International Journal of Technology Assessment in Health Care, **25:4** (2009), 497–504.

doi:10.1017/S026646230999050X

Economic evaluation of a minimal psychological intervention in chronically ill elderly patients with minor or mild to moderate depression: A randomized trial (the DELTA-study)

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Objectives: Depression is associated with high healthcare utilization and related costs. Effective treatments might reduce the economic burden. The objective of this study was to establish the cost-utility of a minimal psychological intervention (MPI) aimed at reducing depression and improving quality of life in elderly persons with diabetes or chronic obstructive pulmonary disease and co-occurring minor, mild, or moderate depression.
Methods: Trial-based cost-utility analysis was used to compare the MPI with usual care. Annual costs and quality-adjusted life-years (QALYs) based on the Euroqol (EQ5D) and on depression-free days were calculated.
Results: Annual costs and effects were not significantly different for the MPI group and care as usual. Bootstrap analysis indicated a dominant intervention, with a probability of 63 percent that the MPI is less costly and more effective than usual care.
Conclusions: The cost-effectiveness analysis does not support dissemination of the MPI in its current form. The economic evaluation study showed limited probability that MPI is cost-effective over usual care. Further adjustments to the MPI are needed to make the intervention suitable for dissemination in regular care. *Trial registration:* isrctn.org, identifier: ISRCTN92331982.

Keywords: Cost-benefit analysis, Depressive disorder, Aged, Chronic disease, Quality of life

Depression is a common disorder in older persons and is associated with a reduced quality of life (21), increased morbidity, and increased physical disability (17). This applies especially to older persons with chronic illnesses, such as type II diabetes mellitus (DM) and chronic obstructive pulmonary disease (COPD) (1;25). Patients with depression run the risk of sliding into a downward spiral, because depression and disability are mutually reinforcing (17). Depression may impair one's ability to adhere to medical regimens (diet, exercise, quitting smoking, taking medication regularly), potentially worsening the course of the chronic illness, and may also lead to greater healthcare utilization and related costs (5;24). It is, therefore, of great importance to develop treatments for chronically ill elderly persons that help reduce the burden of depression. This is especially true for the treatment of depression in primary care, because persons with

We thank Kitty Daemen, Henny Geelen, Francine Hendriks, and Mieke Witte, for administering the intervention with dedication and enthusiasm; Wendy Engering for her contribution to the patient recruitment; Dorien Mintjes for her contribution to the data entry; as well as MEMIC (Centre for Data and Information Management) for providing us with a data management system. This study was funded by the Netherlands Organisation for Health Research and Development (ZonMw), Health Care Efficiency Research Program, grant number 945–03-047.

depression often present initially to a general practitioner (5).

Although attempts have been made to study the cost-effectiveness of collaborative care depression treatment, offering both pharmacological and psychological treatment options (5;24), the societal impact of psychological depression treatment among elderly persons with chronic somatic illnesses, incorporating healthcare costs as well as production losses, remains largely unclear (5). The Depression in Elderly with Long-Term Afflictions (DELTA) study has been designed to evaluate the effectiveness and cost-effectiveness of a minimal psychological intervention (MPI) to reduce depression and improve quality of life in elderly persons with DM or COPD and co-occurring minor or mild to moderate depression. The MPI was carried out by primary care nurses and is based on principles of self-management and cognitive behavioral therapy (CBT).

The aim of this article is to assess, from a societal perspective, the cost-effectiveness of the MPI compared with usual care.

METHODS

Design

The economic evaluation was embedded in a two-armed randomized controlled trial (RCT). A detailed description of the design of the DELTA-study has been published elsewhere (13). A block randomization was used, with stratification for chronic illness and the general practice where the patient was registered. The researchers entered each patient's identification number into a computer system connected to an external agency. Patients were then randomized by the agency, using a computerized random number generator. Data were entered by the researchers, who were blinded for the allocation. Costs and effects were assessed at baseline (before randomization) and at 3, 6, 9 (only costs), and 12 months after baseline. The first follow-up in the intervention group was one week after the final intervention contact, and depended upon the duration of the tailor-made intervention. The economic evaluation was performed from a societal perspective, which suggests that all relevant costs and effects are taken into account (6). Approval for this study was granted by the Medical Ethics Committee of Maastricht University/University Hospital Maastricht.

