Effects of Mindfulness-Based Stress Reduction on the Mental Health of Clinical Clerkship Students: A Cluster-Randomized Controlled Trial

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Abstract

Purpose
To examine the effect of mindfulness-based stress reduction training (MBSR) on the mental health of medical students during clinical clerkships.

Method
Between February 2011 and May 2014, the authors conducted a cluster-randomized controlled trial of clerkships as usual (CAU) and clerkships with additional MBSR in medical students during their first year of clinical clerkships at a Dutch university medical center. MBSR consisted of eight weekly two-hour sessions, comprising didactic teaching, meditation exercises, and group dialogues. Students completed online assessments at baseline and after 3, 7, 12, 15, and 20 months. Outcome measures were psychological distress, positive mental health, life satisfaction, physician empathy, mindfulness skills, and dysfunctional cognitions as measured by validated tools.

Results
Of 232 eligible students, 167 students (72%) participated and were randomized by clerkship group into MBSR (n = 83) or CAU (n = 84). The MBSR group reported a small reduction of psychological distress (P = .03, Cohen's d = 0.20) and dysfunctional cognitions (P = .05, Cohen's d = 0.18) and a moderate increase of positive mental health (P = .002, Cohen's d = 0.44), life satisfaction (P = .01, Cohen's d = 0.51), and mindfulness skills (P = .05, Cohen's d = 0.35) compared with CAU during the 20-month follow-up. The authors detected no significant effect on physician empathy (P = .18, Cohen's d = 0.27).

Conclusions
MBSR appeared feasible and acceptable to medical clerkship students and resulted in a small to moderate improvement of mental health compared with CAU over the 20-month follow-up.

Most medical students begin to experience the full effect of their future profession for the first time during their clinical clerkships. These senior years of medical school, in which students rotate through different medical specialties, can be stressful because of the high workload and professional socialization process.[1,2] Levels of overall psychological distress among U.S. and Canadian medical students are higher than in the general population and age-matched peers.[3] Prevalence rates outside these two nations vary widely (12%–97%), and higher-quality studies report lower prevalences.[4]

Compared with psychological distress, there is a paucity of literature on positive mental health in medical students, although Dyrbye and colleagues suggest that positive mental health attenuates some adverse consequences of burnout.[5] According to Ryff and Keyes,[6] positive mental health consists of the six dimensions of psychological well-being: self-acceptance, positive relationships, autonomy, ability to master one's environment, purpose in life, and personal growth. In later research, Keyes[7] added aspects of emotional and social well-being to these dimensions. Keyes[7,8] has shown repeatedly that positive mental health is not just the opposite of psychological distress but is actually an independent contributor to psychosocial functioning over and above psychological distress.

A possible intervention to reduce distress and increase positive mental health is mindfulness-based stress reduction training (MBSR), an eight-week group training program that teaches participants to be aware of bodily sensations, thoughts, and emotions in a curious, nonjudgmental attitude.[9]

Effects of MBSR on preclinical medical students have previously been examined by Shapiro and colleagues,[10] who conducted a randomized waitlist controlled trial. Compared with the control group (n = 36), students who chose MBSR as an enrichment elective (n = 37) reported a significant reduction in depression, in both state and trait anxiety, and in psychological distress, plus a significant increase in empathy and spirituality.[10] Authors of a second, nonrandomized, cohort-controlled study found a significant reduction in psychological distress in students who chose to participate in a 10-week MBSR seminar (n = 140) in comparison with those participating in a seminar on complementary medicine (n = 160).[11] In both studies, the participants were self-selected, the response rates were modest, and the authors did not report follow-up data. A more recent randomized controlled trial conducted by Erogul and colleagues[12] has reported less perceived stress and more self-compassion in students participating in MBSR (n = 30) than those allocated to the control group (n = 28); however, after six months, only the difference in self-compassion continued.

Two studies have focused on the effect of mindfulness on clinical clerkship students. Garneau and colleagues[13]

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described a significant reduction in depression, emotional exhaustion, and perceived stress and a significant increase in self-compassion and mindfulness after a four-week mindfulness elective (n = 58); however, this study lacked both a control group and a follow-up. A set of investigators conducting a randomized controlled trial comparing the eight-week use of a 30-minute, CD-based mindfulness exercise with treatment as usual demonstrated a reduction of perceived stress, which was maintained at eight weeks post intervention.[14] So far, to our knowledge, no authors have reported the effectiveness, including the long-term effectiveness, of the classical eight-week MBSR integrated into clinical clerkships.[15–18]

In their survey of 14 medical schools offering mindfulness training, Dobkin and Hutchinson[17] reported that although such training might be useful, issues regarding timing, format, and long-term effect remained unresolved. In our current study, we have addressed some of these issues by examining the effects of MBSR on both psychological distress and positive mental health, by integrating the intervention into the existing curriculum, and by including long-term follow-up. We hypothesized that MBSR would reduce psychological distress and improve the positive mental health of clinical clerkship students.

