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# Ayurvedic versus conventional dietary and lifestyle counseling for mothers with burnout-syndrome: A randomized controlled pilot study including a qualitative evaluation

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## 1. Introduction

Burnout seems to have become a relevant societal and health-economic factor in Western countries during the last decades; the European Agency for Safety and Health at Work estimates the economic costs of burnout in the European Union at around twenty billion Euros per year.[1] In contrast, health insurance companies, e.g. in Germany, recently reported a drop in the numbers of sickleave due to burnout and suggested that its significance is being overestimated.[2] Issues related to medical relevance, social impact and in particular to clear definitions of burnout remain controversial and are being debated globally.[3]

Burnout is most commonly defined as a state of work-related exhaustion, cynicism, and inefficacy with reduced work performance and/or reduced interest in work.[4] It can be described as a result of a dynamic process, which may start as enthusiasm and, via frustration, disillusionment and apathy, may eventually lead to psychosomatic disorders, depression, fatigue, anxiety, aggressive tendencies and an increased risk of addiction.[5] As it bears similarities to depressive

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disorders, and several studies have noted that it may in fact be a form of depression,[6–8] burnout has not been classified as a distinct diagnosis by the 5th edition of the Diagnostic and Statistical manual of Mental Disorders (DSM-5).[9] However, it is included in the ICD-10 and is defined as a state of exhaustion (Z73). According to this classification burnout is an additional Z-diagnosis and not a treatment diagnosis that allows health-insurance reimbursable hospitalization in Germany.[10]

Available treatment options for burnout include treatment of somatic disorders (if existent), basic physical activities, relaxation exercises, psychotherapy and pharmacotherapy.[11] The evaluation of burnout prevention and multimodal treatment programs are still in the beginning, for example one review evaluated the effectiveness of intervention programs aimed at preventing burnout,[12] by including therapies like cognitive behavioral training, psychotherapy, social support and relaxation exercises. 80 percent of all programs led to a reduction in burnout, however, these interventions are cost-intensive due to their multimodal approaches and comparatively high personnel demand.

The traditional Indian medicinal practice known as Ayurveda is widely used in Asia and recognized by the WHO as a medical science.[13] In Europe, Ayurvedic medicine has become increasingly popular and recognized over the last years, particularly in the treatment of chronic[14,15] and psychosomatic[14,16] diseases. Multi-component and individualized Ayurvedic treatment strategies for burnout-syndrome include various non-pharmacological measures and are based on the assumption that combinations of various treatment elements may exert synergistic therapeutic effects.[17–19] As a whole medical system Ayurveda offers complex diagnostic procedures and complex treatment approaches. Ayurvedic treatment is based on Ayurvedic diagnosis and traditionally has a focus on tailored lifestyle- and nutritional counseling, based on the individual constitution of the patient. Ayurvedic counseling can easily be followed by the patients in their day-to-day life and thus is a comparatively inexpensive method of self-care. In Ayurveda lifestyle- and nutritional counseling is often used for the treatment of burnout-syndrome. However, no systematic data is available on its effectiveness in comparison to conventional diet and lifestyle counseling for burnout patients, particularly not for mothers, where burnout symptoms are frequently being reported.[20–24]

The aim of this study was to evaluate the effectiveness of Ayurvedic nutritional and lifestyle counseling compared to conventional nutritional and lifestyle counseling in outpatient mothers with burnout-syndrome due to career and family responsibilities. This trial examined, whether elements of Ayurvedic burnout therapy, which patients are able to perform independently by themselves in their domestic environment, can exert sustainable therapeutic effects.

The qualitative part of this study, using the methods of Conversation Analysis[25] and participant observation,[26] examines the meaning of communication processes in both treatment groups. Empirical research in linguistics and sociology has demonstrated “how insufficient attention to patient-relevant issues results in a lower quality of doctor-patient-communication, and lower satisfaction of patients and doctors”.[27] Gülich noted the significance of the conversational process, precise wording and phrasing, when taking into account the subjective experience in doctor-patient-interaction.[28] Peräkylä, a conversation analytical and psychoanalytical researcher, demonstrated how medically relevant biographies of patients are negotiated and produced in doctor-patient interactions.[29] Ruusuvuori[30] compared homeopathic and general practice consultations and examined the phase of problem presentation, “discovering the reason for the patient‘s attendance”.[31] She demonstrated the consequences of this crucial phase in terms of the outcome of the consultations and showed how “in homeopathy, professionals worked to realize the patient-centered ideal to let patients speak in their own words, to elicit their own formulation of the problem”.[30] Considering these empirical studies and based on the conversation analysis approach, the aim of this study was to focus on differences in conversational styles and counseling techniques between Ayurveda and conventional nutritional counseling and their specific relevance in the treatment process.

## 2. Methods

### 2.1. Study design

In a two-armed randomized controlled trial mothers suffering from burnout syndrome were allocated to two treatment groups: (1) Ayurvedic lifestyle- and nutritional counseling and (2) conventional lifestyle- and nutritional counseling.

