Sustained Effects of a Mindfulness-Based Stress-Reduction Intervention in Type 2 Diabetic Patients

Design and first results of a randomized controlled trial (The Heidelberger Diabetes and Stress-Study)

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OBJECTIVE—To determine whether a mindfulness-based stress reduction (MBSR) intervention is effective for reducing psychosocial distress (i.e., depression, psychosocial stress) and the progression of nephropathy (i.e., albuminuria) and for improving the subjective health status of patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS—Patients with type 2 diabetes and microalbuminuria were randomized to a mindfulness-based intervention (n = 53) or a treatment-as-usual control (n = 57) group. The study is designed to investigate long-term outcomes over a period of 5 years. We present data up to the first year of follow-up (FU).

RESULTS—At FU, the MBSR group showed lower levels of depression (d = 0.71) and improved health status (d = 0.54) compared with the control group. No significant differences in albuminuria were found. Per-protocol analyses also showed higher stress reduction in the intervention group (d = 0.64).

CONCLUSIONS—MBSR intervention achieved a prolonged reduction in psychosocial distress. The effects on albuminuria will be followed up further.

Several studies reported not only an increased incidence of depression among patients with type 2 diabetes (1), but also a putative causal role of psychological distress in the pathogenesis of diabetes (2) and its complications (3,4). As shown by our research group, psychological stress is linked to the activation of proinflammatory transcription factors known to be involved in late diabetes complications (3,6). Because previous studies in diabetes and other medical diseases indicate that mindfulness-based stress reduction (MBSR) or an MBSR component may be effective in reducing or preventing depression and stress as well as increasing health status (7–10), we initiated a 5-year trial with albuminuria progression as the primary endpoint and psychological distress, health status, mortality, cardiovascular events, and the activation of proinflammatory transcription factors as secondary endpoints.

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RESULTS—Patient characteristics are provided in Supplementary Table 2. There were no significant differences between the groups, except for the history of myocardial infarction. No significant effect was found immediately after the intervention (Table 1 and Supplementary version 9.2 (SAS Institute)).

Table 1—ANCOVA results for clinical and psychosomatic parameters in intention to treat and per-protocol analyses

<table>
<thead>
<tr>
<th></th>
<th>Postintervention</th>
<th>1-year FU</th>
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<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>Albuminuria (mg/24 h)†‡</td>
<td>42.8 (21.1/42.8)</td>
<td>66.5 (20.2/204.5)</td>
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<tr>
<td>HbA1c (%)</td>
<td>7.2 ± 0.10</td>
<td>7.1 ± 0.11</td>
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<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>137.6 ± 1.95</td>
<td>140.8 ± 2.14</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td>77.7 ± 1.09</td>
<td>80.7 ± 1.20</td>
</tr>
<tr>
<td>SF-12 mental composite score‡</td>
<td>47.9 ± 1.39</td>
<td>46.0 ± 1.53</td>
</tr>
<tr>
<td>SF-12 physical composite score‡</td>
<td>38.8 ± 0.89</td>
<td>39.0 ± 1.00</td>
</tr>
<tr>
<td>PHQ-9 Depression score</td>
<td>5.7 ± 0.53</td>
<td>5.8 ± 0.98</td>
</tr>
<tr>
<td>PHQ Stress score</td>
<td>4.9 ± 0.47</td>
<td>5.1 ± 0.98</td>
</tr>
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</table>

Data are presented as adjusted means ± SE unless otherwise indicated. *Effect sizes were calculated as the ratio of difference of adjusted means and the square root of mean squared error. †Albuminuria data were log-transformed prior to the analysis in order to attain sufficient normality of distribution. Descriptive results are presented as unadjusted medians (25th/75th percentiles). ANCOVA results are reported with log values. ‡A higher number indicates improved functioning.
Because nine patients in the intervention group did not attend the training sessions as required (less than five sessions; for reasons, see Supplementary Fig. 1), a per-protocol analysis was performed. The findings confirm the abovementioned results and show consistently higher effect sizes, including a significantly lower level of stress in the MBSR group (d = 0.64).

CONCLUSIONS—The HEIDIS-Study is the first randomized controlled trial to assess whether an MBSR intervention is effective in reducing stress and depression as well as late diabetes complications (i.e., nephropathy) in patients with type 2 diabetes. In agreement with our hypothesis, we found that MBSR led to better health status and lower levels of depression. Among regular attendees, psychological stress also decreased significantly. However, at baseline, the patients had rather low rates of depression compared with previous reports (1); the effect of the intervention on depression, therefore, is largely based on preventing progression rather than a true reduction in the level of emotional distress. In accord with previous studies on MBSR in medical patients (10), our results suggest that effects may even accumulate over time.

However, although the effect sizes were remarkable, no significant effect could be demonstrated for the main outcome (albuminuria) or other physiological parameters, with the exception of diastolic blood pressure.

Psychosocial stress activates proinflammatory transcription factors, which mediate micro- and macrovascular disease (6,7). Therefore, a sustained reduction in the distress induced by MBSR may lead in the future to an effect on long-term diabetes complications. To further assess the influence of psychological distress on late diabetes complications, FU over a total period of 5 years is essential. The HEIDIS-Study takes this approach.

Despite the limitations of the study due to the small number of participants, this study adds to the sparse literature on stress and late diabetes complications and emphasizes the potential of psychosocial interventions. The specific advantage of MBSR is its preventive nature and broad applicability for a variety of symptoms.

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No potential conflicts of interest relevant to this article were reported.

M.H., S.K., and C.K. researched data and wrote the manuscript. V.F.-L. researched data and reviewed and edited the manuscript. Z.D. and F.A. researched data. H.-C.F., A.B., P.M.H., W.H., and P.P.N. contributed to the discussion and reviewed and edited the manuscript. M.K. contributed to the discussion. M.H. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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References