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Effects of a mindfulness-based intervention versus a social contact control in alleviating loneliness among older adults: a randomised controlled trial

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ABSTRACT

Background Loneliness is highly prevalent among Chinese older adults. Mindfulness-based interventions for older adults (MBOA) have demonstrated potential in alleviating loneliness. However, few studies have employed active controls with long-term follow-up.

Objective This study aimed to assess the efficacy of MBOA in reducing loneliness compared with social contact control (SCC).

Methods This parallel, randomised controlled trial (RCT) assigned community-dwelling lonely Chinese older adults (≥60 years) in Hong Kong to MBOA or SCC. Both interventions comprised 8 weekly 1.5-hour group-based face-to-face sessions. Assessments were conducted at baseline, postintervention and at 6-month and 12-month postrandomisation. The primary outcome was loneliness score at 12 months, analysed using analysis of covariance under the intention-to-treat approach. Secondary outcomes included depression, anxiety, health-related quality of life and healthcare utilisation. Changes in psychological measures were analysed using linear mixed models.

Findings A total of 245 eligible participants were randomised to MBOA (n=123) or SCC (n=122). No significant between-group difference in primary outcome was found (mean difference=−0.14, p=0.52, effect size=−0.21), although both groups showed improvement in loneliness (within-group effect size: MBOA=−0.58, SCC=−0.31). MBOA participants reported reduced depressive symptoms and a decreasing trend in anxiety at 6 months compared with SCC.

Conclusion This is the first RCT examining efficacy of MBOA in alleviating loneliness among Chinese older adults using an active control with long-term assessments. MBOA is not superior to SCC in reducing loneliness, although it may reduce psychological symptoms.

Clinical implication Clinicians could consider prioritising mindfulness-based interventions for lonely older adults when depressive or anxiety symptoms are prominent.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Previous meta-analyses of group-based mindfulness-based interventions for loneliness showed small, non-significant effects with high risk of bias and small sample sizes.

⇒ No rigorous randomised controlled trials (RCTs) have examined group-based mindfulness interventions for loneliness in Chinese older adults using active control groups with long-term assessments.

WHAT THIS STUDY ADDS

⇒ This first large-scale RCT (n=245) found no between-group differences in loneliness reduction at 12 months between group-based mindfulness-based intervention and active social contact control among Chinese older adults.

⇒ Both interventions produced significant within-group improvements, with mindfulness showing additional benefits for depressive symptoms.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Findings challenge presumed superiority about mindfulness superiority over social engagement for loneliness, suggesting both approaches may be comparable in efficacy in community mental health programmes and supporting development of tailored interventions for specific subgroups.

BACKGROUND

Loneliness is defined as '*one's subjective feeling of social isolation, irrespective of one's objective social status*'[1] and is a state of distress that arises from a discrepancy between one's desired and actual social relationships.[2] It is different from objective social isolation, which solely describes the lack of relationships with others. Loneliness is associated with various chronic illnesses and all-cause mortality.[3] It is comparable in effect to other well-established risk factors such as cigarette smoking and obesity.[4]

Loneliness can result from dysfunctional or maladaptive ruminative social cognition, and lonely individuals pay more attention to negative social information.[5] Thus, people who experience loneliness tend to hold more negative social expectations and focus on and remember more negative social interactions, which in turn confirm their negative social expectations and behaviours.[6] Globally, one in five older adults is lonely, making it a global public health challenge. They are particularly affected by loneliness due to perceived deterioration of health and reduction in social resources.[7] Among the Chinese population, the prevalence of loneliness is notably higher, with 36.6% of older adults reporting some degree of loneliness,[8] and nearly half of older adults in Hong Kong reported feeling lonely.[9] The heightened prevalence of loneliness in the Chinese population is closely linked to Chinese cultural values that emphasise family support and emotional engagement, such as filial piety and collectivism.[10] Societal factors such as urban migration, diminished family interactions[10] and reduced social contact intensify the discrepancy between culturally shaped expectations and their actual experiences of support.[11]

Contemporary strategies typically focus on social facilitation and health promotion through group activities, health talks and recreational programmes. A comprehensive review of 101 unique intervention studies revealed that multicategory interventions were generally more effective, as they increased the likelihood that participants engage with at least one element they find beneficial. Notably, 78% of those aimed at altering maladaptive social cognition were effective or partially effective, outperforming those focusing on other intervention strategies.[12] A separate review reported similar findings for remotely delivered interventions.[13] These results align with the Cognitive Discrepancy Theory that cognition and attributions play a pivotal role in shaping the experience of loneliness and individuals' reaction and coping.[14] In this regard, merely increasing social opportunities is not sufficient, when the root cause of loneliness lies in how older adults perceive their social relationships. This issue is particularly salient in Chinese cultural contexts, where the gap between traditional family support expectations and actual experiences can exacerbate subjective loneliness.[10] Interventions grounded in social facilitation and social skills training are exemplified approaches that target social network building; however, they often have mixed findings of reducing loneliness.[15 16] Building on these insights, there has been a growing shift of attention to interventions that tackle the cognitive and emotional processes underpinning loneliness.