Participants

Between October 2003 and May 2005, participants were recruited in 89 primary care practices in the south of the Netherlands. Patients with an established diagnosis of DM or COPD, aged 60 years and over, who were community-dwelling and did not meet exclusion criteria (treatment with antidepressants for depression, major psychiatric problems, current psychosocial/psychiatric treatment, serious cognitive problems, being on a waiting list for nursing home, being bedridden, loss of spouse within the last 3 months, and not being fluent in Dutch) were sent the Patient Health Questionnaire (PHQ-9) (22). Patients who reported having at least two symptoms of depression present for more than half of the days, one of them being loss of interest or depressed mood, were invited to take part in a structured diagnostic interview for DSM-IV axis I disorders, the Mini International Neuropsychiatric Interview (MINI) (19). In addition, the Hamilton Depression Rating Scale (HDRS) (10) was used to determine the severity of the depression. The MINI and HDRS were administered at the patients' home by trained nurses. Patients with minor depression, mild to moderate major depression, or dysthymia were invited to participate in the trial. Patients with suicidal risk and patients with severe major depression (HDRS$>$18) were excluded and referred to their general practitioner (GP). After signing an informed consent form and completing a baseline questionnaire, patients were randomly allocated to the MPI ($n = 183$) or usual care ($n = 178$).

Intervention and Usual Care

Patients allocated to the intervention group received the MPI supplementary to usual care. The intervention was delivered at the patient's home by nurses, who were trained in the DELTA intervention, based on principles of CBT and self-management, but had not received additional training for DM or COPD. The DELTA intervention consists of five phases, which have been described in more detail elsewhere (13). Briefly, in phase 1, the nurse explores the patient's feelings, cognitions, and behaviors. During phase 2, the patient keeps a diary, in which they record symptoms, complaints, thoughts, worries, and related feelings and behaviors. In phase 3, the patient is challenged to link their mood to the consequent behavior, using information from the diary. The self-management approach is introduced in phase 4, where the patient explores possibilities to alter their behavior and where they draw up an action plan. Phase 5 consists of an evaluation of the degree to which goals from the action plan have been achieved. The intervention is tailor-made, and a home visit could comprise one or more phases. During the study, patients received two to ten visits over a period of at most 3 months, depending on the patient's progress. The mean number of visits was four, with a mean duration of 61 minutes (11).

Patients assigned to usual care received regular treatment according to the practice guidelines of their chronic somatic illness. These practice guidelines, produced by the Dutch College of General Practitioners, encompass regular check-ups for medical symptoms, but do not involve detection and treatment of depressive symptoms. Care providers remained blinded for the results of the depression screening for the duration of the study.

https://doi.org/10.1017/S026646230999050X Published online by Cambridge University Press

Measurements

Costs. To establish the costs, relevant cost items were identified, after which these costs were measured and values were placed on the cost items.

We started by identifying program costs, healthcare costs, patient and family costs, and productivity losses. *Program costs* include the costs that can be attributed to the process of developing and administering the MPI, for example the costs of the home visits, MPI training for nurses, and nurses' travel expenses. Research-specific costs, such as costs of questionnaires, were excluded. *Healthcare costs* in our study were all costs related to patients' visits to a GP's office, hospital care (inpatient and outpatient), allied health professionals such as physiotherapists or dieticians, professional home care, medical devices and assistive devices, and prescribed and over-the-counter medication. *Patient and family costs* included costs of informal care (help from family and friends) and paid domestic help. *Productivity losses* consisted of sick leave from work and loss of activities in and around the home.

We then measured the cost categories identified above. The program costs were measured by means of a questionnaire in which nurses recorded time spent on home visits and travelling. The time spent developing the MPI and training nurses to use it was recorded by the researchers. Payroll information was used to calculate the hourly wages of nurses, developers, and trainers. Cost diaries (9) were used to measure volumes of healthcare utilization, patient and family costs, and productivity losses. Patients kept a prospective diary for 2 weeks at baseline and for 4 weeks at all four follow-up measurements. After each measurement, a telephone operator, blinded for allocation, contacted patients to retrieve information from the diary.