The study protocol was reviewed and approved by the ethics committee of the Charité-University Medical Center, Berlin, Germany. The trial was registered at Clinical Trials (registration number: NCT01797887, acronym: VEDA-trial). Trained study personnel performed collection of data at Immanuel Hospital Berlin, Department of Internal and Complementary Medicine, Berlin, Germany.

### 2.2. Participants

Female volunteers, who lived in the community, were recruited from local newspaper advertisements and flyers that offered mothers with burnout-syndrome cost-free Ayurvedic or conventional lifestyle- and nutritional counseling. Subjects were included if they (1) were female and aged 18–50 years, (2) were mothers of at least one biological child (twelve years of age or less), (3) had an employment with at least 20 h workload per week or the equivalent time spent on education, training, studies, etc., (4) had a subjective feeling of physical and mental exhaustion of at least 3 months prior to entry into the study, and (5) scored two or more on the MBI subscale “emotional exhaustion” at screening visit. Subjects were excluded if they (1) had started or modified a psychotropic drug medication therapy during six weeks preceding the study entry, (2) were pregnant or breastfeeding at the time of their screening visit, (3) had a previously diagnosed depression episode, (4) had an acute psychotic illness, (5) had an ongoing treatment with psychotropic drugs, opioids and/or sleeping medication, (6) had severe acute somatic diseases, (7) had severe chronic co-morbidities, (8) were undergoing application processes for pension or retirement or disability and (9) participated in another clinical trial or had participated in another clinical trial within the last six months prior to study entry.

After signing informed consent and collection of baseline data, subjects were randomized to either (1) Ayurvedic lifestyle- and nutritional counseling (n = 16) or (2) conventional lifestyle- and nutritional counseling (n = 18).

### 2.3. Outcomes and measurements

All subjects were asked to complete standardized validated questionnaires at the onset of the study (baseline), at three months (visit 2) and at a six months follow-up (visit 3). The primary outcome was the change of the mean score of the validated German version of the Maslach Burnout Inventory (MBI-D) at three months.[32] The MBI-D includes four subscales with twenty five items, three of them were adopted from the US version: (1) emotional exhaustion, (2) depersonalization, and (3) personal accomplishment. The MBI-D includes an additional scale “involvement” (e.g. empathy and dedication). Higher scores for emotional exhaustion, depersonalization and involvement indicate more intense burnout symptoms; lower scores for personal accomplishment indicate a higher degree of burnout. The items can be rated from zero (never) to six (very often).

Pre-specified secondary outcomes included the following validated questionnaires in German:

1. Maslach Burnout Inventory (MBI-D) at six months.
2. Cohen Perceived Stress Scale (CPSS) at three and six months. The

CPSS consists of ten items about current personal levels of experienced and perceived stress.[33]

3. Hospital Anxiety and Depression Scale (HADS-D) at three and six months,[34] a fourteen-item scale designed for the assessment of anxiety and depression symptoms in general populations.
4. Medical Outcomes Study 36-Item-Short Form (SF-36) for measuring Quality of life (QoL), using its eight dimensions of health, at three and six months.[35]
5. Aspects of Spirituality (ASP) questionnaire at three and six months. ASP measures aspects of spirituality, religious issues, and cognitive transcendence convictions.[36]
6. Pittsburgh Sleep Quality Index (PSQI) at three and six months,[37] an eighteen-item questionnaire that assesses sleep quality.

### 2.4. Qualitative methodology

In addition we conducted a qualitative evaluation of diagnostic and counseling sessions, using participant observation,[26] transcribed audio recordings, and Conversation Analysis.[25]

Over a period of one week two participant observers alternately attended nine Ayurvedic and eight conventional counseling sessions and made field-notes. These concerned the individual consultations as well as the entire study context. In addition, all consultations were audio-taped and subsequently transcribed. The general objective of Conversation Analysis is to describe people's methods for producing orderly social interaction.[38] This approach is based on an "empirical grounding of analysis",[39] therefore it was also necessary to have detailed transcripts of so-called naturally occurring talk.

After an overall evaluation of the seventeen consultations (nine involving Ayurveda counseling, eight involving conventional counseling), adequate and comprehensive cases were selectively chosen to represent "ideal types" of each therapy group.[40] For further in-depth analysis selective sequences were transcribed in more detail using G-AT2-convention.[41] Preliminary results were further validated in an interdisciplinary "data session"[42] involving the whole research team after completion of the six month active trial period.

### 2.5. Interventions

For each patient, an individual patient history was taken and all patients then received a sixty ± fifteen min. personal lifestyle- and nutritional counseling session (baseline consultation), followed by four further sixty-minute group counseling sessions two, five, eight and eleven weeks after baseline consultation. The study was conducted in a German outpatient setting in Berlin.

The Ayurvedic approach included individualized recommendations for lifestyle modifications based on the traditional Ayurvedic constitutional paradigm (*tridosha*-approach),[43] guidance to Ayurvedic self-massage, and personalized Ayurvedic nutritional counseling with concrete suggestions for wholesome foods and recipes. Recommendations for food items, dishes, food preparations etc. were adapted to local availability in order to maximize practicability and patients' adherence. An experienced German physician with more than five hundred hours of academic training in Ayurveda and more than five years of continuous clinical experience with Ayurveda in Germany performed the counseling.