Method

Design and setting

We conducted a cluster-randomized controlled trial of MBSR during clinical clerkships versus clinical clerkships as usual (CAU) in first-year clinical clerkship students (who are similar to late second- or early third-year U.S. or Canadian students) of the Radboudumc in Nijmegen, the Netherlands (Figure 1). Recruitment took place between February 2011 and August 2012, and follow-up assessments lasted until May 2014. The medical curriculum in Nijmegen consists of three years of preclinical bachelor study and three years of master study, which involve rotating through a fixed order of hospital placements alternated with short periods of didactic classroom teaching.

We informed the students about the trial during classroom teaching in the fifth month of their clerkships. Interested students left their e-mail address and received an information leaflet by e-mail within two days, thus enabling them to decide to participate (or not) outside of the teaching environment free of any external pressure. Students did not receive any incentives for participation. Students unwilling to participate indicated their lack of interest by not leaving their e-mail address at the time of invitation, by not replying to the e-mail with the information leaflet, or by stating that they were not interested in participation in their reply to the invitation e-mail. We asked nonparticipants if they would be willing to complete the baseline assessment for the sake of assessing possible selection bias.

After providing informed consent, the students willing to participate in the trial completed an online baseline assessment, and we sent links to follow-up assessments 3, 7, 12, 15, and 20 months after baseline, during periods of didactic classroom teaching. We purposefully sent these assessments between (not during) clerkships to avoid variations in measures due to the nature of the clerkship. We did not inform instructors and supervisors of subsequent placements about student participation in the study, to preclude students from different groups being treated differently. The medical ethical research committee of Arnhem-Nijmegen approved the trial.

Participants

During the recruitment period, between February 2011 and August 2012, 232 students from 18 clerkship groups started their neurology clerkships in Nijmegen (where the MBSR was taught) and were eligible to participate in the study. Exclusion criteria were as follows:

(1) under 18 years of age;
(2) non–Dutch speaking; and
(3) previous participation in MBSR.

Randomization

One of us (the coordinating researcher, I.v.D.) was responsible for randomizing the groups by means of a computer-generated number every six months during the inclusion period. For the sake of feasibility and to integrate the intervention in the existing curriculum, we cluster-randomized students by their clerkship groups. The Faculty of Medicine determines the composition of groups (and, as a result, the timing of when students start their clerkships) based on a random allocation system which is not related to student performance. We did not inform students of their allocation to either the MBSR or CAU study group until all participants in each clerkship group had completed the online baseline assessment.

MBSR

The intervention for the MBSR group consisted of eight weekly two-hour sessions (4:30 to 6:30 PM) which took place during the classroom teaching period (n = 2), the neurology clerkship (n = 4), and the psychiatry clerkship (n = 2). Appendix 1 provides a detailed description of the intervention, including Home Practice, and its similarities with and differences from the original MBSR. The MBSR was taught by a psychiatrist (A.E.M.S.) and a physician. Both teachers met the standards for UK good practice guidelines for teaching mindfulness-based courses[19] and were not otherwise involved in the medical curriculum.

Outcome measures

We measured the following mental health outcome measures using validated tools (see below): psychological distress (our primary outcome measure), positive mental health, life satisfaction, physician empathy, mindfulness skills, and dysfunctional cognitions. Students completed all the tools described below online.

Brief Symptom Inventory (BSI). The BSI is a 53-item questionnaire that measures psychological distress in both clinical and nonclinical populations on a five-point Likert-type scale that ranges from 0 = "none at all" to 4 = "extremely."[20] The BSI is composed of nine primary symptom dimensions (somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism), which can be summarized in three global indices of distress (overall psychological distress level, intensity of symptoms, and number of symptoms). In this study, we have used the overall psychological distress level (Global Severity Index) as our outcome measure, which is the mean score of all 53 items. A higher score indicates a higher level of psychological distress.[20] The Dutch BSI has been found to have a high reliability ($\alpha = 0.96$) and high validity.[21]