Finally, the valuation was based on volumes obtained from the cost diary and questionnaires, multiplied by cost prices derived from the updated Dutch manual for costing (16). Costs due to productivity losses were estimated using the friction cost approach. Prices of informal care were based on shadow prices for unpaid work. Where no standard cost prizes were available, real costs or tariffs were used to estimate costs (volumes and cost price details are available upon request). Baseline costs were used to examine the comparability of the groups at baseline. The total annual costs were determined by extrapolation by multiplying the costs from the available 4 months of follow-up measurements by three to obtain the total costs during 12 months of follow-up. The annual costs are presented in euros and the baseline year was 2004. The discounting rate was 4 percent (16).

Effects. The generic effects on quality of life were assessed with the Euroqol (EQ5D) (8). This widely used quality-of-life instrument includes five dimensions of health-related quality of life, namely mobility, self-care, daily activities, pain/discomfort, and depression/anxiety. These five dimensions were combined into a health state. Utility values were calculated for these health states, using preferences elicited from a general Dutch population (14). The utility values were used to compute quality-adjusted life-years (QALY-EQ5D) by means of the area under the curve method. In addition, depression-specific effects were assessed with the Beck Depression Inventory (BDI) (2). We used depression scores from the BDI over time to estimate days free of significant depressive symptoms (DFD). A health utility improvement of 0.4 for depression-free days was used to estimate the QALY-DFD (15;18).

The EQ5D and BDI were assessed by means of self-administered questionnaires, sent together with the cost diaries, at baseline and at the 3, 6, and 12 months' follow-up assessments.

Analyses

Analyses were based on the intention-to-treat principle. An analysis of baseline characteristics and baseline costs examined the comparability of the groups at baseline. Missing items on the BDI scale were replaced by the individual's own mean of nonmissing items at that follow-up measurement, if at least half of the items for that follow-up were available. This method could not be applied to the EQ5D and cost data, because domains of the EQ5D and cost category levels (e.g., hospital-related costs or costs of informal care) consisted of one item. Therefore, missing data on EQ5D domains and cost categories were replaced by the individual's own mean of nonmissing data at follow-up measurements, if at least half of the follow-up measurements were available. By using mean imputation techniques per person rather than group means of effect and cost categories, variances between persons were maintained (7). The number of imputations for the different domains of the EQ5D ranged from zero to twenty-three (over all assessments in time). For the cost-categories, the number of imputations ranged from five to nineteen. After imputation, the number of patients with missing data ranged from 5 to 112 for the EQ5D per follow-up measurement and from 25 to 98 for the cost per follow-up measurement. In cost-effectiveness analysis, only persons with complete sets of cost and effect data should be included. Therefore, thirty-four persons were excluded because only cost data were available and five persons were excluded because only effect data were available. This reduced the number of patients available for analyses to 228.

We used bootstrap estimation with 1,000 replications to obtain means and standard deviations of our cost and effect data. We separately bootstrapped the cost and effect data because these data were highly skewed. The differences between the intervention and control groups were estimated by means of linear regression. We used linear regression analysis, enabling adjustment for age, sex, education, chronic somatic illness, and baseline value of either the cost category or the effect measure. The regression models provided us with a correction term which was used to calculate adjusted

annual total cost and adjusted annual effects (QALY-EQ5D and QALY-DFD). These adjusted costs and effects (also called predicted costs and effects) were used in our further cost-utility analysis.

Cost-utility analysis. The incremental cost-utility ratio (ICUR) was calculated as: ICUR = (Ci – Cc) / (Ei – Ec), where Ci is the adjusted annual total cost of the intervention group, Cc is the adjusted annual total cost of the control group, Ei is the adjusted effect for the intervention group, and Ec is the adjusted effect for the control group. To establish the cost-utility of our intervention, we bootstrapped the predicted annual total cost and the predicted effects (QALY-EQ5D and QALY-DFD) derived from the linear regression models. The bootstrap analyses were preplanned to address the issue of uncertainty in the analyses, in particular uncertainty due to sample variation (6). Because confidence interval of the ICUR (being a ratio) poses statistical problems, bootstrap analyses were used to estimate the sampling distribution of the ICUR and the accompanying confidence intervals.