Mindfulness-based interventions (MBIs) present a promising approach, specifically addressing negative social cognition loops and ruminative thought patterns that affect the subjective experience of loneliness. Mindfulness is defined as '*the awareness that arises from paying attention, at the present moment, non-judgmentally*'.[17] MBIs typically include formal practices, such as walking meditation, sitting meditation, mindful eating, mindful movements and body scan.[18] Based on the Monitor and Acceptance Theory (MAT), beneficial mental health outcomes can be achieved by attention monitoring skills and experiential acceptance simultaneously, forming an emotional regulation mechanism. Mindfulness practice may foster emotion regulation through recurrent engagement and disengagement of emotional stimuli.[19] People who report higher levels of loneliness may have more belonging deficits, heightened social monitoring, intensified social memory and social anxiety.[5] Within MBIs, participants learn to recognise their automatic reactions in challenging situations, such as negative thoughts and feelings related to social interactions, and to relate to these experiences with greater awareness and acceptance. Through persistent mindful practices, participants gradually develop a sense of self-compassion, detaching from rigid social expectations and refraining from avoidance of negative social encounters. Instead of viewing their thoughts as reality, they develop a decentred perspective that can disrupt the negative social cognition loop.[20] It might help alleviate rumination in terms of heightened social memory and improve self-regulation of social anxiety emotions.

Although a recent meta-analysis of seven studies suggested that MBIs might alleviate loneliness, several notable limitations were identified.[21] Together with several studies that were beyond the scope of this review, most of them included in the meta-analysis had small sample sizes of fewer than 90 participants,[21–23] resulting in lower statistical power and reduced generalisability. In addition, a lack of an active control group limited the ability to account for non-specific group effects such as increased social contact and time spent on group activities.[22] The use of waitlist controls may have exaggerated the reported effects of MBIs, as participants in the control groups were often motivated by the prospect of receiving the intervention later but remained in the baseline or the suboptimal condition during the study period. Most studies included in the meta-analysis had a relatively short follow-up period from 2 weeks to 3 months,[21] low quality of evidence and a high risk of bias.[21] Additionally, few studies focused on older adults[24] or specifically targeted Chinese older adults.[25] Notably, a recently published study of individual telephone-based mindfulness-based intervention with a 3-month follow-up period and active control groups of behavioural activation and befriending provided important evidence for supporting the efficacy of mindfulness in alleviating loneliness among Chinese older adults in Hong Kong.[26] However, there remained limited understanding of how the effects can be maintained for a longer period and whether group-based mindfulness interventions are equally effective. These research gaps highlight the need for a high-quality study with a longer follow-up period that examines the efficacy of group-based MBI on loneliness among Chinese older adults.

Objective

This study aimed to examine the effectiveness of a group-based mindfulness intervention for Chinese older adults (MBOA) in Hong Kong, relative to a social contact control (SCC) group, in reducing loneliness and improving other health-related outcomes. Drawing on MAT, MBOA may reduce loneliness by interrupting negative cognitive loops and enhancing acceptance of social encounters. In contrast, SCC may primarily provide external social opportunities without targeting cognitive-emotional mechanisms. We therefore hypothesised that MBOA would result in a greater and more sustained reduction in loneliness levels compared with the active control SCC at 12 months. Additionally, we hypothesised that MBOA would lead to additional improvements in health-related quality of life, larger reductions in depressive and anxiety symptoms and less healthcare utilisation compared with SCC at 12 months.

METHODS

Study design

This was a 12-month parallel-arm randomised controlled trial (RCT), in which older adults were randomised to either MBOA intervention or SCC active control. The study was conducted in community settings in Hong Kong, specifically across six outpatient clinics.

Participants

We planned to recruit 240 participants in total. The inclusion criteria were: (1) aged 60 years or above; (2) a score of 3 or above on the validated Chinese six-item De Jong Gierveld Loneliness Scale signifying a presence of significant loneliness,[27] (3) normal cognitive functioning assessed by Montreal Cognitive Assessment conducted by trained personnel such that they could understand the materials delivered in mindfulness training and could complete home practice every week[28]; and (4) receiving stable dosages of psychiatric medication(s) for 3 months or more, if any. Exclusion criteria were: (1) inability to communicate in Chinese; (2) possession of a medical or mental health condition rendering him/her incapable of participating; and (3) previous participation in a structured mindfulness-based training lasting more than or equal to 4 weeks. Potential participants were screened with inclusion and exclusion criteria by trained research staff online or face-to-face. An individual interview was scheduled with the investigators to explain the study details and confirm eligibility.

Randomisation and masking

Included participants were randomised in a 1:1 ratio by simple randomisation to the MBOA group and the SCC group. The randomisation sequence was generated by an experienced independent statistician using computer-generated random numbers. Group allocation was handled by a trained research assistant, concealed by using sequential, sealed and opaque envelopes, which were opened only after written consent was obtained. Allocation was not allowed to change after randomisation. The statistician and the personnel involved in manuscript preparation were blinded from group allocation.

Procedures

Intervention: MBOA

The MBOA was modified from the well-established group-based mindfulness-based stress reduction (MBSR) programme, consisting of 8 weekly mindfulness classes.[29] The intervention protocol was adapted to 90 min sessions without a full-day retreat, implementing adjustments for age-related physical/cognitive limitations. This aligns with gerontological evidence demonstrating streamlined protocols reduce fatigue while preserving therapeutic fidelity, as abbreviated formats prevent cognitive overload through focused engagement.[30] MBOA was shown to improve psychological well-being in local older adults in a previous study.[29] Each MBOA group consisted of 9–18 participants. Participants were encouraged to practice mindfulness for 30 min per day as homework, which was recorded by participants' diary. The MBOA instructors were trained clinical psychologists who had completed a teacher training programme on an 8-week mindfulness course, either MBSR or mindfulness-based cognitive therapy. The content of each session of MBOA is detailed in online supplemental table S1.

Active control: group SCC

The SCC provided the same amount of contact time (8 weekly 90 min sessions) as the MBOA to control for non-specific effects such as increased opportunities for social contact that could have accounted for the positive effects on loneliness. These social contact activities were the usual activities for older adults, including health talks, physical activities and Bingo games organised in the community centres with the aim to improve cognitive ability (online supplemental table S2). These sessions were administered by a health professional with at least 2 years of experience facilitating group activities for older adults. Participants were asked to listen to music for 30 min daily to control for the MBOA homework practice.