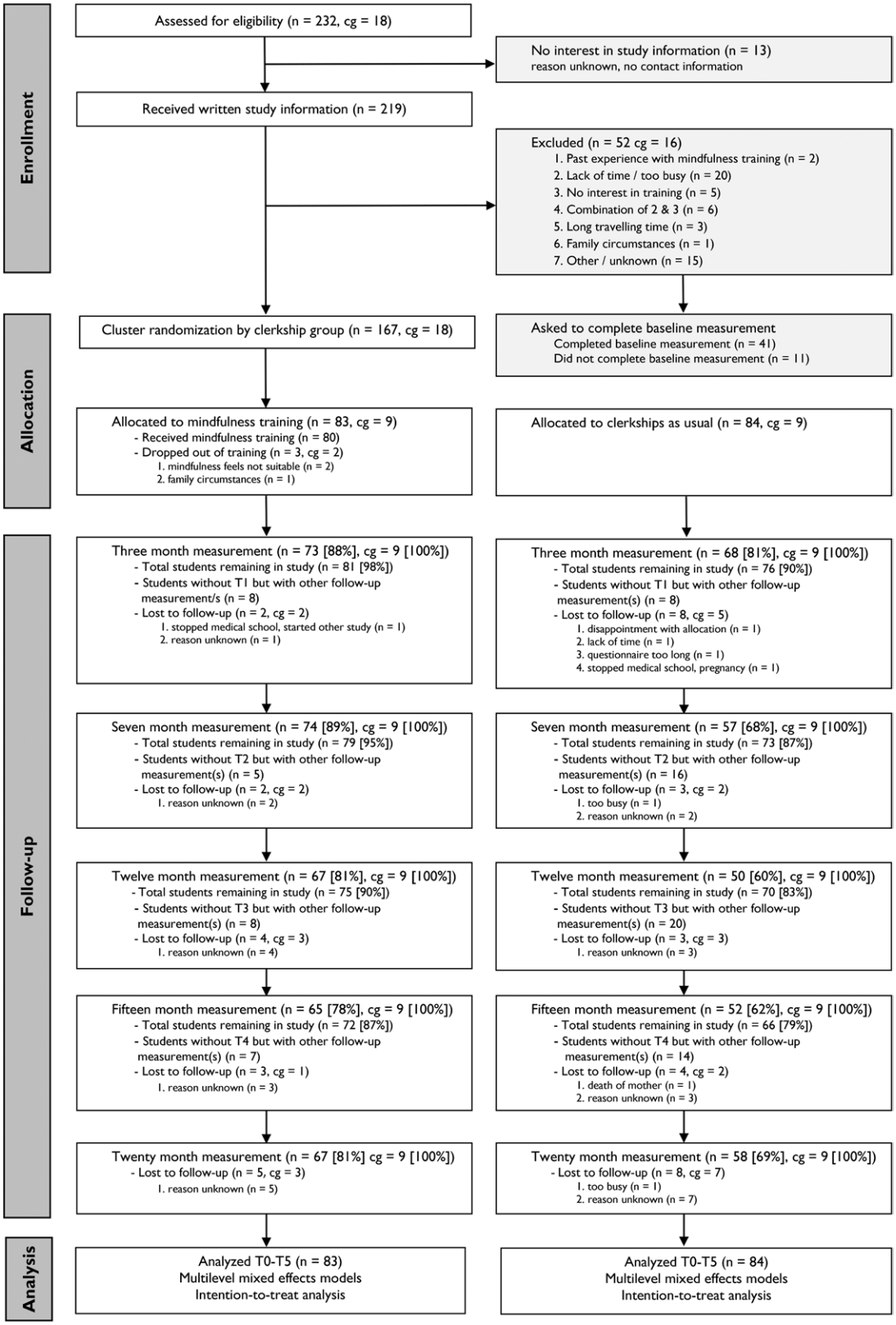

Figure 1 Flowchart of enrollment, allocation, follow-up, and analysis of the cluster-randomized controlled trial examining the effect of clerkships with additional mindfulness-based stress reduction compared with clerkships as usual on the mental health of first-year clinical clerkship students, Radboudumc Nijmegen, the Netherlands, 2011–2014. Abbreviations: n indicates number of students; cg, number of clerkship groups the students are from; T0 to T5 indicate the time of assessment (T0: baseline; T1: 3 months; T2: 7 months; T3: 12 months; T4: 15 months; and T5: 20 months).

Mental Health Continuum-Short Form (MHC-SF). The 14-item MHC-SF measures emotional, psychological, and social well-being by means of questions such as "During the past month, how often did you feel that you liked most parts of your personality?" and "During the past month, how often did you feel that you had warm and trusting relationships with others?" Items are scored on a six-point Likert-type scale that ranges from 0 = "never" to 5 = "daily" (the total score can range from 0 to 70).[7,8] A higher score indicates higher positive mental health. Studied in a representative sample of the Dutch population, internal reliability of the full MHC-SF has been high ($\alpha = 0.89$) and validity good.[22]

Life Satisfaction Questionnaire (LiSat-9). The LiSat-9 comprises a single item assessing overall life satisfaction and eight additional domain-specific items all scored on a six-point Likert-type scale, ranging from 1 = "very dissatisfied" to 6 = "very satisfied." A higher score indicates a higher level of life satisfaction. The Dutch translation is used in healthy adults as well as different patient populations, mainly in rehabilitation. Studies using the LiSat-9 in different Dutch samples of rehabilitation patients have shown good validity and moderate to good reliability ($\alpha = 0.74$–0.75).[23–26]

Jefferson Scale of Physician Empathy (JSPE). The 20-item JSPE measures empathy in the physician–patient relationship. It contains statements such as "Patients feel better when their physicians understand their feelings." Items are scored on a seven-point Likert-type scale, ranging from 1 = "strongly disagree" to 7 = "strongly agree." The total score may range from 20 to 140, and higher scores indicate a higher level of empathy. Validity and reliability of the JSPE have been demonstrated to be high for physicians ($\alpha = 0.81$–0.85) and medical students ($\alpha = 0.89$).[27–29]

Five Facet Mindfulness Questionnaire (FFMQ). The 39-item FFMQ assesses five domains of mindfulness skills: observing, describing, acting with awareness, nonjudging of inner experience, and nonreactivity to inner experience.[30,31] Items are rated on a five-point Likert-type scale that ranges from 1 = "never or very rarely true" to 5 = "very often or always true," such that the total score may range from 39 to 195. A higher score implies a higher level of mindfulness skills. The Dutch FFMQ has been shown to have good internal consistency ($\alpha = 0.85$) and validity in a sample of Dutch nonmeditating students.[32]