We expected that our intervention group and control group had an equal level of costs. In general, new treatments are considered acceptable if it leads to an improvement in health at no greater costs. However, when either cost or effect differences are not significant, bootstrap replications fail to distinguish between an ICUR that favors the new treatment from an ICUR that favors care as usual. Therefore, results are presented in the form of a cost-effectiveness acceptability curve. These acceptability curves present more information on uncertainty than do confidence intervals and show whether a new intervention is acceptable if we are willing to invest in this new intervention (23).

In addition to the primary (QALY-EQ5D) and secondary (QALY-DFD) analyses, we evaluated a model to examine the sensitivity of our cost-utility results. We conducted an analysis to test whether a reduction of program cost from €337 to €282 would change the cost-utility ratio. The reduction of program costs was based on a scenario in which patients visit the nurse at the GP's office instead of the nurses paying home visits, as was done in our study. This scenario is considered to be a suitable alternative when implementing our intervention in routine practice.

Nonresponse analysis. In longitudinal studies conducted in vulnerable and aged populations, missing data are often a serious concern. Attrition rates up to 30 percent are not uncommon (4). We assessed the matter of missing data by performing a nonresponse analysis. First, we evaluated the potential influence of the drop-out. Because demographic characteristics of intervention and control group remained comparable over time, differential drop-out could be ruled out. Second, we evaluated whether persons with missing data differed from persons for whom complete follow-up data were available (after imputation). Third, we conducted a complete case analysis to study the influence of imputation.

RESULTS

Of the 361 eligible patients, 183 were assigned to the intervention group and 178 to the control group. Complete data were available for 228 persons (control $n = 118$; intervention $n = 110$). Table 1 shows the baseline characteristics of the intervention and control groups. The intervention group had slightly higher costs than the control group in the 2 weeks before the intervention, but differences were not significant. Other characteristics were comparable between groups.

Annual Costs and Clinical Effects

The control group had slightly higher costs than the intervention group (€9,770 versus €9,549; Table 2), but the overall cost difference was not significantly different. The extra costs of the MPI in the intervention group amounted to an average of €337 per person. These costs of the MPI were included in all cost-utility analyses. A significant difference was found in costs of paid domestic help, in favor of the group that received the MPI (€192 versus €81; $p = .01$). No significant differences in mean QALY-EQ5D or mean QALY-DFDs were found between patients from the intervention and control groups (Table 2).

Cost-utility

All ICURs had negative outcomes, indicating that the MPI dominated usual care due to lower costs and more effect. However, the confidence intervals surrounding the ICURs were extremely wide (Table 3). The ICUR of the primary analysis was €−11,508 per QALY-EQ5D. The ICUR of the secondary analysis was €−12,534 per QALY-DFD. The cost per depression-free day was €−14 (data not shown).

Bootstrap replications (Supplementary Figure 1, which can be viewed online at www.journals.cambridge.org/thc) showed a probability of 63 percent that our MPI is the dominant treatment, because the MPI is less costly and more effective than care as usual. In addition, there is a 28 percent probability that a health gain is produced, but at additional costs. On the other hand, there is a probability of 5 percent that the MPI is inferior and 4 percent that the MPI is less costly but also less effective. The percentage of dominance for the secondary analysis, based on DFDs, is slightly higher (67 percent) than that in our primary analysis (Table 3).