Conventional treatment consisted of lifestyle and nutritional counseling in accordance with the German Society for Nutrition (*Deutsche Gesellschaft für Ernährung*, DGE)[44] with concrete suggestions for foods and recipes. Moreover, every patient got a compact disc with a structured program for progressive muscle relaxation. An experienced German specialist for general medicine with more than five years of continuous clinical experience in family medicine and a super-qualification for psychosomatic primary care performed the counseling.

### 2.6. Statistical analysis

This study was conducted as an exploratory study. Therefore, no sample size calculation was performed. We intended to include forty patients and assumed a drop-out rate of fifteen percent. Baseline differences were calculated using two tailed *t*-tests wherever applicable. A per protocol analysis was performed. Treatment effects were reported as group differences including their respective 95% confidence intervals (CI) and *p*-values. A $p$-value $< 0.05$ was considered significant. Cohen's d was provided, if a parameter was significant. Assumptions for repeated ANOVA measures were not fulfilled, thus we conducted non-parametric tests. The Wilcoxon rank sum test was used to compare mean differences at baseline between the groups and to calculate intra-group differences. Differences of change at baseline were calculated for each follow-up visit separately using Wilcoxon rank sum test. All statistical analyses were done within the statistical programming language R (Version 3.2.1).

Patients were randomly allocated to treatment groups following block-randomization (block-size 4) based on the Blockrand-package (Version 1.3). For each patient the biostatistician prepared sealed, sequentially numbered opaque envelopes containing the treatment assignments. Each time a patient fulfilled all enrolment criteria, the study physician opened the lowest numbered randomization envelope to reveal the patient's study group allocation.

## 3. Results

Sixty four subjects responded to the study advertisement (Fig. 1). Three did not fulfill the inclusion criteria. Nine declined participation, citing unavailability due to scheduling problems. Thirteen could not be included because they were unwilling to get randomized and only willing to receive Ayurvedic counseling. Five had unspecified reasons for not wanting to further participate. A total of thirty four subjects fulfilled all entry criteria and were enrolled into the study. Subjects were recruited between March 2013 and June 2014 and were randomly allocated to the Ayurvedic group (n = 16) or the conventional group (n = 18).

One participant in the Ayurvedic group and five in the conventional group withdrew consent after randomization and before the first intervention (timetable problems, illness of child, unwillingness to receive conventional counseling). Two participants in the Ayurvedic group and three subjects in the conventional group dropped out during the study due to causes not related to the study intervention, e.g. personal reasons, unwillingness to remain in the study or to physically return to the study centre, lack of time or health related problems. Thirteen participants in the Ayurvedic group and ten participants in the conventional group completed the study as per protocol and were included in the per protocol analysis.

### 3.1. Baseline characteristics

Subjects' age ranged from 27 to 49 years (mean age 41.7 ± 6.3 years) (Table 1). Baseline characteristics were balanced between groups with the exception of older participants in the Ayurvedic group, a lower SF-36 mental subscale in the Ayurvedic group, and a lower MBI-depersonalization subscale in the conventional group. Baseline scores of the MBI subscale "emotional exhaustion", CPSS, HADS, and the mental health subscale of SF-36 and PSQI scores were in a range that is commonly regarded to indicate clinically relevant burnout. Moreover, the population had clinically relevant distress, reduced mental health and sleep quality, and increased anxiety and depression. Baseline values of ASP showed a stronger spiritual orientation amongst the Ayurvedic group (values more than 60 indicating a positive outcome, less than 40 indicating a negative outcome).

