Mindfulness Training as an Intervention for Fibromyalgia: Evidence of Postintervention and 3-Year Follow-Up Benefits in Well-Being

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Abstract

Background: Mindfulness-based stress reduction (MBSR) proposes a systematic program for reduction of suffering associated with a wide range of medical conditions. Studies suggest improvements in general aspects of well-being, including quality of life (QoL), coping and positive affect, as well as decreased anxiety and depression. Methods: A quasi-experimental study examined effects of an 8-week MBSR intervention among 58 female patients with fibromyalgia (mean, 52 ± 8 years) who underwent MBSR or an active social support procedure. Participants were assigned to groups by date of entry, and 6 subjects dropped out during the study. Self-report measures were validated German inventories and included the following scales: visual analog pain, pain perception, coping with pain, a symptom checklist and QoL. Pre- and postintervention measurements were made. Additionally, a 3-year follow-up was carried out on a subgroup of 26 participants. Results: Pre- to postintervention analyses indicated MBSR to provide significantly greater benefits than the control intervention on most dimensions, including visual analog pain, QoL subscales, coping with pain, anxiety, depression and somatic complaints (Cohen d effect size, 0.40–1.10). Three-year follow-up analyses of MBSR participants indicated sustained benefits for these same measures (effect size, 0.50–0.65). Conclusions: Based upon a quasi-randomized trial and long-term observational follow-up, results indicate mindfulness intervention to be of potential long-term benefit for female fibromyalgia patients.

Fibromyalgia has emerged during the last three decades as one of the most common, albeit intractable pain disorders. With a lifetime prevalence estimated between 1 and 4%, and principally among women [1–4], fibromyalgia is characterized by widespread, severe skeletal muscular pain, fatigue and chronic sleep disturbance and is often associated with depression, post-traumatic stress disorder, and/or early emotional trauma [3, 5–12]. Because of its diffuse and difficult to objectify symptomatology, the very diagnosis of fibromyalgia remains controversial, and the primacy of physiological or psychological factors in its pathogenesis, disputed [13–16]. Nevertheless, few specialists deny the extent of physical pain and suffering of patients, trivialize the difficulties of treatment or underestimate the financial burden of the disorder [17, 18].
Therapeutic interventions for fibromyalgia have primarily focused upon pharmacological, exercise and psychotherapeutic procedures [19–23], and have so far generally met with limited success. This study employs mindfulness-based stress reduction (MBSR) [24] to evaluate whether an intervention that primarily focuses on psychosocial adjustment to and coping with chronic dysfunction [e.g. 25] may provide long-term benefits for female fibromyalgia patients. MBSR has been employed among patients with a wide variety of chronic clinical ailments [26–28]. It is a group program that focuses upon the progressive acquisition of mindful awareness, or mindfulness. Mindfulness is characterized by dispassionate, non-evaluative and sustained moment-to-moment awareness of perceptible mental states and processes. This includes continuous, immediate awareness of sensory sensations, perceptions, affective states, thoughts, imagery or other discernable mental content. An integral part of the practice is to cultivate an attitude of kindness, acceptance, generosity and patience toward even unpleasant emotions or thoughts may unavoidably arise. Benefits of mindfulness training in fibromyalgia have been suggested by previous studies [29–31], although methodological problems hampered conclusions (e.g. short-term evaluation, inappropriate controls, excessive attrition and modification of the MBSR program).

The present quasi-randomized study compared a group program of MBSR to an active control procedure that included social support, relaxation and stretching exercises. Effects of interventions were tested 2 weeks after treatment for all patients. Additionally a 3-year follow-up assessment was performed with patients assigned to the MBSR arm of the study.