Interpretation of these outcomes also depends on how much decision makers are willing to pay for each QALY gained. For instance, if a decision maker is willing to pay €20,000 per QALY gained, the probability of the MPI being cost-effective is approximately 82 percent. In Dutch health care, this ceiling ratio is often considered a reasonable critical level for QALY cost (3). A ceiling ratio of €80,000 per QALY gained has also been proposed, which would result in an 89 percent probability of our intervention being superior to care as usual. This is further illustrated in the cost-effectiveness acceptability curve of our primary analysis (Figure 1). The probability of our intervention being superior

Table 1. Comparability of Intervention and Control Groups in Terms of Sociodemographic Variables and Baseline Values of Outcomes

Variable	Usual care $n = 118$	MPI $n = 110$	p value
Age, yr (SD)	69.98 (6.26)	69.47 (6.17)	.54
Sex, No. (%)			.97
Male	63 (53.4)	59 (53.6)	
Female	55 (46.6)	51 (46.4)	
Chronic illness, No. (%)			.72
Diabetes	64 (54.2)	57 (51.8)	
COPD	54 (45.8)	53 (48.2)	
Education level,[a] No. (%)			.25
Low	41 (34.7)	34 (30.9)	
Medium	26 (22.0)	35 (31.8)	
High	51 (43.2)	41 (37.3)	
Utility,[b] mean (SD)	0.63 (0.20)	0.61 (0.22)	.35
BDI,[c] mean (SD)	17.48 (8.07)	16.73 (7.20)	.46
Costs prior 2 weeks mean euro (SD)	307 (30)	337 (37)	.56

[a] Low refers to primary school only; medium refers to lower vocational training or lower general education; high refers to higher vocational training, general secondary education, higher professional education, and university training.
[b] Based on the Dutch algorithm for the Euroqol (EQ5D) scores; utility scores range from 0 (death) to 1 (full health).
[c] Range of the BDI is 0–63, with 0 as the most favorable outcome.
MPI, minimal psychological intervention; COPD, chronic obstructive pulmonary disease; BDI, Beck Depression Inventory.

Table 2. Mean Annual Cost per Patient and Mean Effect[a]

	Mean (SD)[b]				
	Usual care $n = 118$	MPI $n = 110$	95% CI Difference[b]		p value[c]
Costs					
Program costs		337 (11)			
Healthcare-related costs	8,082 (833)	7,243 (885)	−3,084	1,587	.50
GP	471 (31)	550 (53)	−33	203	.10
Hospital	3,371 (630)	2,885 (701)	−2,294	1,455	.69
Allied health professionals	397 (63)	474 (78)	−1,358	30	.76
Professional home care	1,616 (286)	936 (205)	−111	280	.25
Medical aids and assistive devices	547 (139)	710 (191)	−276	629	.60
Prescribed and OTC medication	1,628 (85)	1,673 (85)	−188	283	.46
Patient and family costs	472 (74)	497 (98)	−217	259	.62
Informal care	281 (66)	410 (91)	−93	370	.61
Paid domestic help	192 (42)	81 (30)	−212	−1	.01
Productivity loss	1,194 (234)	1,432 (272)	−421	940	.83
Paid work	189 (119)	0 (0)	−440	0	.14
Unpaid work	1,014 (208)	1,442 (283)	−266	1,114	.42
Total costs	9,770 (890)	9,549 (1,059)	−2,974	2,411	.53
Effects					
QALY-EQ5D[d]	0.59 (0.02)	0.62 (0.02)	−0.03	0.08	.06
Utility at 3 months	0.61 (0.02)	0.64 (0.02)	−0.03	0.09	.10
Utility at 6 months	0.59 (0.02)	0.61 (0.02)	−0.05	0.08	.33
Utility at 12 months	0.56 (0.02)	0.62 (0.02)	−0.01	0.12	.02
QALY-DFD[e]	0.78 (0.01)	0.80) (0.01)	−0.01	0.05	.31
DFD/year	163 (11)	184 (12)	−12	51	.31

[a] Volumes and cost price details are available upon request.
[b] Unadjusted bootstrapped mean, standard deviation, and 95% confidence interval (CI).
[c] Based on linear regression corrected for age, sex, chronic somatic illness, education, and baseline cost or baseline EQ5D/BDI score.
[d] Based on the Dutch algorithm for EQ5D scores.
[e] Based on the BDI scores.
MPI, minimal psychological intervention; CI, confidence interval; GP, general practitioner; OTC, over-the-counter; QALY, quality-adjusted-life-year; EQ5D, Euroqol; DFD, days free of significant depressive symptoms; BDI, Beck Depression Inventory.