Irrational Beliefs Inventory (IBI). The 50-item IBI assesses dysfunctional cognitions, which are considered to be related to a person's vulnerability for developing psychopathology.[33] Items in five subscales (worrying, rigidity, need for approval, problem avoidance, and emotional irresponsibility) are rated on a five-point Likert scale that ranges from 1 = "strongly disagree" to 5 = "strongly agree." The total score may range from 50 to 250, and a higher score indicates a higher level of dysfunctional cognitions. In a randomly selected Dutch university student sample, validity and reliability were satisfactory ($\alpha = 0.83$–0.85).[34]

Home practice

After the fourth and eighth MBSR sessions, students received an online questionnaire that asked how much time, on average, they had spent each week on home practice (see Appendix 1). They rated their time using the following five-point Likert-type scale:

0 = 0 minutes a day,
1 = 1–15 minutes a day,
2 = 16–30 minutes a day,
3 = 31–45 minutes a day,
4 = 46–60 minutes a day, and
5 = more than 60 minutes a day.

At every follow-up assessment, we asked students if they still practiced and if so, what kind of practice they performed.

Sample size

We based our power calculation on results from our pilot study[35] and the study of Jain and colleagues,[36] who also measured psychological distress as a primary outcome measure by using the the Global Severity Index of the BSI. On the basis of the pilot study,[35] the intraclass correlation coefficient of the Global Severity Index between the groups of students starting their clinical clerkships was 0.00 (negligible). Assuming a difference of 0.10 in Global Severity Index between the intervention and control group on the second measurement with a standard deviation of 0.25 in each group, 100 students per group would be necessary to realize a power of 80% with two-sided testing using a *t* test with an alpha of 0.05. Assuming a correlation of 0.5 between the baseline measurement and second measurement, 75 students per group would be necessary, 150 students in total.

Data analysis

We collected data using an online survey tool (Limesurvey, Hamburg, Germany). Using chi-square and independent-samples *t* tests, we compared baseline characteristics and outcome measures (1) between the MBSR and CAU students and (2) between students who dropped out of and remained in the study. We performed an intention-to-treat analysis of all students who had been randomized into one of the two conditions. We performed both a missing values analysis and Little's missing completely at random test[37] to examine whether data were missing at random or not. For all variables, we defined values exceeding 3.29 standard deviations from the mean as outliers and, as advised by Tabachnick and Fidell,[38] transformed outlier data points to 3.29 times the standard deviation plus the mean. We applied multilevel mixed-effects models to all analyses to examine possible differences in the overall fluctuating change of our outcome measures over time between the intervention and control group. We determined the score on each outcome as a dependent variable, and we added gender and baseline level of the dependent variable as covariates. We defined a random intercept for clerkship group level as well as individual student level, and we defined time, condition (intervention or control group), and time × condition as fixed effects in the model. We used mixed-effects models analyses, as this technique makes use of all available data for each time point, including data from students lost to follow-up. We applied a sensitivity analysis by means of multiple imputations to examine if missing values influenced results. As it is not possible to calculate an overall effect size of the change in all six measurements, we computed effect sizes (Cohen's d) of the 20-month measurement using group differences corrected for baseline. We considered d = 0.2 to be a small effect, d = 0.5 a moderate effect, and d = 0.8 a large effect. We performed all analyses using IBM SPSS Statistics for Windows, Version 21.0 (Armonk, New York), and we created our graphs using Microsoft Excel 2013 (Redmond, Washington).

Results

Of 232 eligible students, 167 (72%) participated, and of these, we allocated 83 to the MBSR and 84 to CAU conditions (Figure 1). Of the 65 nonparticipants, 41 were nevertheless willing to complete a baseline assessment. Although the participants and nonparticipants did not differ in gender and age, participants did report higher levels of psychological distress and lower levels of positive mental health than nonparticipants.[35]

We have provided baseline characteristics of the MBSR and CAU participants in Table 1. We detected no significant differences in age, relationship status, or gender; nonetheless, we added gender as a confounder to the analyses because male students tended to be overrepresented in the MBSR as compared to the CAU group. Students were, on average, 23 years old, and the majority were female. During the eight-week training, students spent on average 1 to 15 minutes a day on home practice. The percentage of students practicing more than that gradually decreased over the course of the MBSR training from 40% in the second week to 16% in the last week. Only 3 students (4%) attended fewer than four sessions of the training. Of 73 students, 63 (86%) applied home practice at 3 months follow-up; and of 67 students, 33 (49%) applied home practice at 20 months' follow-up. They mainly applied the "three-minute breathing space" and "deliberate awareness of routine activities" techniques.

At 20 months post intervention, 67 of 83 MBSR students (81%) and 58 of 84 CAU students (69%) had remained in the study. Students who dropped out of the study did not differ on baseline characteristics from those who remained in the study. Sensitivity analyses using multiple imputations to replace the missing values on all outcome measures revealed that missing values did not influence the overall result. Repeating all analyses without the 10 students who dropped out of the study after baseline (Figure 1) did not influence results either.