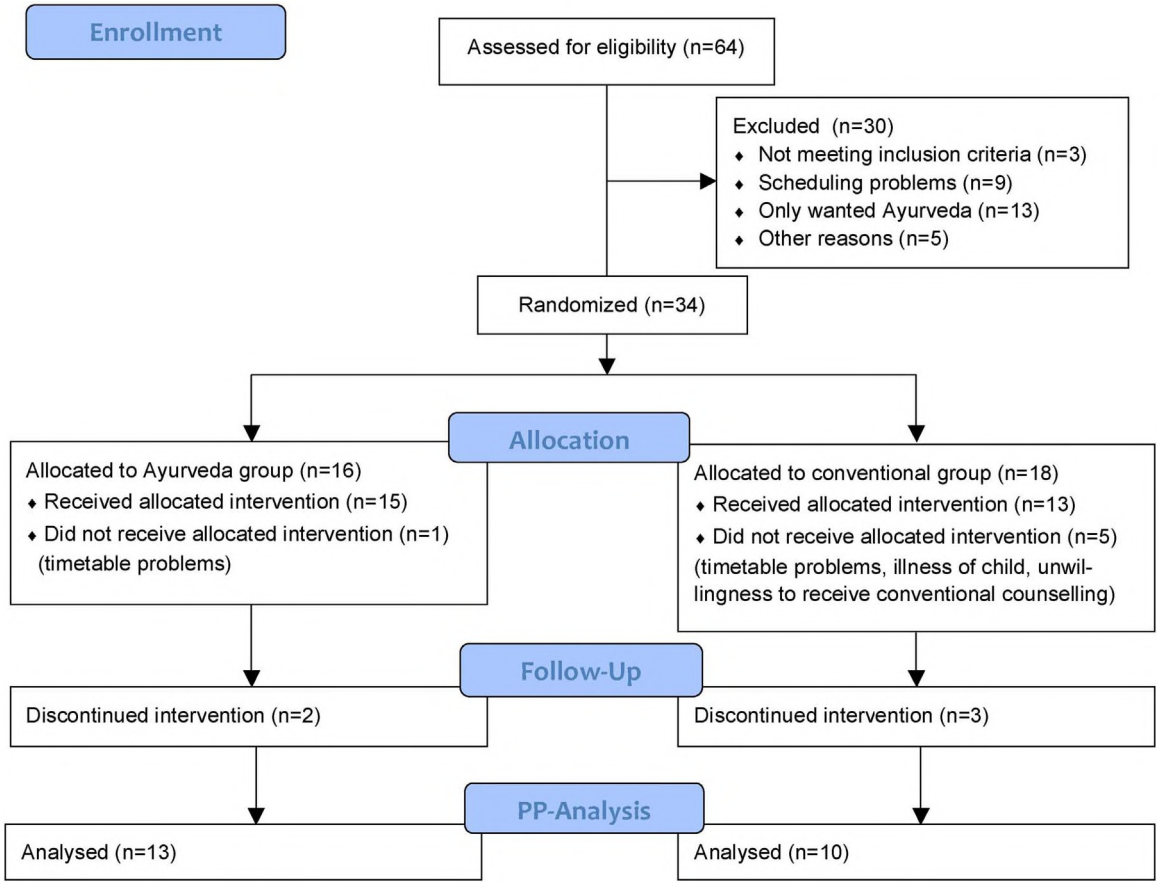


**Fig. 1.** Consort Flow Diagram.
PP-Analysis = Per Protocol-Analysis, n = number.

**Table 1**
Baseline characteristics.

| Characteristics<br>Female, No. | Ayurveda group<br>(n = 13) | Conventional group<br>(n = 10) | *p*-value |
|---|---|---|---|
| Age, years | 43.9 ± 5.8 | 38.7 ± 5.8 | 0.07 |
| Body mass index, kg/m$^2$ | 23.6 ± 4 | 22.4 ± 4.8 | 0.77 |
| Multi-person household, n > 2, % | 100 | 89 | 0.86 |
| > 10 years of school, % | 36 | 36 | 0.8574 |
| Full-time employment, % | 53 | 30 | 0.6754 |
| Part-time employment, % | 46 | 62 | 0.9111 |
| Apprenticeship | 0 | 8 | 0.972 |
| MBI (EE) | 3.3 ± 1.1 | 3.0 ± 0.8 | 0.45 |
| MBI (Dp) | 1.5 ± 1.2 | 1.0 ± 0.7 | 0.94 |
| MBI (PA) | 4.0 ± 1.1 | 4.2 ± 1.2 | 0.69 |
| MBI (In) | 2.8 ± 1.2 | 2.8 ± 0.7 | 0.46 |
| PSQI | 7.6 ± 4.2 | 8.4 ± 3.4 | 0.62 |
| CPSS score | 24.0 ± 4.6 | 22.1 ± 5.3 | 0.38 |
| HADS – Anxiety | 12.2 ± 3.3 | 11.8 ± 2.6 | 0.70 |
| HADS – Depression | 7.9 ± 3.2 | 8.5 ± 3.9 | 0.67 |
| SF36 physical | 48.8 ± 8.1 | 45.6 ± 10.6 | 0.69 |
| SF36 mental | 32.6 ± 7.8 | 40.6 ± 12.6 | 0.30 |
| ASP – Religious Orientation | 41.7 ± 27.9 | 30.8 ± 24.4 | 0.26 |
| ASP – Insight/Wisdom | 67.3 ± 19.0 | 60 ± 33.7 | 0.47 |
| ASP – Conscious interaction | 71.2 ± 15.4 | 72 ± 17.8 | 0.38 |
| ASP – Transcendence conviction | 56.7 ± 30.8 | 48.8 ± 27.9 | 0.50 |

Values are mean ± SD if not indicated otherwise. MBI = Maslach Burnout Inventory, EE = emotional exhaustion, Dp = Depersonalization, PA = Personal Accomplishment, In = Involvement, PSQI = Pittsburgh Sleep Quality Index, CPSS = Cohen Perceived Stress Scale; HADS = Hospital Anxiety and Depression scale; SF36 = Short Form 36 Health Survey, ASP = Aspects of Spirituality.

### 3.2. Primary outcome

Both counseling programs showed beneficial effects with regard to burnout symptoms (Fig. 2).