Methods

Subjects

Fifty-eight women with a diagnosis of fibromyalgia were recruited by referrals from local physicians and by means of contact with fibromyalgia self-help groups in two cities. Criteria for study inclusion were the following: (1) confirmation of a clinical diagnosis of fibromyalgia by the patient’s own physician fulfilling American College of Rheumatology classification criteria for fibromyalgia based on rheumatologic examination (a) widespread pain – axial plus upper and lower segment plus left and right side pain for at least 3 months and (b) tenderness at a minimum of 11 of the 18 specific tender point sites; (2) age between 18 and 70 years; (3) female gender; (4) ability to attend group intervention sessions. Exclusion criteria included pregnancy, substance abuse, any current psychiatric disorder that would interfere with program adherence, or life-threatening disease. Men were excluded because only one male volunteered. The study was conducted according to the guidelines of the Ethics Commission of the University of Freiburg and the Psychology Department of the University of Vienna. All participants completed informed consent prior to commencement of the study. The MBSR group was significantly older (54.4 ± 8.3 SD years) than the control group (48.8 ± 9.1 years; p<0.05); years since diagnosis, 13.8 ± 6.1 vs. 9.9 ± 6.9, respectively.

Educational levels of patients were as follows: basic education (9 years) or less and/or trade school, 35%; mid-level secondary school (10 years), 43%; college-preparatory high school and/or university, 22%. Education level did not differ between the control and experimental groups. Most patients were unemployed, on prolonged sick leave or receiving disability insurance; only 31% reported themselves as actively employed. To investigate psychiatric comorbidity, we used clinical cutoff indices from the baseline, preintervention levels of the Hospital Anxiety and Depression Scale [32]: 31% of the patients manifested probable presence of clinical depression, and 26% scored suggestive of the disorder. Correspondingly, 47% had anxiety scores showing probable presence of clinical anxiety, and 22% suggestive of the disorder. When we considered scores for either scale, 52% manifested probable presence of at least one disorder, and 26% were suggestive of at least one. There were no differences in any of these scores between the control and MBSR groups.

Outcome Measures

Primary Measures

Subjects completed the following inventories within 2 weeks prior to intervention and 2 weeks after intervention. Additionally, a subset of 34 MBSR participants approximately 3 years later (35.6 ± 2.1 months) were requested to complete the same questionnaires. These included the visual analogue scale (VAS) of pain severity over the last 2 weeks [33] and the following standardized, validated German-language inventories:

1. The Quality of Life Profile for the Chronically III (QoL) [34].
2. The German version of the Hospital Anxiety and Depression Scale (HADS) [35].
3. The Pain Perception Scale (PPS) [36].
4. The Inventory of Pain Regulation (IPR) [37].

The QoL is a 40-item scale that assesses 6 dimensions of quality of life over the last 7 days and has been extensively validated [34, 38, 39]: (1) general functional capacity; (2) ability to derive joy and to relax; (3) positive affect; (4) negative affect; (5) ability to maintain and develop social contacts; (6) sense of social connectedness.

The HADS [40] has been translated and validated for the German-speaking population [35].

The PPS is a validated 24-item scale that evaluates pain perception employing a multifactorial concept of pain, including sensory, affective, cognitive and behavioral components; reference period is the previous 2 weeks. Two major subscales reflect sensory and affective dimensions [36].

The IPR is a 56-item instrument that evaluates dimensions related to coping with chronic pain including sense of competence, resignation, avoidance, and pain-related depression, anxiety and pain intensity.

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Secondary Measures

A 13-item Somatic Symptom Inventory (SSI), adapted from Egle [41], was employed to assess intensity of physical symptoms during the last 2 weeks. Items included sleep disturbance, difficulty to concentrate, urinary symptoms, excess sweating, trembling of limbs, headaches and circulatory, respiratory, gastrointestinal, chest and skin complaints.

Quasi-Random Allocation of Treatments

A quasi-random allocation to treatments was based upon alternation of small groups of patients according to time of enrollment. The first 31 patients who enrolled comprised the initial two MBSR groups; the next consecutive 15 patients formed the control group, which was then followed with subsequent MBSR groups. The limited size of the control group was caused by insufficient funding.