Both intervention and control groups were delivered face-to-face, divided into nine batches. Except sharing the experience of mindful practice in the MBOA group and the Bingo games in the SCC group, no other interactions were encouraged among participants and the facilitators outside classes. The intervention fidelity was assessed by audiotaping all group sessions. An independent expert in mindfulness training, who was also a health professional, randomly reviewed 20% of all audiotapes (15 sessions of MBOA) and rated the levels of adherence to the intervention protocol and facilitators' competence. Checklists were modified by an expert panel including psychologists according to the treatment manuals referring to the 17-item Mindfulness-Based Cognitive Therapy Adherence Scale.[31]

Outcome measures

Assessments of primary and secondary outcomes were conducted with self-administered, paper-based questionnaires at baseline (T0), immediately after the 8-week intervention (T1), at 6 months postrandomisation (T2) and at 12 months postrandomisation (T3). Demographic data, including age, gender, educational level, occupation, marital and living status, household income and medical history were collected at baseline. The programme evaluation form was collected at postintervention (T1).

Primary outcome

The primary outcome was the level of loneliness, as assessed by the validated Chinese *Six-item De Jong Gierveld Loneliness Scale* at T3. The scale has good psychometric properties and has been validated among Chinese older adults in Hong Kong.[27] It has a total score and two subscale scores (ie, emotional loneliness and social loneliness). Higher scores indicate a higher level of loneliness, with a score range of 0–6. A total score of 3 or more indicates a presence of loneliness.

Secondary outcomes

Depressive and anxiety symptoms were measured by The Patient Health Questionnaire-9 and the State-Trait Anxiety Inventory, respectively.[32 33] These two scales are widely used, reliable and valid tools assessed with Hong Kong population or Chinese communities.[34 35] *Health-related quality of life* was measured by the EuroQol 5-Dimension 5-Level Index Scores questionnaire and its EuroQol Visual Analogue Scale.[36] It possesses good validity and is widely used for health-related research in the Hong Kong context.[37] Furthermore, *healthcare utilisation* was measured by the number of visits to different medical facilities in the past 3 months. These facilities included public (general outpatient, specialty), private (general, family doctor, specialty, hospital outpatient), Chinese medicine, geriatric day hospital and elderly health centre.

Adverse events (AEs) and serious adverse events (SAEs) were monitored through participant self-reports throughout the study period. Upon receiving an AE/SAE report from participants, the research team followed the procedures outlined in the Standard Operating Procedure handbook from the research ethics committee, which included submitting a formal report to the committee and providing follow-up to the participant until the event was resolved. All reports were subsequently reviewed by an independent SAE review panel within the research ethics committee.

Sample size calculation

Sample size calculation was based on available previous studies before this trial. A study employing an 8-week MBSR intervention for lonely older adults reported a large effect size.[38] Another study examining the effect of a 2-week smartphone-based mindfulness training of both monitoring and acceptance to reduce loneliness in adults had an effect size of 0.44 when comparing pre-intervention and post-intervention.[20] In this study, we conservatively used the effect size of d=0.40. Using a type I and type II error of 5% and 20%, respectively, and a test of two independent groups, the required sample size was 99 participants per arm. With a conservative estimate of about 15% dropout rate based on our previous studies, we aimed to recruit 240 older adults with loneliness in total.

Statistical analysis

Mean and SD, as well as frequency and percentage, were used to describe the sociodemographic characteristics and outcomes at baseline. Independent samples t-tests and χ^2 tests were used to compare continuous and categorical variables between two groups. The primary analysis used analysis of covariance (ANCOVA) to compare between-group differences in loneliness levels at T3, adjusting for baseline loneliness scores. As a secondary analysis, ANCOVA was also applied to examine between-group differences in secondary outcomes at T3. Between-group effect size estimates were calculated by dividing the difference in mean change scores (T3–T0) between groups by the pooled SD of the change scores. Within-group effect size estimates were calculated separately for each group using the means and SDs of the change scores, along with the correlation between baseline and T3.

Linear mixed models (LMMs) were employed to evaluate both short-term and long-term longitudinal effects of intervention outcomes across three time points (from postintervention (T1), 6-month (T2) to 12-month (T3) postrandomisation). In these models, intervention group, time and their interaction term were treated as fixed factors, with baseline values included as covariates. An unstructured covariance matrix was used to account for within-subject correlations, while a variance components structure was applied to model random effects. Adjusted mean differences (AMDs) and corresponding 95% CIs were derived from estimated marginal means to compare outcomes between groups at each time point. Missing data were addressed using full information maximum likelihood, which incorporated all available data to estimate the model parameters under the assumption of missing at random. For within-group comparisons, separate LMMs were conducted for each group. Outcome measure scores were served as dependent variables, with time included as a fixed effect to evaluate changes across follow-up assessments.

Between-group differences in healthcare utilisation at each follow-up were assessed using ANCOVA, adjusting for baseline utilisation level. Dropout was compared across group assignment, demographic variables and study batch.

Post hoc moderation analyses were conducted using ANCOVA models to evaluate whether baseline secondary outcomes and demographic characteristics moderated the intervention effect on overall loneliness at T3. Interaction terms (Group×Moderator) were included in the models, with baseline loneliness scores entered as a covariate. For interactions involving categorical demographic variables that reached statistical significance or were marginally non-significant (p<0.1), subgroup analyses were conducted for each category to assess between-group differences.