The MBI subscales emotional exhaustion (EE) and depersonalization (Dp) were reduced from 3.3 ± 1.1 (EE) respectively 1.5 ± 1.2 (Dp) at baseline to 2.5 ± 1.2 respectively 1.2 ± 1.4 after the intervention in the Ayurveda group, and from 3.0 ± 0.8 respectively 0.9 ± 0.7 to 2.2 ± 0.9 respectively 0.8 ± 0.4 in the conventional group. Post-interventional, the mean group difference in the MBI score between Ayurveda and conventional group was 0.1 (95% CI: −0.78;0.89, p = 0.75) for EE and −0.4 (−1;0.4, p = 0.34) for Dp (Table 2). The MBI subscale personal accomplishment (PA) rose from 4.0 ± 1.1 at baseline to 4.5 ± 1.1 after the intervention in the Ayurveda group, and from 4.2 ± 1.2 to 4.1 ± 1.3 in the conventional group, resulting in a mean group difference in MBI-PA of 0.57 (0.0;1.1, p = 0.06). At the visit 3 parameters were stable in both groups. Both groups showed significant within-group differences in MBI-EE (Table 3). Only the Ayurveda group showed significant within-group differences in MBI-PA. The change of the subscale emotional exhaustion of the MBI was significant within the control group.

### 3.3. Secondary outcomes

The effects of Ayurvedic treatment were more prominent for most predefined secondary outcomes. While no significant difference between groups could be observed for all secondary outcomes, only the Ayurvedic group showed significant within-group differences for the following outcomes (Table 3): sleep (PSQI), stress (CPSS), depression (HADS), mental health (subscale of SF-36) and conscious interaction (ASP). At visit 3 these parameters were stable in both groups. The

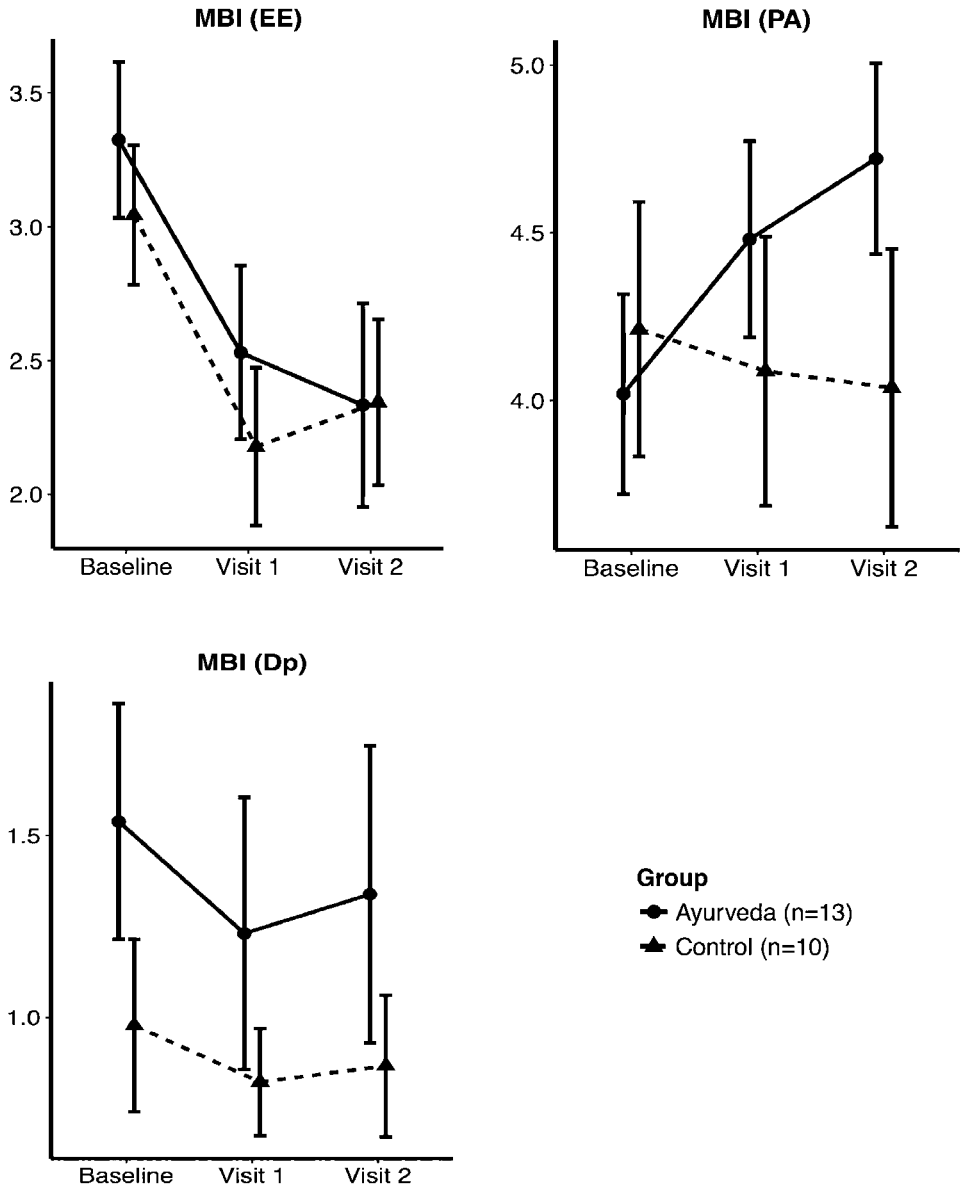


**Fig. 2.** Change of MBI subscales.
MBI = Maslach Burnout Inventory, EE = emotional exhaustion, Dp = Depersonalization, PA = Personal Accomplishment, Note: for graphical reasons the graphs were slightly shifted.

subscales of the ASP, particularly prayer/trust in God and conscious interaction showed a more pronounced increase in the Ayurvedic group; however, without statistical significance. HADS anxiety and the subscale transcendence conviction of the ASP were significant within the control group.