Effects of MBSR on mental health measures

Overall, students in the MBSR group reported lower levels on the primary outcome measure of psychological distress over the course of the 20-month follow-up period ($P = .03$, Cohen's d = 0.20, see Table 2 and Figure 2). They also reported higher levels of positive mental health ($P = .002$, Cohen's d = 0.44).

Effects of MBSR on other measures

Students in the MBSR group reported higher life satisfaction ($P = .01$, Cohen d = 0.51), more mindfulness skills ($P = .05$, Cohen's d = 0.35), and less dysfunctional cognitions over the course of 20-month follow-up than those in the CAU group ($P = .05$, Cohen's d = 0.18). The MBSR and CAU groups did not differ in physician empathy ($P = .18$, Cohen's d = 0.27).

Discussion

On the basis of our findings, MBSR integrated into clinical clerkships as part of the clinical curriculum resulted in a small reduction of psychological

Table 1

Baseline Characteristics of First-Year Clinical Clerkship Students From Radboudumc, Nijmegen, the Netherlands, Who Were Randomized to Either CAU or Clerkships With Additional MBSR, 2011 to 2012

Variable, measure	CAU (no. = 84)	MBSR (no. = 83)
Age, median (SD)	23.3 (1.77)	23.7 (1.91)
Female gender, no. (%)	71 (85)	60 (72)
Marital status, no. (%)		
Single	36 (43)	42 (51)
In relationship, not married	47 (56)	41 (49)
Married	1 (1)	0
Nationality, no. (%)		
Dutch	78 (93)	80 (96)
German	4 (5)	2 (2)
Other	0	1 (1)
Missing	2 (2)	0
Religion, no. (%)		
Atheist	45 (54)	39 (47)
Catholic	21 (25)	26 (31)
Protestant	6 (7)	4 (5)
Muslim	3 (4)	1 (1)
Other	7 (8)	12 (14)
Missing	2 (2)	1 (1)
Mental health measures, mean score (SD)		
Psychological distress[a]	0.42 (0.29)	0.38 (0.26)
Positive mental health[b]	45.2 (8.9)	44.9 (10.6)
Other measures, mean score (SD)		
Life satisfaction[c]	4.77 (0.45)	4.74 (0.52)
Physician empathy[d]	110.3 (9.3)	110.8 (10.3)
Mindfulness skills[e]	128.5 (14.0)	131.3 (14.7)
Dysfunctional cognitions[f]	141.7 (16.6)	138.4 (14.6)

Abbreviations: CAU indicates clerkship as usual; MBSR, mindfulness-based stress reduction training; SD, standard deviation.

[a]Psychological distress was the primary outcome measure. The authors measured this using the Global Severity Index of the Brief Symptom Inventory, range 0–4, where a higher score indicates higher distress.

[b]As measured by the Mental Health Continuum–Short Form, total score range 0–70, where a higher score indicates higher positive mental health.

[c]As measured by the Life Satisfaction Questionnaire, mean score range 1–6, where a higher score indicates higher life satisfaction.

[d]As measured by the Jefferson Scale of Physician Empathy, total score range 20–140, where a higher score indicates greater empathy.

[e]As measured by the Five Facet Mindfulness Questionnaire, total score range 39–195, where a higher score indicates a higher level of mindfulness skills

[f]As measured by the Irrational Beliefs Inventory, total score range 50–250, where a higher score indicates more dysfunctional cognitions

Table 2

Results of Mixed-Models Analyses of Scores on All Outcome Measures Through 20 Months of Clinical Clerkships of First-Year Clinical Clerkship Students From Radboudumc, Nijmegen, the Netherlands, Who Were Randomized Into CAU or Clerkships With MBSR, 2011 to 2014[a]