All analyses were conducted under the intention-to-treat principle. To enhance interpretability,[39] per-protocol (PP) analyses were also performed using both ANCOVA and LMM approaches for the primary and secondary outcome scores, with treatment compliance defined as attendance at five or more of the eight intervention sessions. Statistical significance was set at a two-sided p value of 0.05 or less. Analyses were conducted using IBM SPSS V.30. No data monitoring committee was set up because the study used a low-risk, non-drug intervention in a community setting.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation or writing of the report.

Findings

Between 28 February 2021 and 12 July 2023, a total of 885 subjects were screened, from which 245 eligible participants were recruited and randomly assigned to either MBOA (n=123) or SCC (n=122). Figure 1 presents the Consolidated Standards of Reporting Trials (CONSORT) diagram for the flow of participants. The average age and percentage of female were 68.18 years (SD=5.29) and 82.1% in MBOA; and 68.12 years (SD=4.88) and 90.2% in SCC, respectively. Baseline characteristics were generally comparable between groups in terms of loneliness, depressive symptoms, anxiety symptoms, health-related quality of life, healthcare utilisation and sociodemographic variables (table 1). The mean number of classes attended was 6.19 (SD=2.29) for the MBOA group, while 5.43 (SD=2.59) for the SCC group. The difference in attendance between the two groups was statistically significant (MD=0.76, p=0.02). A total of 188 participants attended five or more sessions, with 99 from the MBOA group and 89 from the SCC group.

The primary ANCOVA analysis included 168 participants (MBOA: 83; SCC: 85). Participants who did not return the 12-month postrandomisation questionnaire were excluded. The result showed no significant differences between MBOA and SCC groups at T3 for overall loneliness (MD=−0.14, 95% CI −0.55 to 0.28, p=0.52, effect size=−0.21), emotional loneliness (MD=−0.11, 95% CI −0.40 to 0.17, p=0.44, effect size=−0.23) and social loneliness (MD=−0.02, 95% CI −0.30 to 0.25, p=0.87, effect size=−0.06) (table 2). Similarly, no significant between-group differences were found across all secondary outcomes at T3, with PP analysis confirming consistent results for both primary and secondary outcomes. Despite the non-significant between-group difference, both groups demonstrated significant within-group improvements in overall loneliness scores at T3 compared with baseline (MBOA: MD=−0.71, 95% CI −1.04 to −0.38, p<0.001, effect size=−0.58; SCC: MD=−0.41, 95% CI −0.72 to −0.10, p=0.01, effect size=−0.31). Although there was no significant difference in any type of healthcare utilisation between groups at T3, the MBOA group reported significantly lower use of private medical services at T2 (general: MD=−0.46, family: MD=−0.30) and lower use of public medical service at T1 (general: MD=−0.47) compared with the SCC group (online supplemental table S3). However, these reductions were not maintained at T3, suggesting short-term effects on healthcare utilisation patterns of these medical facilities.

Figure 2 illustrates the trajectories of overall loneliness level in both groups over the study period across T0, T1, T2 and T3, based on estimated means and 95% CIs generated by LMMs. Significant group-by-time interaction effects from