### *3.4. Qualitative results*

The qualitative part of the study identified differences between conversational styles and counseling techniques during the Ayurvedic and conventional consultations. The overall structure of consultations was similar and consisted of the following sequence: opening, introduction of study setting, anamnesis, diagnosis, counseling, explanation of the study setting, and closing. Both physicians spent approximately half an hour on verbal anamnesis and physical examination. In the conventional consultation questions tended to be category-bound, often based on the medical framework. In comparison, the Ayurvedic physician used open-ended interrogative forms, devices for displaying understanding, and positive re-evaluation more frequently, leading to a less asymmetrical interaction overall. The examples in the appendix depict contrasting "ideal types"[40] of Ayurveda and conventional nutritional counseling sessions to comprehensively illustrate these findings (Appendix A).

In summary, interrogative forms in conventional anamnesis tended to be focused on implicit checklists of diagnostic relevant information, while in the Ayurvedic branch the interrogative forms focused on open-ended narrative generating questions. Furthermore, in the Ayurvedic setting the use of devices for generating and displaying understanding and positive re-evaluation was more frequent. In the controlled setting, pre-established categories implied the knowledgeability of the doctor and resulted in an asymmetrical interaction. By way of contrast the amount of work for generating understanding without negative judgment of patients' performances in the Ayurvedic setting results in a relatively more symmetrical interaction. Thus, it can be concluded that Ayurvedic lifestyle- and nutritional counseling (in this setting) is less "asymmetrical" than conventional lifestyle- and nutritional counseling. This has led to a more patient-centered style of consultation as well as individual resource-oriented recommendations in the Ayurvedic setting.

The typical question-answer/Q & A turn-taking organization in doctor-patient-communication also applies to the Ayurvedic and conventional branches in general, so doctors tend to do most of the questioning and patients do most of the answering. The main difference between these two branches is the less restricted procedure of questions and themes in Ayurvedic counseling.

**Table 2**
Outcomes in both groups at baseline, month 3 and month 6 with group differences as indicators of change.

| | Ayurveda group | | | Conventional group | | | Mean Difference | | Mean Difference | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Baseline (n = 13) | Visit 2 (n = 13) | Visit 3 (n = 13) | Baseline (n = 10) | Visit 2 (n = 10) | Visit 3 (n = 10) | Δ 1–2 (95%CI) | *p*-value | Δ 1–3 (95%CI) | *p*-value |
| MBI (EE) | 3.3 ± 1.1 | 2.5 ± 1.2 | 2.3 ± 1.4 | 3.0 ± 0.8 | 2.2 ± 0.9 | 2.3 ± 1.0 | 0.1 (−0.78;0.89) | 0.75 | −0.17 (−1.1;0.67) | 0.77 |
| MBI (Dp) | 1.5 ± 1.2 | 1.2 ± 1.4 | 1.3 ± 1.5 | 0.9 ± 0.7 | 0.8 ± 0.4 | 0.8 ± 0.6 | −0.4 (−1;0.4) | 0.34 | −0.4 (−1.1;0.8) | 0.61 |
| MBI (PA) | 4.0 ± 1.1 | 4.5 ± 1.1 | 4.7 ± 1.0 | 4.2 ± 1.2 | 4.1 ± 1.3 | 4.0 ± 1.3 | 0.57 (0.0;1.1) | 0.06 | 0.75 (0.0;1.5) | **0.049*** |
| MBI (In) | 2.8 ± 1.2 | 2.6 ± 0.9 | 2.6 ± 1.0 | 2.8 ± 0.7 | 2.4 ± 0.5 | 2.0 ± 0.9 | 0 (−0.3;0.7) | 0.52 | 0.3 (0;1.3) | 0.1 |
| PSQI | 7.6 ± 4.2 | 4.8 ± 3.5 | 5.2 ± 3.6 | 8.4 ± 3.4 | 7.3 ± 4.7 | 6.4 ± 3.1 | −3.0 (−5;0) | 0.5 | −1 (−3;1) | 0.38 |
| CPSS score | 24.0 ± 4.6 | 16.9 ± 6.1 | 16.9 ± 8.4 | 22.1 ± 5.3 | 19.2 ± 8.3 | 21.5 ± 6.3 | −4.0 (−8;1) | 0.14 | −6 (−14;2) | 0.1 |
| HADS Anxiety | 12.2 ± 3.3 | 7.9 ± 3.9 | 8.0 ± 4.0 | 11.8 ± 2.6 | 9.6 ± 4.9 | 9.3 ± 2.0 | −2.0 (−5;1) | 0.23 | −2 (−5;2) | 0.25 |
| HADS Depression | 7.9 ± 3.2 | 4.9 ± 2.7 | 5 ± 4.5 | 8.5 ± 3.9 | 7.1 ± 5.7 | 8.1 ± 5.4 | −1.0 (−4;2) | 0.51 | −2 (−4;1) | 0.26 |
| SF36 physical | 48.8 ± 8.1 | 50.6 ± 7.1 | 49.7 ± 7.3 | 45.6 ± 10.6 | 48.0 ± 8.0 | 47.5 ± 8.7 | 0.5 (−7.2;10.1) | 0.62 | 2.7 (−8.4;13.6) | 0.56 |
| SF36 mental | 32.6 ± 7.8 | 46 ± 10.8 | 50.2 ± 7.2 | 40.6 ± 12.6 | 42.3 ± 13.7 | 46.2 ± 10.0 | 10.7 (−0.3;20.1) | 0.98 | 10.4 (−2.6;22) | 0.15 |
| ASP – Religious Orientation | 41.7 ± 27.9 | 40.8 ± 34.6 | 48.3 ± 30.4 | 30.8 ± 24.4 | 38.1 ± 30.6 | 36.4 ± 25.9 | −5.6 (−19.4;5.6) | 0.36 | 2.8 (−8.3;11.1) | 0.64 |
| ASP – Insight/Wisdom | 67.3 ± 19.0 | 71.1 ± 28.3 | 75.3 ± 18.7 | 60 ± 33.7 | 65.4 ± 34.6 | 67.5 ± 32.7 | 0 (−10.7;14.3) | 0.73 | 3.6 (−10.7;14.3) | 0.55 |
| ASP – Conscious interaction | 71.2 ± 15.4 | 70.4 ± 19.7 | 76.2 ± 15.3 | 72 ± 17.8 | 74.5 ± 11.7 | 72.0 ± 16.4 | −5 (−15;5) | 0.61 | 2.5 (−10;15) | 0.65 |
| ASP – Transcendence conviction | 56.7 ± 30.8 | 56.3 ± 35.4 | 58.7 ± 33.0 | 48.8 ± 27.9 | 50.6 ± 28.9 | 54.4 ± 26.2 | 0 (−6.3;6.3) | 0.72 | 0 (−12.5;6.3) | 0.64 |