Measures	Baseline, mean (SD) [95% CI]	Three months, mean (SD) [95% CI]	Seven months, mean (SD) [95% CI]	Twelve months, mean (SD) 95% CI	Fifteen months, mean (SD) [95% CI]	Twenty months, mean (SD) [95% CI]	F	*P* value	Cohen's d[b]
Mental health measures									
Psychological distress[c]							2.5	.03	0.20
CAU	0.42 (0.29)	0.36 (0.28)	0.45 (0.38)	0.40 (0.36)	0.28 (0.21)	0.37 (0.32)			
	[0.35–0.48]	[0.29–0.43]	[0.34–0.55]	[0.30–0.50]	[0.23–0.34]	[0.29–0.46]			
MBSR	0.38 (0.26)	0.31 (0.26)	0.30 (0.23)	0.32 (0.25)	0.31 (0.26)	0.30 (0.23)			
	[0.32–0.44]	[0.25–0.37]	[0.24–0.35]	[0.26–0.38]	[0.24–0.37]	[0.24–0.35]			
Positive mental health[d]							4.0	.002	0.44
CAU	45.2 (8.9)	46.1 (9.1)	44.4 (10.4)	42.3 (11.7)	46.7 (9.6)	46.2 (10.2)			
	[43.3–47.2]	[43.8–48.3]	[41.4–47.4]	[38.9–45.8]	[43.9–49.6]	[43.4–49.0]			
MBSR	44.9 (10.6)	46.7 (10.0)	49.5 (8.9)	48.4 (10.6)	49.4 (11.5)	51.4 (11.6)			
	[42.6–47.2]	[44.3–49.1]	[47.4–51.5]	[45.7–51.1]	[46.5–52.3]	[48.5–54.3]			
Other measures									
Life satisfaction[e]							3.0	.01	0.51
CAU	4.77 (0.45)	4.77 (0.54)	4.67 (0.52)	4.60 (0.59)	4.69 (0.61)	4.63 (0.59)			
	[4.67–4.87]	[4.64–4.90]	[4.53–4.80]	[4.44–4.77	[4.52–4.86]	[4.47–4.78]			
MBSR	4.74 (0.52)	4.78 (0.49)	4.85 (0.49)	4.85 (0.46)	4.84 (0.55)	4.82 (0.61)			
	[4.62–4.85]	[4.66–4.89]	[4.70–4.98]	[4.74–4.96]	[4.70–4.98]	[4.67–4.96]			
Physician empathy[f]							1.5	.18	0.27
CAU	110.3 (9.3)	108.4 (10.0)	109.8 (8.6)	108.0 (9.8)	110.4 (9.9)	108.9 (11.2)			
	[108.3–112.4]	[105.9–110.8]	[107.4–112.2]	[105.1–110.2]	[107.5–113.4]	[105.9–111.9]			
MBSR	110.8 (10.3)	111.9 (9.7)	110.9 (11.5)	110.8 (11.6)	109.7 (12.3)	112.0 (11.6)			
	[108.5–113.0]	[109.6–114.2]	[108.2–113.6]	[107.9–113.7]	[106.5–112.8]	[109.0–114.9]			
Mindfulness skills[g]							2.3	.05	0.35
CAU	128.5 (14.0)	127.7 (13.9)	125.9 (14.9)	127.8 (15.8)	131.6 (15.0)	127.7 (16.6)			
	[125.4–131.5]	[124.3–131.1]	[121.7–130.0]	[123.2–132.4]	[127.2–136.1]	[123.3–132.1]			
MBSR	131.3 (14.7)	134.0 (13.7)	135.0 (14.1)	135.2 (14.7)	134.0 (18.4)	135.6 (17.9)			
	[128.1–134.5]	[130.8–137.3]	[131.7–138.3]	[131.6–138.8]	[129.3–138.6]	[131.1–140.0]			
Dysfunctional cognitions[h]							2.3	.05	0.18
CAU	141.7 (16.6)	142.2 (13.9)	145.0 (12.5)	141.5 (13.8)	138.7 (14.4)	140.7 (16.0)			
	[138.1–145.3]	[138.8–145.6]	[141.5–148.5]	[37.5–145.5]	[134.4–142.9]	[136.4–145.0]			
MBSR	138.4 (14.6)	135.8 (15.2)	132.1 (16.6)	132.5 (17.5)	132.5 (18.2)	133.5 (20.3)			
	[135.2–141.6]	[132.1–139.4]	[128.2–136.0]	[128.2–136.9]	[127.9–137.1]	[128.4–138.6]			

Abbreviations: CAU indicates clerkships as usual; MBSR, mindfulness-based stress reduction; SD, standard deviation; CI, confidence interval.

[a]All analyses are corrected for clustering, gender, and baseline values. The authors randomized 84 students into the CAU group and 83 into the clerkships with MBSR group.

[b]The authors calculated Cohen's d of the 20-month measurement using group differences corrected for baseline.

[c]Psychological distress is the primary outcome measure; the authors measured this using the Global Severity Index of the Brief Symptom Inventory, range 0–4, where a higher score indicates higher distress.

[d]As measured by the Mental Health Continuum–Short Form, total score range 0–70, where a higher score indicates higher positive mental health.

[e]As measured by the Life Satisfaction Questionnaire, mean score range 1–6, where a higher score indicates higher life satisfaction.

[f]As measured by the Jefferson Scale of Physician Empathy, total score range 20–140, where a higher score indicates greater empathy.

[g]As measured by the Five Facet Mindfulness Questionnaire, total score range 39–195, where a higher score indicates a higher level of mindfulness.

[h]As measured by the Irrational Beliefs Inventory, total score range 50–250, where a higher score indicates higher level of dysfunctional cognitions.