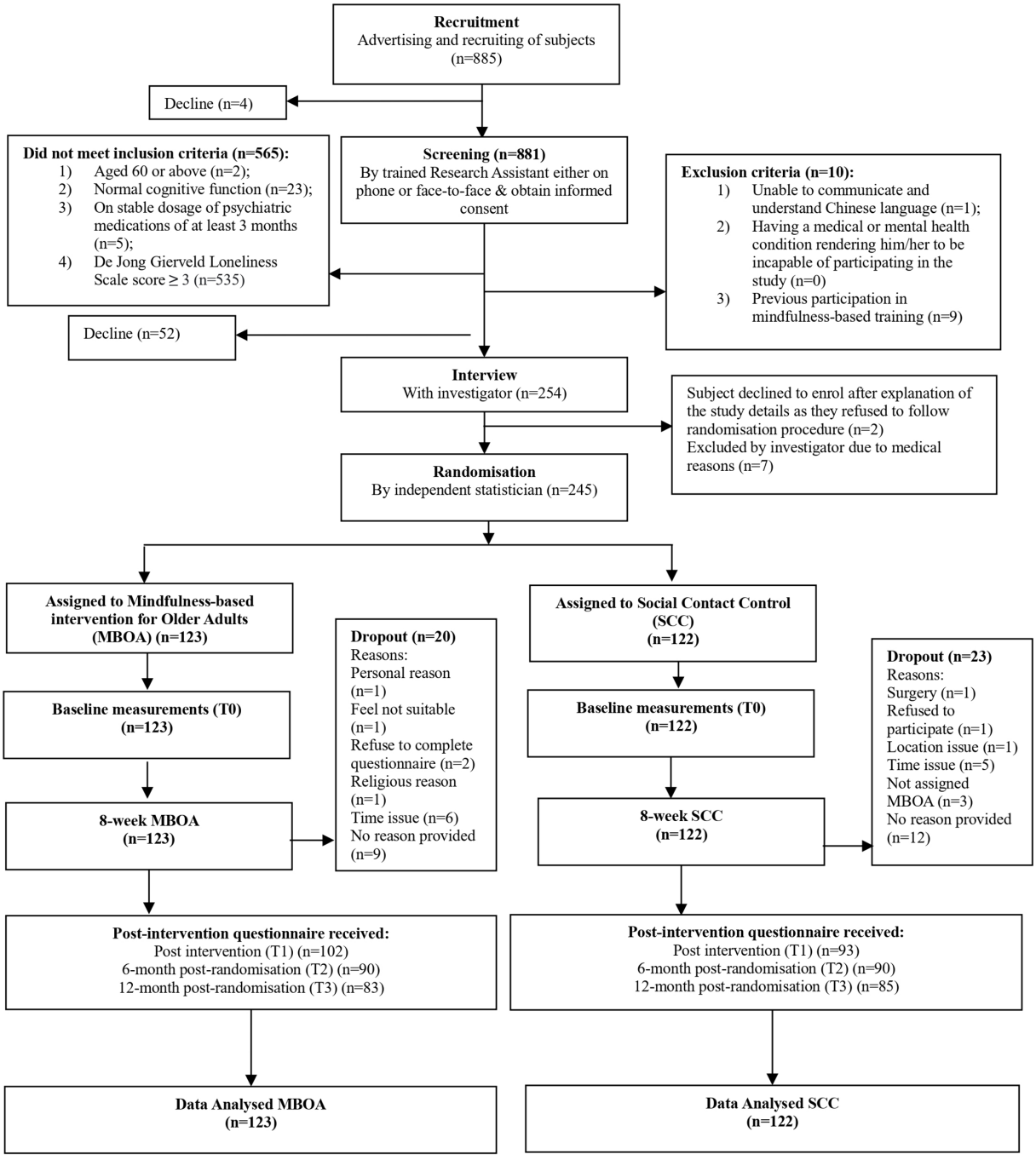

Figure 1 Consolidated Standards of Reporting Trials diagram. MBOA, mindfulness-based interventions for older adults; SCC, social contact control.

LMMs indicated that the trajectories of anxiety outcomes differed between groups over time (online supplemental table S4). The MBOA group showed reductions in state anxiety at T2 (interaction term=−3.09) and in trait anxiety at both T2 (interaction term=−1.75) and T3 (interaction term=−1.81), whereas anxiety levels increased relative to T1 in the SCC group. However, AMDs at these time points were not statistically significant, suggesting that although the patterns of change differed, the differences in adjusted means at each time point were not sufficient to reach significance. In contrast, between-group comparisons at T2 showed significantly lower depressive symptoms (AMD=−1.14) and better quality of life (AMD=0.05) in the MBOA group, despite non-significant interaction terms. This reflects group differences at T2 without compelling evidence of differing trajectories over time. No significant between-group differences were observed for the primary outcome of loneliness or other secondary outcomes at any time point including T1, T2 and T3.

Similar results were observed in the PP analysis using LMMs (online supplemental table S5). However, the interaction effect for trait anxiety (p=0.08) and the AMD for quality of life (p=0.07) at T2 became marginally non-significant after excluding participants who attended fewer than five sessions.

Within-group comparisons revealed significant improvements in overall and emotional loneliness only at T3 in the MBOA group, while no significant changes were observed in the SCC group for any loneliness measures at any time points. For other secondary outcomes, the only significant finding was an increase

Table 1 Baseline characteristics of participants

	MBOA (n=123)	SCC (n=122)	Total (n=245)	P value
Age (years) (mean, SD)	68.18±5.29	68.12±4.88	68.15±5.08	0.93
Gender (n, %)				
Male	22 (17. 9%)	12 (9.8%)	34 (13.9%)	0.07
Female	101 (82.1%)	110 (90.2%)	211 (86.1%)	
Education				
No education (n, %)	2 (1.6%)	1 (0.8%)	3 (1.2%)	0.68
Primary (n, %)	31 (25.2%)	25 (20.8%)	56 (22.9%)	
Secondary (n, %)	54 (43.9%)	61 (50.8%)	115 (46.9%)	
Tertiary or above (n, %)	36 (29.3%)	33 (27.5%)	69 (28.2%)	
Occupation				
Full-time (n, %)	2 (1.6%)	1 (0.8%)	3 (1.2%)	0.37
Part-time (n, %)	12 (9.8%)	8 (6.6%)	20 (8.2%)	
Housewife/husband (n, %)	18 (14.6%)	27 (22.3%)	45 (18.4%)	
Retired (n, %)	91 (74.0%)	85 (70.2%)	176 (71.8%)	
Marital status				
Single (n, %)	25 (20.3%)	24 (19.8%)	49 (20.0%)	0.93
Married and cohabitant (n, %)	64 (52.0%)	60 (49.6%)	124 (50.6%)	
Divorced (n, %)	12 (9.8%)	14 (11.6%)	26 (10.6%)	
Widowed (n, %)	21 (17.1%)	22 (18.2%)	43 (17.6%)	
No response (n, %)	1 (0.8%)	1 (0.8%)	2 (0.8%)	
Number of people living together including oneself (mean, SD)	2.0±1.2	1.8±0.8	1.9±1.0	0.19
Household income (HKD)				
No income (n, %)	47 (38.5%)	37 (31.9%)	84 (35.3%)	0.44
Below $5000 (n, %)	19 (15.6%)	19 (16.4%)	38 (16.0%)	
$5000–$9999 (n, %)	10 (8.2%)	15 (12.9%)	25 (10.5%)	
$10 000–$19 999 (n, %)	21 (17.2%)	17 (14.7%)	38 (16.0%)	
$20 000–$29 999 (n, %)	6 (4.9%)	12 (10.3%)	18 (7.6%)	
$30 000–$39 999 (n, %)	8 (6.6%)	7 (6.0%)	15 (6.3%)	
$40 000–$49 999 (n, %)	7 (5.7%)	2 (1.7%)	9 (3.8%)	
$50 000 or more (n, %)	4 (3.2%)	7 (6.0%)	11 (4.6%)	
Presence of chronic condition				
Yes (n, %)	101 (82.1%)	108 (88.5%)	209 (85.3%)	0.16
No (n, %)	22 (17.9%)	14 (11.5%)	36 (14.7%)	
Healthcare utilisation in past 3 months (mean, SD)				
Public (general outpatient)	1.65±1.71	2.07±1.83	1.86±1.78	0.07
Public (specialty)	1.44±1.48	1.92±1.99	1.68±1.76	0.04
Private (general)	0.76±1.25	0.66±1.47	0.71±1.36	0.61
Private (family)	0.44±0.94	0.37±1.01	0.41±0.97	0.60
Private (specialty)	0.43±1.22	0.57±1.27	0.50±1.24	0.37
Chinese medicine	1.97±2.43	1.93±2.53	1.95±2.48	0.90
Private (hospital outpatient)	0.10±0.38	0.16±0.58	0.13±0.49	0.35
Geriatric day hospital	0.10±0.57	0.05±0.27	0.07±0.45	0.42
Elderly health centre	0.29±1.07	0.34±1.02	0.32±1.04	0.72
Loneliness (DJGLS total score)	4.84±1.05	4.64±1.09	4.74±1.07	0.15
Emotional loneliness	2.15±0.87	1.98±0.89	2.07±0.88	0.15
Social loneliness	2.69±0.70	2.66±0.74	2.67±0.72	0.70
PHQ-9	8.19±5.16	8.11±4.98	8.15±5.06	0.90
STAI—State	47.16±9.82	46.34±10.55	46.24±10.35	0.53
STAI—Trait	49.28±7.64	48.53±9.03	48.35±8.82	0.49
EQ-5D-5L index	0.78±0.15	0.73±0.22	0.76±0.19	0.05
EQ-VAS	69.12±15.59	69.21±17.74	69.17±16.66	0.97