Values are mean ± SD if not indicated otherwise. MBI = Maslach Burnout Inventory, EE = emotional exhaustion, Dp = Depersonalization, PA = Personal Accomplishment, In = Involvement, PSQI = Pittsburgh Sleep Quality Index, CPSS = Cohen Perceived Stress Scale, HADS = Hospital Anxiety and Depression scale, SF36 = Short Form 36 Health Survey, ASP = Aspects of Spirituality. Δ 1–2 = difference between groups from baseline to visit 2 at 3 months, Δ 1–3 = difference between groups from baseline to visit 3 at 6 months.

* *p*-values for between group difference of change, Exact Wilcoxon Mann-Whitney Rank Sum Test.

**Table 3**
Mean change within groups.

| | | Ayurveda group | | | | | Conventional group | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Baseline (n = 13) | V2 from Baseline (n = 13) | *p*-value $d_{cohen}$ | V3 from Baseline (n = 13) | *p*-value $d_{cohen}$ | | Baseline (n = 10) | V2 from Baseline (n = 10) | *p*-value $d_{cohen}$ | V3 from Baseline (n = 10) | *p*-value $d_{cohen}$ |
| MBI (EE) | 3.3 ± 1.1 | −0.8 ± 1 | **0.02*** 0.7 | −1.0 ± 12 | **0.02*** 0.8 | | 3.0 ± 0.8 | −0.9 ± 7.6 | **0.006**** 0.95 | −0.7 ± 0.7 | **0.03** 0.78 |
| MBI (Dp) | 1.5 ± 1.2 | −0.3 ± 0.8 | 0.15 | −0.2 ± 0.9 | 0.37 | | 0.9 ± 0.7 | −0.1 ± 0.8 | 0.96 | −0.1 ± 1.0 | 0.88 |
| MBI (PA) | 4.0 ± 1.1 | 0.5 ± 0.7 | **0.03*** 0.46 | 0.7 ± 0.8 | **0.006**** 0.66 | | 4.2 ± 1.2 | −0.1 ± 0.7 | 0.57 | −0.2 ± 1.1 | 0.84 |
| MBI (In) | 2.6 ± 1.2 | −0.2 ± 0.5 | 0.37 | −0.2 ± 0.7 | 0.36 | | 2.9 ± 0.9 | −0.3 ± 0.6 | 0.14 | −0.7 ± 0.7 | **0.02*** |
| PSQI (total) | 7.6 ± 4.2 | −2.9 ± 4.0 | **0.03*** 0.72 | −2.4 ± 3.7 | **0.03*** 0.61 | | 8.4 ± 3.4 | –1 ± 3.3 | 0.3 | –1 ± 1.7 | 0.12 |
| CPSS score | 24.0 ± 4.6 | −7.2 ± 6.3 | **0.001***** 1.3 | −7.2 ± 9.4 | **0.03*** 1.08 | | 22.1 ± 5.3 | −2.9 ± 4.8 | 0.09 | −0.6 ± 6.4 | 0.77 |
| HADS Anxiety | 11.6 ± 2.9 | −3.7 ± 2.6 | **0.003**** 0.5 | −3.6 ± 3.6 | **0.01*** | | 11.4 ± 2.6 | −1.8 ± 4.2 | 0.23 | −2.1 ± 2.6 | **0.03*** |
| HADS Depression | 7.5 ± 3.2 | −2.5 ± 2.6 | **0.01*** 1.0 | −2.5 ± 2.9 | **0.01** 0.75* | | 8.5 ± 3.9 | −1.6 ± 3.0 | 0.12 | −0.6 ± 2.6 | 0.47 |
| SF36 physical | 47.3 ± 8.3 | 3.4 ± 7.5 | 0.2 | 3.0 ± 10.1 | 0.54 | | 45.8 ± 9.2 | 2.3 ± 11.1 | 0.56 | 0.4 ± 12.5 | 0.85 |
| SF36 mental | 31.6 ± 7.1 | 14.7 ± 13.7 | **0.005**** 1.6 | 13.1 ± 12.7 | **0.006**** 2.6 | | 36.7 ± 13.4 | 5.7 ± 11.7 | 0.19 | 3.5 ± 13.8 | 0.63 |
| ASP – Religious Orientation | 41.3 ± 26.6 | −0.9 ± 17.0 | 0.96 | 6.6 ± 10.2 | 0.07 | | 30.3 ± 23.6 | 7.22 ± 9.7 | 0.07 | 5.6 ± 10.9 | 0.18 |
| ASP – Insight/ Wisdom | 70.2 ± 19.0 | 3.9 ± 25.0 | 0.31 | 8.0 ± 16.0 | 0.07 | | 62.2 ± 32.4 | 5.4 ± 12.1 | 0.12 | 7.5 ± 12.1 | 0.09 |
| ASP – Conscious interaction | 71.2 ± 15.4 | −0.8 ± 17.7 | 0.66 | 5.0 ± 8.7 | **0.02*** | | 72 ± 17.8 | 2.5 ± 12.1 | 0.67 | 0 ± 15.3 | 0.91 |
| ASP – Transcendence conviction | 56.7 ± 30.8 | −0.5 ± 15.2 | 0.59 | 1.9 ± 14.1 | 0.53 | | 48.8 ± 27.9 | 1.9 ± 8.7 | 0.50 | 5.6 ± 6.9 | **0.04*** |