https://doi.org/10.1017/S026646230999050X Published online by Cambridge University Press

Table 3. Incremental Cost-utility Ratio and Percentage of Dominance

Type of analysis	*N*		ICUR (95% CI)[a]	Probability of cost-effective MPI,[a] %			
	Usual care	MPI		More effect higher costs	Less effect higher costs (inferior)	Less effect lower costs	More effect lower costs (dominant)
Primary analysis QALY-EQ5D	118	110	Dominance (−160,502–192,027)	28	5	4	63
Secondary analysis QALY-DFD	118	110	Dominance (−190,366–101,049)	29	2	2	67
Sensitivity analyses: reduction of program costs[b]	118	110	Dominance (−158,691–143,458)	23	5	4	68
Nonresponse analysis: complete case	58	65	Dominance (−687,933–357,800)	3	5	30	62

[a] MPI compared to usual care based on 1,000 bootstrap replications.
[b] Reduction of program cost from €337 to €282, based on scenario where patients visit general practice instead of home visits
MPI, minimal psychological intervention; ICUR, incremental cost-utility ratio; CI, confidence interval; QALY, quality-adjusted-life-year; EQ5D, Euroqol; DFD, days free of significant depressive symptoms.

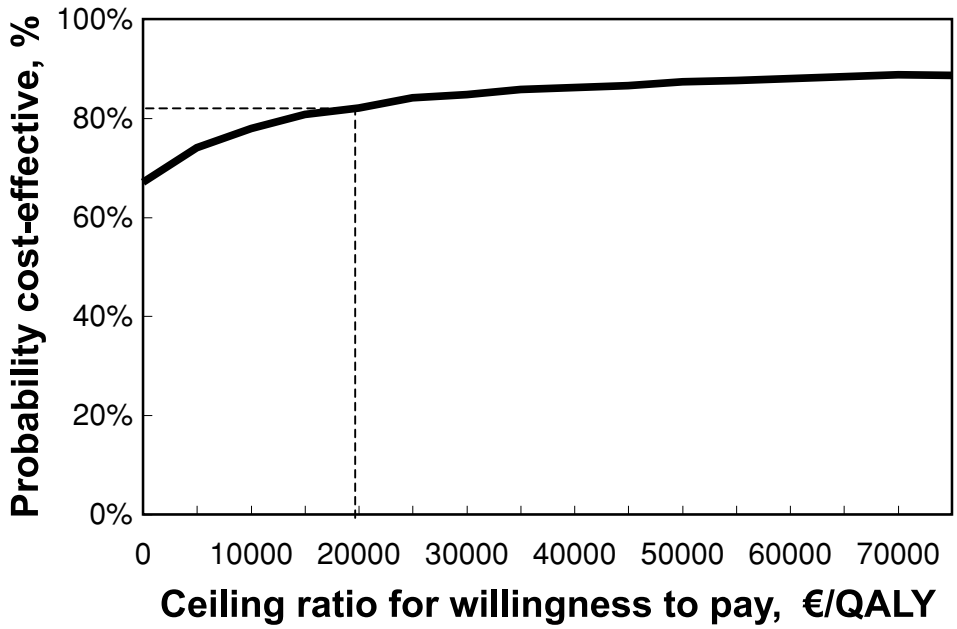

Figure 1. Cost-utility acceptability curve: probability that the minimal psychological intervention (MPI) is cost-effective (vertical axis) given various ceiling ratios for willingness to pay (horizontal axis).

to usual care (y-axis) is shown for varying ratios for willingness to pay for each QALY gained. The probability of an inferior intervention remained stable at 5 percent.