Interventions

Individual semistructured, 1- to 1.5-hour interviews were conducted by instructor before and after the 8-week periods of intervention, aimed at collecting information about the health-related problems and expectations of patients concerning the intervention, answering questions and building rapport and trust between patient and instructor. Postintervention interviews assessed individual goal attainment and participant feedback.

Mindfulness-Based Stress Reduction

The MBSR intervention comprised an 8-week group program with groups of 10–15 participants. Participants took part in a 2.5-hour session each week, and there was an additional all-day session on a weekend day after the 5th week. Each session covered specific exercises and topics within the context of mindfulness practice and training. These included different types of formal mindfulness practice, mindful awareness during yoga postures, and mindfulness during stressful situations and social interactions. The all-day retreat was composed of varied mindfulness exercises during a 7-hour period. Because development of mindfulness is predicated upon regular and repeated practice, participants committed themselves upon enrollment to carry out daily 45-min homework assignments, primarily mindfulness exercises sitting and lying, mindful yoga and mindfulness applications in everyday life. The MBSR instructor was female, trained and previously employed at the UMass Medical Center for Mindfulness, Worcester Mass., USA, and with 5 years of previous experience teaching MBSR at the start of the study.

Active Control Procedure

This intervention was designed to control for the nonspecific elements of the MBSR curriculum. Those elements included the presence of a trained, experienced group facilitator, participation in an 8-week group setting of the same size and weekly format as the MBSR program, similar curriculum structure, equivalent amount of homework assignments, social support, and relaxation training, gentle stretching exercises designed for fibromyalgia patients, and weekly topical discussions. Each component has its counterpart in the MBSR curriculum, but emphasis was placed upon not describing or training mindfulness skills to the control group. The group facilitator was a female clinical psychologist with many years of group and relaxation training experience. Each week, progressive relaxation and gentle stretching exercises were taught, and a different fibromyalgia-related topic was discussed. One notable difference between interventions was the absence of an all-day session in the control group.

Data Analysis

Four subjects dropped out of the MBSR intervention and 2 from the control group. All remaining participants completed at least four sessions and were included in the analyses. Because of the small attrition rate and the preliminary nature of the study, we did not perform intent-to-treat analyses. Several different types of analyses were separately performed to address different aspects of the intervention:

Group Comparisons of Pre- to Postintervention Effects

(1) Analyses of covariance were performed on the change scores for each measure, with preintervention level and age serving as covariates to adjust for possible group differences at baseline. (2) Because of the large difference in sample sizes between MBSR and control groups, as well as the preliminary nature of the study, within-group paired t tests were used to evaluate the immediate, pre- to postintervention effects of the MBSR intervention. (3) In order to assess the extent of MBSR change relative to change in the control group, Cohen’s d effect sizes (es) were calculated for each dependent measure by dividing the mean pre- to postintervention differences between groups by their pooled standard deviation. A positive effect size indicated a superior benefit of the MBSR intervention. All three sets of the above-mentioned analyses pertain only to those short-term benefits of treatment assessed just before and shortly after interventions.

Long-Term Follow-Up Analyses of MBSR Participants

Because 8 of the contacted 34 MBSR patients refused to participate in the 3-year follow-up interview and inventory completion, we assessed whether those who had refused differed from the other MBSR participants in terms of either baseline demographic or questionnaire data. Independent t tests between groups with separate estimates of variance were employed to adjust for the different sample sizes per group. Similarly, independent t tests compared refusers and follow-up participants in terms of the pre- to postintervention change scores on all dependent measures in order to assess whether those who had refused to participate in the follow-up differed in immediate benefits of the MBSR intervention. Subsequently, repeated measures ANOVAs were performed across three time points (preintervention, postintervention and 3-year follow-up); Huynh-Feldt corrections were made for multiple repeated measures; and Fisher’s LSD tests were performed for post-hoc comparisons. This procedure allowed us to determine if parameters changed significantly (1) from preintervention to follow-up, and (2) from postintervention to follow-up; the pre- to postintervention effects specifically reflected the MBSR within-group effects reported above.

