



Mindfulness-based cognitive therapy for patients with medically unexplained symptoms: A cost-effectiveness study

Hiske van Ravesteijn^{a,b,*}, Janneke Grutters^{c,d}, Tim olde Hartman^a, Peter Lucassen^a, Hans Bor^a, Chris van Weel^a, Gert Jan van der Wilt^c, Anne Speckens^b

^a Department of Primary and Community Care, Radboud University Nijmegen Medical Center, Nijmegen, The Netherlands

^b Department of Psychiatry, Radboud University Nijmegen Medical Center, Nijmegen, The Netherlands

^c Department for Health Evidence, Radboud University Nijmegen Medical Center, Nijmegen, The Netherlands

^d Department of Operating Rooms, Radboud University Nijmegen Medical Center, Nijmegen, The Netherlands

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ABSTRACT

Objective: Our aim was to assess cost-effectiveness of mindfulness-based cognitive therapy (MBCT) compared with enhanced usual care (EUC) in treating patients with persistent medically unexplained symptoms (MUS).

Methods: A full economic evaluation with a one year time horizon was performed from a societal perspective. Costs were assessed by prospective cost diaries. Health-related Quality of Life was measured using SF-6D. Outcomes were costs per Quality-Adjusted Life Year (QALY). Bootstrap simulations were performed to obtain mean costs, QALY scores and incremental cost-effectiveness ratios (ICERs).

Results: MBCT participants (n = 55) had lower hospital costs and higher mental health care costs than patients who received EUC (n = 41). Mean bootstrapped costs for MBCT were €6269, and €5617 for EUC (95% uncertainty interval for difference: –€1576; €2955). QALYs were 0.674 for MBCT and 0.663 for EUC. MBCT was on average more effective and more costly than EUC, resulting in an ICER of €56,637 per QALY gained. At a willingness to pay of €80,000 per QALY, the probability that MBCT is cost-effective is 57%.

Conclusion: Total costs were not statistically significantly different between MBCT and EUC. However, MBCT seemed to cause a shift in the use of health care resources as mental health care costs were higher and hospital care costs lower in the MBCT condition. Due to the higher drop-out in the EUC condition the cost-effectiveness of MBCT might have been underestimated. The shift in health care use might lead to more effective care for patients with persistent MUS. The longer-term impact of MBCT for patients with persistent MUS needs to be further studied.

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Introduction

Medically unexplained symptoms (MUS) are commonly encountered across all healthcare settings. About one in five patients presenting at the general practitioner (GP)'s office has medically unexplained symptoms [1,2]. Often, these symptoms resolve spontaneously. However, in 10–16% of primary care patients the symptoms persist and result in functional impairment [1,3]. Frequent attendance because of persistent medically unexplained symptoms is seen in 2.5% of primary care patients. This group mainly consists of women with a lower socioeconomic status [4].

Societal costs associated with persistent MUS are substantial [5,6], they mainly consist of health care costs and costs of lost productivity. Health care costs of patients with persistent MUS are high due to high

consultation rates in both primary and secondary care [7,8] and due to often unnecessary medical procedures with the potential for iatrogenic harm [5,9,10]. In the United Kingdom the incremental annual health care cost incurred by patients with MUS was estimated at approximately 10% of the total health care expenditure for the working-age population [11]. In the United States 16% of the total medical care costs are attributable to the incremental costs of MUS [7]. In addition, disabilities caused by MUS lead to diminished employment participation: patients with persistent MUS are more on sick leave and have higher rates of unemployment [12].

Clearly, effective interventions for MUS are needed in order to diminish functional impairment and societal costs. Mindfulness-based cognitive therapy (MBCT) is a promising treatment in the field of MUS as it appears to be effective [13] and provides us with a new approach: MBCT stimulates acceptance of symptoms [14]. An economic evaluation of MBCT for patients with somatization disorder has been performed within a recent Danish trial. MBCT was compared to a specialized treatment consisting of a two-hour individual consultation by a psychiatrist [15]. Total health care costs did not differ

* Corresponding author at: Department of Primary and Community Care, internal code 117, Radboud University Nijmegen Medical Centre, P.O. Box 9101, 6500HB Nijmegen, The Netherlands. Tel.: +31 243614646; fax: +31 243541862.

E-mail address: h.vanravesteijn@psy.umcn.nl (H. van Ravesteijn).

between the conditions, but the percentage of patients on disability pension had decreased significantly more in the MBCT condition.

In a recently randomized controlled trial the effectiveness of MBCT was compared to enhanced usual care (EUC) for frequently attending patients with persistent MUS [13]. Both MBCT and EUC succeeded in improving current health status and mental and physical functioning. However, MBCT led to an earlier improvement of mental functioning, especially with regard to vitality and social functioning. In the context of health care budget constraints, an economic evaluation of this effect can inform decisions which health care services to offer to these patients. Therefore, we performed a cost-effectiveness analysis comparing MBCT versus EUC for patients with persistent MUS.

