main effect of the interaction between groups and time, similar to that of the ITT analysis.

The post hoc analysis presenting the between group mean difference during the LOCF analysis is presented in Supporting Table 1. The post hoc analysis presenting the within group mean difference during the LOCF analysis is documented in Supporting Table 2. The significant increase in the FACT-HN total, social-, and emotion-related QOL scores across the three time points (from T_0 to T_1, from T_1 to T_2, and from T_0 to T_2); the small increase in the physical health-related and the functional-related QOL scores from T_0 to T_1, but not from T_1 to T_2, and the overall increase in the H & N-related QOL score from T_0 to T_2 in the MBSR group through the LOCF analysis were similar to that of the ITT analysis. The findings in the TAU group through the LOCF analysis were similar to that of the ITT analysis.

4. Discussion

This study evaluated the effectiveness of MBSR in improving QOL among HNC patients. The findings demonstrated that MBSR significantly enhanced the overall QOL immediately after the intervention, with continued improvements observed up to 12 weeks postintervention (follow-up). Regarding QOL components, MBSR led to a significant improvement in social relationship-related QOL immediately postintervention, with further enhancements during

follow-up. In contrast, emotion-related QOL showed a significant increase immediately postintervention, but this effect was not maintained at follow-up. However, there was still an overall improvement in emotion-related QOL from baseline to follow-up in the MBSR group. In comparison, the TAU control group also exhibited an increase in the overall QOL from baseline to follow-up but was not statistically significant compared with that observed in the MBSR group. Otherwise, there were no significant changes in the social relationship- and emotion-related QOL in the TAU group across time. Additionally, although MBSR also enhanced the physical health-, functional-, and H & N-related QOL from baseline to follow-up, its effect was small. In fact, an increase in the physical health-related QOL in the MBSR group from baseline to follow-up was similar to that of the TAU group, with a small effect size. Nonetheless, there were no changes in the functional- and H & N-related QOL in the TAU group.

In summary, MBSR may enhance the overall QOL of HNC patients by improving social relationship-related and emotion-related QOL. In comparison to other cancer types, a systematic review and meta-analysis on the effects of MBSR in lung cancer patients found that while MBSR improved QOL, the improvement was not statistically significant ($p = 0.06$) [6]. However, considerable MBSR effect was noted in all domains of QOL, such as emotion, physical, social, cognitive, and role aspects of well-being ($p < 0.001$) [6]. For breast cancer patients, an 8-week MBSR significantly increased QOL both immediately after the intervention and at 3 months postintervention. However, no significant effects were found for a 6-week MBSR [7]. A systematic review and meta-analysis of the MBSR effect in breast cancer patients also reported that MBSR significantly improved the social-, emotion-, and functional-related QOL after completion of the intervention, but no significant changes were observed in physical- and breast cancer-related QOL [10]. In the context of HNC patients, a pilot pre–post-intervention study on the effects of individualized MBSR reported findings that MBSR induced improvements in the total QOL, as well as social and emotional domains of QOL [20].

Based on the comparison of the findings of this study with previous studies on the effect of MBSR on QOL among cancer patients, there are a few learning points or new insight to address. First, MBSR is effective to enhance the overall QOL among cancer patients (including HNC patients). Second, the effects of MBSR on the domains of QOL are different across different types of cancer (e.g., MBSR could enhance all domains of QOL in lung cancer, but only social-, emotion-, and functional-related QOL in breast cancer, while MBSR is only effective to increase social- and emotion-related QOL in HNC patients). Third, this study was the first RCT to confirm the findings of the pilot pre–post-intervention study on MBSR effect on QOL among HNC patients [20], wherein MBSR improves the overall QOL, social-, and emotion-related QOL. Finally, MBSR has minimal but significant effect on the physical-, functional-, and H & N-related QOL up to 12 weeks after completion of MBSR sessions as shown in this study.

The advantages of group-based MBSR sessions in improving social relationship-related QOL were well documented in this study. Group-based MBSR brings together individuals facing similar stressors, such as surviving on HNC and the severe side effects of cancer treatment. These individuals often experience similar physical challenges, including facial disfigurement and various psychosocial complications associated with HNC. This shared experience fosters a sense of belonging among group members, allowing them to openly share unpleasant thoughts, feelings, and behaviors in response to HNC. Through acceptance and a nonjudgmental approach, participants develop greater willingness to confront these difficult emotions, which, in turn, facilitates personal growth [21]. As a result, group members are able to redefine themselves and expand their social networks. Additionally, HNC patients may become more open in sharing their cancer journey with family members and partners/spouses, thereby receiving increased social support from these important sources [10].

In essence, the MAT of mindfulness suggests that MBSR helps improve attention to the present moment while fostering the acceptance of unpleasant thoughts, feelings, and behaviors stemming from the stress of living with cancer and its treatments [21]. This process enables cancer patients to approach trauma-related psychological experiences with openness and in a nonjudgmental way. As a result, this facilitates the development of positive affectivity, which enhances the emotion-related QOL of cancer patients, as observed in this study [8].