All contacted MBSR patients (including those who refused to participate in the follow-up assessment) were also briefly asked by telephone whether they still regularly employed any mindfulness practices learned in the course. Refusers were also asked why they decided against follow-up participation. Six of the 8 who did not participate in the follow-up said they were unavoidably absent during the study period due to such reasons as hospitalization or vacation.
Results

Baseline Levels and Pre- to Postintervention Effects

Table 1 provides means and SDs of inventory scales, separately for the MBSR and control groups. Baseline levels were similar for all variables, except for the life enjoyment/relaxation subscale (p < 0.03, t test for independent samples); control patients had higher initial ratings for enjoyment/relaxation. There was also a tendency toward significance in VAS pain severity in the previous 2 weeks (p = 0.06), with MBSR patients reporting higher initial levels of pain.

Table 1 also presents results of the ANCOVA analyses that compared groups on the extent of change among outcome variables, after having adjusted for preintervention levels. Even with the substantial loss of statistical power due to inclusion of control subjects, only three variables did not reach or approach statistical significance.

Within-group paired t tests were performed to evaluate whether either group had changed from pre- to postintervention on any variable. Because of the exploratory nature of the study, no adjustments were made for number of comparisons. As evident from table 1, all dependent measures significantly improved for the MBSR group, with all p values < 0.01. On the other hand, there was no significant change for any measure for the control group, although there were tendencies (p < 0.20) toward improvement for sense of competence and positive affect and worsening for VAS pain. Mean differences at this 0.20 significance level would reflect approximately p = 0.05 if the sample size of the control group had been the same as the MBSR group (n = 39).

Examination of the effect sizes (table 1) also indicates that these results were not merely due to the substantially greater statistical power of the MBSR group due to group size. With each dependent variable, the absolute positive change was much larger in the MBSR group. Across all individual items, the average effect size was 0.66. The largest effect sizes were found for the VAS pain scale, SSI somatic complaints, and each of the QoL subscales, many of these measurements approximating an effect size of 1.0. The smallest effect sizes were found for the standardized pain subscales and items from the IPR ‘coping with pain’ inventory also showed improvements that were maintained from postintervention to long-term follow-up.

In all PLC ‘quality of life’ subscales, there were significant improvements from preintervention to follow-up. However, there was also a clear and substantial decline from postintervention to follow-up, indicating an attenuation of effects over time.

The within-group effect sizes for preintervention and follow-up are presented in figure 1 for selected, clinically relevant variables (VAS pain, HAD depression and anxiety, the composite QoL measure and somatic complaints). As can be seen, the follow-up effect sizes were somewhat lower than those immediately after intervention. Nevertheless, even at follow-up, effects sizes were about 0.5 or greater for all measures, and the largest effect sizes remained for quality of life.

Continued and regular practice of some form of mindfulness was reported by 26 of the 34 (76%) patients contacted during follow-up: Three ‘refusers’ and 5 follow-up participants reported that they no longer practiced regularly.
The findings of this study provide tentative evidence for short- and long-term effectiveness of mindfulness training in improving well-being among female fibromyalgia patients. The immediate postintervention effects of MBSR manifested themselves in almost every assessed dimension. These findings did not appear secondary to nonspecific benefits of treatment, as indicated by the lack of improvement in the controls, who had also received a credible intervention aimed at controlling for nonspecific effects of intervention.

**Discussion**

Table 1. Individual means (SDs) of inventory items for the MBSR and control groups