DJGLS, De Jong Gierveld Loneliness Scale; EQ-5D-5L index, EuroQol 5-Dimension 5-Level Index Score; EQ-VAS, EuroQol Visual Analogue Scale; MBOA, mindfulness-based interventions for older adults; PHQ-9, Patient Health Questionnaire-9; SCC, social contact control; STAI, State-Trait Anxiety Inventory.

in state anxiety at T2 in the SCC group (online supplemental table S6).

The number of dropouts was comparable between the two groups (MBOA: n=20; SCC: n=23), with time constraints being the most common reason. Before the intervention commenced, 11 participants withdrew (MBOA: n=3; SCC: n=8). Reasons included time constraints (MBOA: n=2; SCC: n=1), and single cases of surgery, disappointment with group assignment and location issues in the SCC group. Five participants did not provide reasons (MBOA: n=1; SCC: n=4). During the intervention period, 25 participants withdrew (MBOA: n=13; SCC: n=12). Reasons included time constraints (MBOA: n=3; SCC: n=3), and single cases attributed to refusal to complete questionnaires, personal reasons, perceived lack of appropriateness

Table 2 Analysis of between-group difference in primary and secondary outcomes at T3

	MBOA (n=83)	SCC (n=85)	Between-group*		
	Estimated marginal means (SE)		Mean difference (95% CI)	P value	Effect size estimates (95% CI)†
Overall loneliness	4.11 (0.15)	4.25 (0.15)	−0.14 (−0.55, 0.28)	0.52	−0.21 (−0.51, 0.10)
Emotional loneliness	1.56 (0.10)	1.67 (0.10)	−0.11 (−0.40, 0.17)	0.44	−0.23 (−0.54, 0.07)
Social loneliness	2.55 (0.10)	2.58 (0.10)	−0.02 (−0.30, 0.25)	0.87	−0.06 (−0.37, 0.24)
PHQ-9	6.25 (0.45)	6.73 (0.44)	−0.48 (−1.73, 0.77)	0.45	−0.16 (−0.46, 0.15)
STAI—State	44.80 (0.93)	45.06 (0.91)	−0.26 (−2.84, 2.32)	0.84	−0.08 (−0.39, 0.23)
STAI—Trait	46.07 (0.69)	47.27 (0.68)	−1.20 (−3.11, 0.72)	0.22	−0.24 (−0.55, 0.06)
EQ-5D-5L index	0.75 (0.02)	0.75 (0.02)	0.004 (−0.05, 0.06)	0.89	−0.05 (−0.36, 0.26)
EQ-VAS	68.28 (1.98)	64.65 (1.93)	3.63 (−1.83, 9.09)	0.19	0.19 (−0.12, 0.49)

This table considers only those who filled out both T0 and T3 questionnaires.
*ANCOVA comparing MBOA and SCC group in scores at T3 with baseline score as covariate (means of MBOA minus means of SCC).
†Effect sizes (Cohen's d) were computed by dividing the between-group difference in mean change scores (T3–T0) by the pooled SD of those change scores.
ANCOVA, analysis of covariance; DJGLS, De Jong Gierveld Loneliness Scale; EQ-5D-5L index, EuroQol 5-Dimension 5-Level Index Scores; EQ-VAS, EuroQol Visual Analogue Scale; MBOA, mindfulness-based interventions for older adults; PHQ-9, Patient Health Questionnaire-9; SCC, social contact control; STAI, State-Trait Anxiety Inventory.

of the intervention and religious concerns in the MBOA group, and disappointment with group assignment (n=2) and refusal to participate (n=1) in the SCC group. Twelve participants did not provide reasons (MBOA: n=6; SCC: n=6). Between T1 and T2, seven participants withdrew (MBOA: n=4; SCC: n=3). Reasons included time constraints (MBOA: n=1; SCC: n=1) and questionnaire refusal (MBOA: n=1), while four participants did not disclose their reasons (MBOA: n=2; SCC: n=2).

Dropout rates were significantly associated with study batches, dropping from 8 to 11 participants in the first three batches to just 1–4 in the last three. Dropout was not significantly associated with age, gender or education level. Even after adjusting for batch (grouped as batch 1–3, 4–6 and batch 7–9), the ANCOVA revealed no significant differences between MBOA and SCC groups at T3 in overall loneliness, emotional loneliness or social loneliness.