4.1. Limitation. Despite the interesting findings reported in this study, several limitations should be considered. First, assessments were only carried out across three time points and the time interval between postintervention (time of completion of intervention) and the follow-up assessment being limited to just 12 weeks. Hence, the long-term effects of MBSR could not be evaluated. This limitation is consistent with previous evidence, such as a meta-analysis of randomized controlled trials of MBIs, which also highlighted the lack of longer-term follow-up as a common gap in the literature [22]. Future studies with longer follow-up periods are warranted to determine whether the positive effects of MBSR can be sustained beyond the immediate postintervention phase.

4.2. Clinical Implications. Based on the learning points derived from the study findings highlighted above, this study offers several valuable insights for clinicians treating HNC patients. First, MBSR improves only the psychosocial measurements of well-being (social- and emotion-related well-being), but has only minimal effects on the physical aspects of well-being (such as physical and functional well-being and additional physical aspects of well-being related to HNC). Therefore, MBSR should primarily be considered as a means to safeguard the mental well-being of HNC patients. Second, MBSR facilitates the enhancement of well-being through improvements in social- and emotion-related

well-being. As such, it could be incorporated into the treatment protocol for HNC patients to address their psychosocial needs. Third, a shorter 6-week MBSR intervention program may be sufficient to improve the QOL of HNC patients and allowed maintenance of effectiveness up to 12 weeks postintervention. Hence, MBSR could be used as a pivotal psychotherapy for short-term improvement of QOL or well-being among HNC patients.

Finally, the attrition rate in this study was only 5%, which was excellent. There were several strategies used to minimize attrition, such as (1) clear communication and close contact between the research assistant and the participants, (2) constant telephone calls to remind the participants regarding the upcoming assessment appointments and the close cooperation between the research assistant and the caregivers of the cancer patients, (3) if participants were unable to attend an assessment appointment, a nearest appointment to replace the missed appointment was arranged according to patient's time schedule, physical condition, and the feasibility of the caregivers to bring the participants for the new appointment, ensuring flexibility in appointment scheduling, (4) incentive to compensate for the time, transport, and effort of the participants to come for appointment was provided, (5) participants were given options for participating in the assessment sessions, such as either administration of questionnaires (in paper and pencil form) via face-to-face appointments or online administration of questionnaires, and (6) simplicity of the questionnaires used for assessment, which consisted of only two questionnaires (sociodemographic and clinical characteristics questionnaire and the WHOQOL-BREF). In the context of subject recruitment, initially 200 patients were approached for participation in the study, but ultimately only 120 patients participated in the study as 80 patients were excluded due to reasons described above. The research assistant who recruited study participants did explain to patients regarding the flexibility of the appointment arrangement but yet the patients refused to participate. Hence, we abide by the research ethics practice that patients should not be coerced to participate in the study and respected patients' decision.

5. Conclusion

In conclusion, this study is the first RCT to comprehensively investigate the effect of MBSR on the degree of QOL and its components among HNC patients across time, in comparison with TAU controls. A 6-week MBSR program has been shown to be effective in enhancing the overall QOL through the improvement of its social- and emotion-related components up to 12 weeks postintervention compared with treatment-as-usual where no significant changes in the overall QOL and its components were observed. MBSR also minimally improved the physical health-, functional-, and H & N-related QOL among HNC patients up to 12 weeks postintervention. Hence, MBSR may be considered as treatment regime to safeguard the mental health status of HNC patients. This study also integrates patient-reported outcome measures into routine oncology healthcare to promote a patient-centered approach. This promotes the ease of understanding on the actual concerns and issues experienced by cancer patients by treating clinicians to improve communication and to allow treatment decisions to be made involving patients and clinicians. This will facilitate the personal health goals and outcomes of patients to be set in order to improve symptom management and patient's compliance to treatment.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

The authors declare no conflicts of interest.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.

Supporting Information 1. Supporting File 1: The CONSORT guideline checklist for conduct of this randomized controlled trial.

Supporting Information 2. Supporting Table 1: The post hoc comparison of the FACT-HN-total and its domain scores between the MBSR and TAU control groups in each time point (T_0, T_1, and T_2) after controlling for confounding demographic and clinical characteristics (age of participants, monthly household income, marital status, employment status, mode of treatment received, types of HNC, and stages of cancer) and following last observation carry forward (LOCF).

Supporting Information 3. Supporting Table 2: Post hoc comparison of the changes in the FACT-HN-total and its domain scores across time points in the MBSR and the TAU control groups after controlling for confounding demographic and clinical characteristics (age of participants, monthly household income, marital status, employment status, mode of treatment received, types of HNC, and stages of cancer) and following last observation carry forward (LOCF).

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