<table>
<thead>
<tr>
<th></th>
<th>MSBR group (n = 39)</th>
<th>Control group (n = 13)</th>
<th>Effect size</th>
<th>ANCOVA p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>pre</td>
<td>post</td>
<td>t test p</td>
<td>pre</td>
</tr>
<tr>
<td><strong>PPS pain perception</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Sensory pain</td>
<td>22.87</td>
<td>20.53</td>
<td>≤0.01</td>
<td>20.54</td>
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<td>(6.52)</td>
<td>(6.56)</td>
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<td></td>
<td>(6.72)</td>
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<td>Affective pain</td>
<td>34.92</td>
<td>28.18</td>
<td>≤0.0001</td>
<td>36.62</td>
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<td>(9.66)</td>
<td>(10.68)</td>
<td></td>
<td></td>
<td>(7.87)</td>
</tr>
<tr>
<td><strong>VAS pain</strong></td>
<td>64.36</td>
<td>49.49</td>
<td>≤0.001</td>
<td>52.07</td>
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<td>(20.26)</td>
<td>(24.07)</td>
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<td>(18.31)</td>
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<td><strong>SSI complaints</strong></td>
<td>21.50</td>
<td>14.21</td>
<td>≤0.0001</td>
<td>19.62</td>
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<td>(7.42)</td>
<td>(7.06)</td>
<td></td>
<td></td>
<td>(7.24)</td>
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<tr>
<td><strong>HADS</strong></td>
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<tr>
<td>Depression</td>
<td>8.23</td>
<td>6.10</td>
<td>≤0.0001</td>
<td>8.54</td>
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<tr>
<td>(4.00)</td>
<td>(3.59)</td>
<td></td>
<td></td>
<td>(3.97)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>10.28</td>
<td>7.59</td>
<td>≤0.0001</td>
<td>8.54</td>
</tr>
<tr>
<td>(4.18)</td>
<td>(3.75)</td>
<td></td>
<td></td>
<td>(3.97)</td>
</tr>
<tr>
<td><strong>IPR coping</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Competence</td>
<td>30.74</td>
<td>36.82</td>
<td>≤0.0001</td>
<td>31.15</td>
</tr>
<tr>
<td>(8.52)</td>
<td>(9.01)</td>
<td></td>
<td></td>
<td>(4.39)</td>
</tr>
<tr>
<td>Pain intensity</td>
<td>38.13</td>
<td>35.64</td>
<td>≤0.01</td>
<td>36.38</td>
</tr>
<tr>
<td>(4.34)</td>
<td>(5.81)</td>
<td></td>
<td></td>
<td>(3.48)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>38.22</td>
<td>33.94</td>
<td>≤0.01</td>
<td>38.31</td>
</tr>
<tr>
<td>(9.57)</td>
<td>(9.83)</td>
<td></td>
<td></td>
<td>(9.18)</td>
</tr>
<tr>
<td>Depression</td>
<td>33.72</td>
<td>29.45</td>
<td>≤0.01</td>
<td>36.15</td>
</tr>
<tr>
<td>(9.21)</td>
<td>(9.49)</td>
<td></td>
<td></td>
<td>(6.97)</td>
</tr>
<tr>
<td>Avoidance</td>
<td>29.91</td>
<td>27.35</td>
<td>≤0.01</td>
<td>29.00</td>
</tr>
<tr>
<td>(7.81)</td>
<td>(6.73)</td>
<td></td>
<td></td>
<td>(7.09)</td>
</tr>
<tr>
<td>Resignation</td>
<td>37.18</td>
<td>33.36</td>
<td>≤0.01</td>
<td>40.23</td>
</tr>
<tr>
<td>(8.11)</td>
<td>(8.84)</td>
<td></td>
<td></td>
<td>(5.82)</td>
</tr>
<tr>
<td><strong>QOL</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional status</td>
<td>11.56</td>
<td>16.97</td>
<td>≤0.0001</td>
<td>11.85</td>
</tr>
<tr>
<td>(4.18)</td>
<td>(5.63)</td>
<td></td>
<td></td>
<td>(4.32)</td>
</tr>
<tr>
<td>Enjoyment/relaxation</td>
<td>16.13</td>
<td>21.51</td>
<td>≤0.0001</td>
<td>19.46</td>
</tr>
<tr>
<td>(4.62)</td>
<td>(5.02)</td>
<td></td>
<td></td>
<td>(5.29)</td>
</tr>
<tr>
<td>Positive affect</td>
<td>7.72</td>
<td>11.18</td>
<td>≤0.0001</td>
<td>6.84</td>
</tr>
<tr>
<td>(3.56)</td>
<td>(3.26)</td>
<td></td>
<td></td>
<td>(3.24)</td>
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<tr>
<td>Negative affect</td>
<td>17.41</td>
<td>23.10</td>
<td>≤0.0001</td>
<td>19.54</td>
</tr>
<tr>
<td>(7.17)</td>
<td>(5.94)</td>
<td></td>
<td></td>
<td>(5.13)</td>
</tr>
<tr>
<td>Social contact</td>
<td>12.64</td>
<td>16.18</td>
<td>≤0.0001</td>
<td>14.08</td>
</tr>
<tr>
<td>(4.06)</td>
<td>(3.62)</td>
<td></td>
<td></td>
<td>(4.89)</td>
</tr>
<tr>
<td>Sense of belonging</td>
<td>12.77</td>
<td>14.74</td>
<td>≤0.0001</td>
<td>13.15</td>
</tr>
<tr>
<td>(4.13)</td>
<td>(3.58)</td>
<td></td>
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<td>(5.30)</td>
</tr>
</tbody>
</table>