Moderation analysis indicated a marginally significant moderating effect of marital status on the intervention's impact on overall loneliness at T3, with results favouring the MBOA group (p=0.05). Subgroup analysis revealed that among divorced participants, the MBOA group was significantly more effective in reducing loneliness (MD=−1.59, 95% CI −2.60 to −0.59, p=0.004). No significant moderating effects were observed for other secondary outcomes or demographic characteristics (online supplemental table S7a and b).

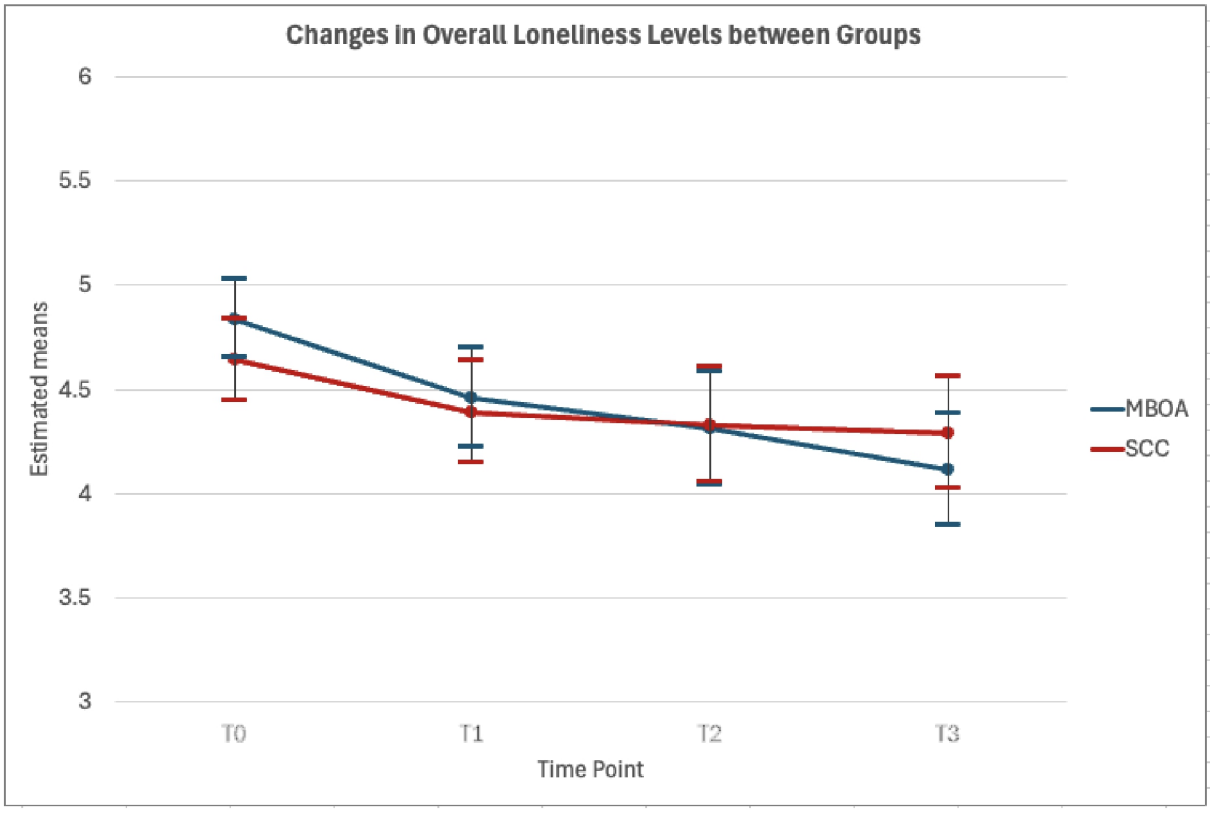

Figure 2 Overall loneliness levels at each time point for MBOA and SSC. MBOA, mindfulness-based interventions for older adults; SCC, social contact control.

The MBOA was delivered according to the protocol. Out of the 15 sessions being reviewed, 11 (73.3%) sessions were highly adherent to the protocol (mean=2.55, SD=0.48), while for the facilitators' competence, 13 (86.7%) sessions were rated good (mean=5.13, SD=0.75). MBOA participants rated the programme as more helpful and reported greater satisfaction compared with SCC participants. However, they also found the programme more challenging and felt it was less aligned with their expectations (online supplemental table S8).

One SAE was reported during the study period. A participant in the intervention group was hospitalised due to high blood pressure and neck pain associated with lumps in the neck region. The event was assessed as unrelated to the intervention. The participant resumed study participation following hospitalisation.

DISCUSSION

To our knowledge, this is the first and the largest RCT to date investigating the effectiveness of group-based MBI in alleviating loneliness in Chinese older adults, using an active control group as comparison with long-term assessments at 12 months. The primary analysis showed no significant between-group differences in loneliness at T3. Thus, the results did not support the hypothesis that MBOA would be more effective than SCC in alleviating loneliness among older adults. Notably, among divorced individuals, the MBOA group was more effective in reducing loneliness at T3. The MBOA group showed a trend of longer-term improvement in loneliness at T3, but the modest magnitude of change did not reach statistical significance compared with the SCC group, in which no such trend was observed. While research on mindfulness-based approaches for loneliness remains limited,[40] this study adds to the emerging evidence base by showing that it may be beneficial for older adults with loneliness.