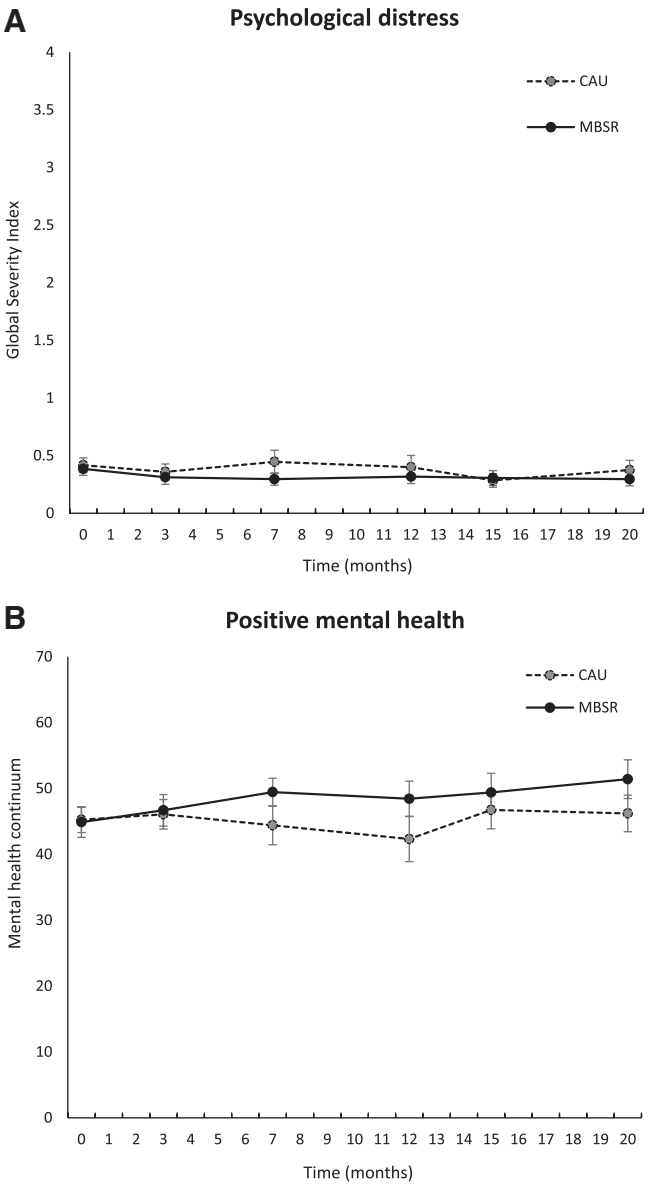

Figure 2 Means and 95% confidence intervals of mental health outcome measures for A (psychological distress) and B (positive mental health) through 20 months of clinical clerkships of first-year clinical clerkship students from Radboudumc, Nijmegen, the Netherlands, 2011 to 2014, randomized to either following clerkships as usual or clerkships with additional mindfulness-based stress reduction.

distress (Cohen's d = 0.20) and a moderate increase in positive mental health (Cohen's d = 0.44). In addition, the MBSR group reported a higher life satisfaction, more mindfulness skills, and less dysfunctional cognitions (Cohen's d = 0.18–0.51) over the course of a 20-month follow-up period. We detected no effect of MBSR on self-reported empathy.

Feasibility

In contrast with previous studies which often comprised only self-referred samples,[10,11,13] we offered MBSR to a consecutive sample of students as an integral part of their clinical clerkship curriculum. The percentage of medical students responding that they were willing to engage in an MBSR course was surprisingly high (72%). In addition, the dropout rate from the MBSR training was very low (4%), and follow-up rates were high.

The high attendance rate might have been influenced by the fact that the MBSR occurred during working hours, during the possibly less demanding neurology and psychiatry clerkships, and that the format and content had been adapted to the medical context. Still, these findings imply that integrating MBSR into clinical clerkships is feasible and that despite contending with high workload and long hours, clinical clerkship students find integrated MBSR training acceptable.

Effectiveness

Although the finding—that an eight-week MBSR training results in consistent improvements even at a 20-month follow-up period—is certainly encouraging, the absolute differences between the MBSR and CAU group are small, especially given the wide range of some of the questionnaire scores. On the other hand, our measure of psychological distress officially ranges from 0 to 4, but in practice in nonclinical samples, the actual range is much smaller because the data distribution is highly skewed to the right and a cutoff of 0.58 is used for screening for psychopathology.[21] Improvements in psychological distress in our student sample occurred within the normal, nonpathological range. Although not addressing psychopathology, this finding might still be relevant—for example, in students' capability to cope with patient-care-related work stress. Further research should include this long-term perspective. To assess the clinical relevance better, outcome measures other than self-report questionnaires might be used; for example, investigators might use either blinded interviews to assess mental health or patient-rated measures to evaluate the professional attitude of students.

The small effect on psychological distress might be partly due to the lower baseline levels of distress in the participants of this study compared with medical students beginning their clinical rotations in the United States and Canada, offering less room for improvement. Although these relatively low levels of psychological distress could be explained by possible cultural differences or differences between medical curricula, a more important explanation could be that our consecutive study population might report less distress than the often selective self-referred populations of previous studies. This possibility aligns with the review of Hope and Henderson,[4] who found that higher-quality studies reported a lower prevalence of psychological distress.

The finding that, in our sample, positive mental health improved more than

psychological distress supports previous results that these are two related yet distinctive concepts, rather than two ends of the same continuum.[7,8,22,39]

Contrary to the findings of Krasner and colleagues[40] in general practitioners, we did not find an effect of MBSR on self-reported empathy. This lack of effect might be explained by the different stage of professional development and the younger age of these students compared with the physicians in the Krasner study. In addition, several studies in medical students show that self-reported empathy does not correlate with observer- or patient-reported empathy.[41–43]

Strengths and limitations

To our knowledge, this is the only randomized controlled study of an eight-week MBSR course in clinical clerkship students. The integration of the MBSR into the clinical clerkships, the consecutive sample, the large sample size, the high response rate, the low dropout, and the 20-month follow-up are all important strengths of the study.