T tests p values indicate within-group paired t test comparisons. ANCOVA between groups with baseline values and age included as covariates.
The 3-year follow-up results of 26 MSBR group participants seem particularly noteworthy in suggesting long-term benefits of mindfulness training and practice. To the best of our knowledge, this is the first report that indicates general improvements in well-being among fibromyalgia patients that are largely sustained 3 years after intervention. Although these results are observational, most longitudinal studies of female fibromyalgia patients indicate an absence of spontaneous improvement of symptoms or remission in the natural course of the syndrome [42–45]. Therefore, the rather stable levels of improved outcomes from postintervention to follow-up in our study may indeed indicate long-lasting benefits of mindfulness training.

Fig. 1. Three-year follow-up effect sizes for MBSR participants (based on improvement from preintervention).
A plausible explanation for such long-term benefit is that mindfulness-based interventions, unlike other behavioral therapies, provide techniques, practices and perspectives that, once learned, can be applied to everyday life, and patients are encouraged to continue to practice these. Indeed, over three quarters of all contacted MBSR patients reported having maintained some aspect of mindfulness practice 36 months after study. Furthermore, mindfulness training is not aimed at symptom reduction but more fundamentally toward altering how perceptible mental processes and content are experienced, toward greater awareness, acceptance and tolerance of the unavoidable vagaries of life. Additionally, development of self-acceptance, mastery, purpose and positive social relations may facilitate enhanced well-being, even in the face of continued symptoms [25, 46, 47]. Positive 3-year effects upon coping with pain provide evidence in this direction.

Findings related to clinically significant pain reduction were mixed. Although patients appeared to show pain reduction at 3 years on VAS global ratings, long-term benefits were not seen for other pain variables. These findings may underline the difficulties in assessing pain perception. Also slippage of 3-year follow-up QoL should be noted, although subscales were still generally substantially improved when compared to preintervention.

Due to the preliminary nature of the investigation, we did not perform intention to treat analyses. Nevertheless, the very low level of participant dropout in the MBSR intervention (10%) is in contrast to reports of significant attrition in other studies [48–50] and suggests that many fibromyalgia patients are, in fact, able to garner motivation over an 8-week MBSR program requiring prolonged periods of daily practice.

Despite promising findings, this study has several limitations. The study was not strictly randomized from pre- to postintervention. Our findings are restricted to female patients and may not apply to males. Because of funding constraints, the control group was quite small in relation to the MBSR group, and differed somewhat in certain baseline parameters. The 3-year follow-up did not include results from the control group, and we also did not directly assess medical utilization. Clearly, a larger-scale fully randomized replication study is warranted. Nevertheless, the findings demonstrate the feasibility of MBSR intervention for fibromyalgia and suggest long-term improvements in well-being.

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References