Previous systematic reviews have reported inconsistent evidence for the effectiveness of MBI in reducing loneliness among older adults. Teoh and colleagues noted that studies reporting positive effects of mindfulness often employed no-treatment or waitlist control groups,[21] making it difficult to attribute improvements solely to mindfulness practice. Similarly, in Patil and Braun's review of reviews,[12] despite evidence supporting the effectiveness of psychosocial interventions in various kinds, nearly all these RCTs targeting loneliness in older adults reporting positive results compared the intervention to a waitlist control or care as usual, rather than with active controls. These findings underscore a methodological limitation in the existing literature, the lack of comparison with active interventions that provide equivalent social engagement and group experiences. The present RCT addressed this gap by comparing MBOA with an active control (SCC). Contrary to our expectation, the MBOA group was not superior to the SCC group in reducing loneliness. This aligns with previous less common RCTs comparing MBI to active control groups, such as spiritual therapy,[23] health enhancement programme[25] and behavioural activation with peer support,[26] which also found no significant between-group differences.

One plausible interpretation is that loneliness in older adults may be responsive to multiple forms of meaningful engagement rather than to specific therapeutic content of mindfulness alone. In this sense, both the MBOA and SCC groups may have provided the older adults with comparable benefits through non-specific group effects, such as social engagement, purpose-driven structured group activities and positive expectations, which can foster modest improvements in their well-being. Furthermore, the lack of group differences may also reflect the chronic and cumulative nature of loneliness in later life-course experiences in older adults, which is often related to the loss of a partner, reduced social engagement, increased physical limitations and emotional distress.[40] Evidence indicates that interventions fostering productive engagement involving active and creative participation are particularly effective in reducing loneliness.[15]

Notably, older adults who experience loneliness often also present with coexisting symptoms of anxiety, characterised by fear of social interactions and negative evaluations.[41] The current findings, which showed MBOA's additional benefits in decreasing anxiety over a longer period, support the role of mindfulness in targeting such comorbidity. MBIs may offer a more integrated approach, being particularly suitable for lonely older adults with concurrent mood or anxiety symptoms. Health professionals may tailor intervention recommendations based on older adults' concerns and social environment to optimise outcomes.

In line with evidence that marital status significantly influences loneliness,[7] this study found a moderation effect indicating that the MBOA group may be particularly beneficial for divorced older adults. Divorced older adults, who often experience loneliness alongside social stigma and relatively complex family dynamics, may be more responsive to MBI, which emphasises acceptance and self-care. They may face unique relational challenges, stemming from typically difficult or troubled loss of a relationship. Mindfulness may be beneficial for managing loneliness and social expectations through non-judgmental observation and emotional regulation. This approach may increase self-awareness and self-care, which may support other relationships in the future. Aligned with the previous findings, the MBOA group showed greater effectiveness in reducing healthcare utilisation.[42] This effect may be attributed to improvement in emotional well-being, enhanced quality of life and reduced somatic complaints among participants in the MBOA group.

Within-group analysis revealed a reduction in overall and emotional loneliness in the MBOA group. The findings of this study can be conceptually explained by the existing MAT[19] and cognitive model of loneliness,[2] though the mechanisms were not directly tested in this trial. According to MAT, mindfulness may enhance the awareness and acceptance of emotional experiences when facing negative social interactions and detachment from cognition arising from these experiences. These processes may foster the management of affective and cognitive components of loneliness, such as internalised negative social appraisals. Detailed mediation analyses of rumination, monitoring and acceptance were beyond the scope of this paper and will be explored in future research. Nevertheless, the pattern of findings of the reduced anxiety and loneliness aligns with the proposition that mindfulness may alleviate loneliness through enhanced acceptance and reduced reactivity to negative social circumstances.

MBOA demonstrated a higher attendance rate, better retention and received more positive feedback regarding perceived helpfulness and satisfaction. Compared with intervention delivered by trained volunteers,[26] a group-based format offered by health professionals appeared to be better received, suggesting better potential for implementation in real-world settings if trained health professionals who can deliver MBI are available.

The underlying mechanisms through which MBOA could mitigate loneliness and reduce healthcare utilisation require further investigation. Furthermore, whether mindfulness is particularly effective among older adults with both loneliness and clinically relevant depressive and anxiety symptoms will require further

studies with a larger sample size in this population. Finally, research investigating the effectiveness of interventions specifically for divorced older adults would contribute to building a more comprehensive approach to reducing loneliness.

Strengths and limitations

The large sample size in this study enhanced the robustness and reliability of the findings. The inclusion of an active control group accounted for the potential benefits of social interaction and structured activities. Assessing multiple secondary outcomes enabled the exploration of intervention mechanisms and additional effects. Finally, the 12-month follow-up period allowed for evaluation of the intervention's long-term sustainability.

Like most psychosocial RCTs, participants' blinding was not possible, though outcome assessors and statisticians were blinded. The study faced substantial external influences of COVID-19. However, the research personnel tried to minimise the impact of social distance restrictions by arranging the interventions when the corresponding measures were lessened. All interventions were able to be implemented in person. Besides, a higher proportion of female participants may affect generalisability. Also, the subgroup findings on marital status were based on small sample sizes, which limits the statistical power and precision of these findings. As such, readers should interpret the observed effects with caution and consider them exploratory rather than conclusive. In addition, future qualitative research may help identify facilitators contributing to the higher attendance rates observed in the MBOA group.

Conclusion and clinical implications

We have demonstrated that both MBOA and social contact group appear to be potentially feasible interventions for alleviating loneliness among older adults. Further research is needed to further explore whether mindfulness may have additional benefits in alleviating depressive and anxiety symptoms among older adults with loneliness.

Clinicians could consider prioritising MBIs for lonely older adults when depressive or anxiety symptoms are prominent, and implementing MBIs in community or primary care settings to support holistic care for ageing populations.

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