As expected, the sensitivity analysis, based on a reduction of program costs due to practice visits instead of home visits, led to an increase in dominance, although the confidence interval remained wide. To study the nonresponse, baseline characteristics of persons with complete data (n = 228) were compared with those of persons without complete follow-up data (n = 133). Persons with complete data were significantly younger ($p < .00$) and had significantly higher utility scores at baseline ($p = .01$) than persons for whom complete follow-up data were not available (not tabulated). No other significant differences in characteristics were found between these groups. The complete case analysis showed an increase of the probability of the MPI being less effective and less costly, while the probability of the MPI being more costly but also more effective decreased (Table 3).

DISCUSSION

In this group of elderly patients with DM or COPD and co-occurring minor, mild to moderate major depression or dysthymia, our MPI did not lead to differences in quality of

https://doi.org/10.1017/S026646230999050X Published online by Cambridge University Press

life, depression-free days, or mean annual costs. The bootstrap analysis, however, showed that the MPI was the dominant treatment over care as usual, which is supported by the cost-effectiveness acceptability plane showing a 63 percent probability that the MPI is less costly and more effective than usual care. If decision makers are willing to pay €20,000 per QALY gained, the probability increases to 82 percent.

Limitations of this study include the attrition rate. This could have influenced our findings, although it is difficult to establish the extent of this influence. We did, however, include a nonresponse analysis, which showed that our imputation techniques may have caused a higher probability of our intervention being cost-effective. We used person specific mean imputation techniques and, although this method is considered valid, more refined techniques might have provided better estimates (7). A second limitation is the poor validity of the DFD method to establish cost-utility (18). Cost-utility analyses have been introduced to provide a generic outcome measure for the comparison of costs and effects across diseases (6). However, the cost-utility estimate of the DFD method is not based on generic outcomes but on depression severity, making it invalid for comparison with other diseases than depression. Nevertheless, we decided to include the DFD method as a secondary analysis, to be able to compare our results with those of studies using the DFD method. A third limitation concerns the generalizability of our findings across the two chronic somatic illnesses. We added chronic somatic illnesses to our regression models, but the individual cost-effectiveness outcomes for diabetic and COPD patients remain unclear, as our study population was too small for disease-specific analyses. Fourth, we used a cost diary to assess the cost data. This method has some advantages over questionnaires, because it measures healthcare consumption prospectively and might be more accurate (9). However, cost diaries often have relatively high levels of missing values. Finally, to reduce the burden for the patients, we used discontinuous measurements. Previous studies revealed that measuring at least 3 months of a year provides good estimates of annual costs (9). Nevertheless, high one-time expenses, such as inpatient hospital stays, might be missed or overestimated by measuring discontinuously. In addition, the estimate of the QALY would have been more precise if we had used more measurement times.

Our study found a negative cost-effectiveness ratio of €14 per depression-free day, indicating a small additional costs saving versus a limited increase in effects. According to a review by Wang et al., most other studies found an additional cost per depression-free day ranging from €7 to €26, instead of a cost saving (24). However, none of these studies found a significant cost difference. In addition, none of these studies focused on persons with chronic somatic illnesses. Recently, two additional studies were published that focused on depression treatment of persons with DM (12;20). In line with our findings, these studies found a negative ratio, although both studies only reviewed healthcare-related costs, not including production losses, and had a follow-up of 24 months instead of 12 months.

POLICY IMPLICATIONS

The lack of cost-effective findings in this study raises the question of how we could improve the MPI. One of the strengths of our MPI is the case finding element. Nurses have shown to be able to detect symptoms of depression in patients which would have remained undetected without the MPI. Therefore, stronger emphasis on detection of depressive symptoms with referral to the GP and less attention for the therapeutic intervention might be a worthwhile approach to explore. Furthermore, as studied in our sensitivity analyses, it might be feasible to let patients visit a GP's office to receive the MPI instead of nurses visiting patients at home. Further translational research is needed to study these scenarios.

In conclusion, the cost-effectiveness analyses do not support dissemination of the MPI in its current form. The economic evaluation study showed only limited probability that MPI is cost-effective over usual care. Further adjustments to the MPI are needed to make the intervention suitable for dissemination in regular care for elderly persons with a chronic illness.

SUPPLEMENTARY MATERIAL

Supplementary Figure 1: www.journals.cambridge.org/thc

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