Methods

Design of RCT

This study was embedded in a randomized controlled trial examining the effects of MBCT on frequently attending patients in primary care with persistent MUS. 125 Patients were randomly allocated to either MBCT ($n=64$) or EUC ($n=61$) [13]. All patients belonged to the 10% most frequently attending patients of the participating GPs ($n=19$), and they fulfilled the DSM-IV criteria of an undifferentiated somatoform disorder, which means that they had at least one physical symptom which was not (fully) explained by a physical disorder or by substance abuse, lasted for at least 6 months, led to functional impairment and could not be put down to another psychiatric disorder. All patients received a psychiatric interview at the pre-randomization assessment which included the Mini-International Neuropsychiatric Interview (MINI) [16] and the section on somatoform disorders of the Structural Clinical Interview for DSM IV axis I disorders (SCID-I) [17].

Primary outcomes were current health status and mental and physical functioning (SF-36 PCS and MCS) [18]. Assessments took place at baseline, end of treatment and 9-month follow-up by filling out postal or online questionnaires. Patients randomized to the EUC condition were requested to refrain from attending mindfulness training during the study period and they had the possibility to participate in the mindfulness training after completion of the study.

Interventions

Participants randomized to MBCT received eight 2.5-hour sessions of MBCT from experienced mindfulness trainers. Both trainers had participated in an intensive two-year teacher training course for mindfulness teachers, had many years of ongoing meditation practice, and both trainers taught more than 30 MBCT or MBSR courses to patients with psychiatric disorders and/or physical conditions. Participants were instructed to practice at home 6 days a week for approximately 45 min a day. To support home practice, patients received a folder with information about the individual sessions, homework assignments and forms to keep a record of their practice, together with CDs with guided meditations and movement exercises. Group size varied between 7 and 14 participants. Our training protocol was based on the MBCT format for patients with recurrent depression [19]. We made minor adaptations to the MBCT training protocol to make it more suitable for patients with physical symptoms. The program consisted of formal meditation exercises such as the body scan, sitting meditation, walking meditation and mindful movement. Participants were encouraged to cultivate awareness of everyday activities, such as eating or taking a shower. In line with the original Mindfulness-Based Stress Reduction format [20], we incorporated a silent day to give participants the opportunity to deepen their mindfulness practice [21].

Patients in the EUC condition received usual care provided by their GP and other health care professionals. The term 'enhanced usual care' was considered appropriate as all patients received a psychiatric

interview. The GP was explicitly informed about the psychiatric diagnoses resulting from the interview [22].

Main results RCT

In the randomized controlled trial, current health status and physical functioning did not significantly differ between groups. However, participants in the MBCT group reported a significantly greater improvement in mental functioning at the end of treatment (adjusted mean difference 3.9, 95%CI 0.24 to 7.6), in particular with regard to vitality and social functioning. Within the MBCT group, almost half of the secondary outcome measures had significantly improved at end of treatment, whereas in the EUC group none had.

Assessments cost-effectiveness study

A face-to-face pre-randomization assessment was performed in which we assessed socio-demographic and clinical characteristics, the current employment status and medication use in the past month. Further assessments were performed with online or postal questionnaires at baseline, 3 months and 12 months after randomization. To assess health care use and employment participation we used a prospective cost diary in which patients were asked to note their health care use and their employment participation per calendar day. Given a societal perspective, the prospective cost diaries covered employment participation and health care use per day. The prospective diaries were mailed to the patients before the start of each month during the whole year of the trial. Patients were requested to send the diary back at the end of each month. If the patient did not send in the diary in time, our research team made a phone call to the patient. We kindly requested patients to keep filling out the diaries. A final follow-up assessment was made by telephone at 12 months after baseline in which we assessed again the current employment status and medication use in the past month. The number of attended MBCT sessions was registered by the mindfulness trainer.

Unit prices

We used Standardized Dutch unit prices [23]. When a standardized unit price was not available, prices were based on tariffs. Medication costs were obtained from the Dutch 'Pharmacotheapeutic Compass' (the most used drug reference in The Netherlands) [24]. Medication costs which were not retrieved from these resources (e.g. vitamin pills), were derived from suppliers on the Internet. If these medication costs varied, we used the lowest price.

Productivity costs (i.e. when patients are unable to perform paid work) were calculated according to the Friction Cost (FC) method [25], implying that the number of hours patients were absent from their job is multiplied with the actual gross wage per hour. The cause for absence is not taken into account. Absence could for example be due to illness, being fired or resigning from a job. In FC, productivity costs are only counted as long as it takes to replace someone. The friction period is defined as the time needed to restore the initial production level. After this friction period, costs to society fall back to zero. For FC, standardized FC tariffs as well as the friction period of 160 days were obtained from the Dutch Manual for Costing studies [23]. The tariffs are calculated based on the average value added per working person. FC was calculated according to the standards, implying that when a patient was continuously absent for more than 160 days, it was assumed that this patients' place in the production process was filled again and productivity returned to its original level. Therefore, after these 160 days had passed, productivity costs were considered zero. Price indices were used to convert costs to the 2010 price level.

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