We also note some limitations. The study occurred in a single medical school in the Netherlands, which might limit generalizability, even though students were allocated for their clinical placements at different, affiliated hospitals in the region. Clinical clerkship students in Europe are usually younger than students in the United States and Canada, which could be another aspect limiting international generalizability. As the study lacked an active control condition, we cannot assume that effects are specifically related to the MBSR and not to peer support or attention. Social spread of the intervention to the control group (cross-contamination) seems unlikely as the cluster randomization prevented students from the intervention and control conditions taking classes together either during or after the training; however, we cannot guarantee that students did not have contact with each other and share information about MBSR, which could have reduced group differences.

Other factors that might have reduced group differences are the lack of booster sessions during the 20-month follow-up period and the fact that many students completed the 15-month follow-up assessment during a holiday, which started shortly after they received that questionnaire. Regarding the possible influence of seasonality, our inclusion period lasted 18 months, and measurements were scattered across all seasons; therefore, we believe seasonality had little to no effect on the results.

Although allocation of the groups was not concealed to the coordinating researcher (I.v.D.), we expect the impact of this lack of blinding on the results to be limited. The researcher had no knowledge of clerkship group composition at the time of randomization and therefore could not influence the allocation of specific students to a condition. In addition, scores on outcome measures could not be influenced as both baseline and follow-up assessments were completed online, without personal contact.

Finally, as our study focused on feasibility and integration of the intervention in the curriculum, we did not examine possible individual differences in response to the intervention. Future research will have to address this question.

Conclusions

Integrating MBSR training into the core curriculum of clinical clerkships appears to be both feasible and acceptable. Participating in this training resulted in a small to moderate improvement in the mental health of clinical clerkship students over a 20-month follow-up period. One of the key competencies listed in the CanMEDS physician competency framework for the professional role is demonstrating a commitment to physician health and well-being so as to foster optimal patient care.[44] The development of competencies such as "exhibiting self-awareness," "managing influence on personal well-being and professional performance," and "managing personal and professional demands" are not usually addressed in clinical clerkships, which are mainly focused on developing knowledge and clinical skills. MBSR, however, specifically addresses these competencies and could therefore be a valuable part of the curriculum, supporting the development of students into balanced professionals. However, as this is, to our knowledge, the first randomized controlled trial of the eight-week MBSR with a long-term follow-up, replication studies with active control conditions and outcome measures assessing professional attitude are needed to strengthen the evidence supporting these assertions.

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Appendix 1

Information on Mindfulness-Based Stress Reduction Training (MBSR)

Original curriculum

- Developed by Kabat-Zinn[9] for use in patients with unexplained somatoform disorders
- Eight-week, 2.5-hour training with a fixed program
- Comprehensive folder containing an explanation of the exercises and home practice
- Formal exercises comprise body scan, sitting meditation, and mindful movement
- Informal exercises include awareness of breathing, awareness of routine activities such as eating, walking, cycling
- One-day silent retreat during the sixth week of the program
- Daily home practice with help of CDs/audio recordings comprising weekly alternating formal and informal exercises such as the body scan, sitting meditation, and awareness of routine activities
- Group dialogue and inquiry oriented around weekly in-session exercises and at-home assignments

Alterations to the curriculum used with first-year clinical clerkship students from Radboudumc, Nijmegen, the Netherlands

- Two-hour weekly program instead of 2.5 hours each week (therefore, some exercises were shorter)
- Addition of 10 minutes of interactive presentation each week related to the session theme (e.g., awareness of stress) with examples of (or examples of a lack of) mindful awareness in hospital daily practice
- No silent retreat
- Adaptation of the folder material for use in clinical clerkship students instead of patients, plus addition of examples related to clerkships and resources related to the session themes

Summary of weekly theme with core exercises and home practice

Week 1: Recognizing Automatic Behavior ("the automatic pilot")	• Raisin practice: using all senses to explore an object • Bodyscan: practice being aware of different parts of the body • A routine activity with deliberate awareness (e.g., taking a shower)
Week 2: Influence of Perception	• Bodyscan: practice being aware of different parts of the body • Sitting meditation: awareness of breathing • A routine activity with deliberate awareness (e.g., taking a shower)
Week 3: Recognizing Boundaries	• Yoga: awareness of movement, respecting physical boundaries • Pleasant events log: inquiry thoughts, feelings, bodily sensations • Three-minute breathing space, a short pause during the day
Week 4: Awareness of Stress	• Sitting meditation: awareness of breathing, body, sounds • Unpleasant events log: inquiry thoughts, feelings, bodily sensations • Yoga: awareness of movement, respecting physical boundaries
Week 5: Mindful Response to Stress	• Sitting meditation: breathing, body, sounds, thoughts, difficult situation • Stressful events log: automatic reaction versus mindful response
Week 6: Communication	• Yoga; awareness of movement, respecting physical boundaries • Walking meditation • Practice mindful communication + group inquiry
Week 7: Work–Life Balance	• Sitting meditation: choiceless awareness • Group dialogue: activities demanding energy and giving energy
Week 8: Week 8 Lasts the Rest of Your Life	• Bodyscan: practice being aware of different parts of the body • Make a plan of action for keeping up your skills