Values are mean ± SD if not indicated otherwise. MBI = Maslach Burnout Inventory, EE = emotional exhaustion, Dp = Depersonalization, PA = Personal Accomplishment, In = Involvement, PSQI = Pittsburgh Sleep Quality Index, CPSS = Cohen Perceived Stress Scale, HADS = Hospital Anxiety and Depression scale, SF36 = Short Form 36 Health Survey, ASP = Aspects of Spirituality.

*p-values for within group difference, Wilcoxon signed rank test.

* < 0.05.

** < 0.01.

*** < 0.001.

### 3.5. Safety issues

There were no serious adverse events in both groups. Less than ten percent in each group reported minor temporary digestive side effects due to nutritional changes (Ayurveda n = 2, conventional n = 1). Counseling was safe in both groups.

## 4. Discussion

We conducted this two-armed randomized controlled pilot study to investigate potential effects of Ayurvedic lifestyle- and nutritional counseling compared to conventional lifestyle- and nutritional counseling in outpatient mothers with burnout-syndrome. Only mothers in the Ayurvedic group showed statistically significant and clinically relevant within-group improvements for the primary outcome burnout (MBI subscale PA) and for the secondary outcomes sleep (PSQI), stress (CPSS), depression (HADS) and mental health (subscale of SF-36). Differences between groups were not significant for any of the outcome parameters. Summarized, positive counseling effects for both groups could be observed; however, more pronounced in the Ayurveda group.

Baseline scores of the subscales of the MBI indicated clinically relevant burnout in the studied population. Moreover, the participants had clinically relevant distress, reduced mental health and sleep quality, and increased anxiety and depression. Despite randomization there were baseline characteristic differences. The most likely reason for this is the small sample size.

This pilot trial has a number of strengths. In particular, this is the first clinical trial to assess potential effects of Ayurvedic lifestyle- and nutritional counseling in mothers with burnout-syndrome. Looking at the lack of qualitative data in the field of whole systems research (particularly in Western settings), where patient expectations, patient-therapist interactions, context, setting, culture, and other qualitative aspects play crucial roles, one of the study's strengths is its mixed-methods approach including a qualitative analysis. Moreover, the study has well-defined inclusion and exclusion criteria. Also, the use of internationally validated questionnaires and the adoption of high-quality and well-comparable lifestyle- and nutritional counseling in both groups pose other advantages.

The study has a number of limitations weakening the impact of the results and generalizability. First, the small sample size is its most obvious limitation, however this study was designed as a pilot study with an intentionally low sample size. Also, long term follow-ups are missing. In addition, as in all studies with self-applied and non-pharmacological interventions, it was not possible to blind treatments, thus bias was introduced. We cannot estimate the extent to which the observed effects were non-specific due to the influence of the setting, the attention of physicians, the participants' beliefs about the health effects of Ayurveda and meaning-responses,[45] and social interaction within the groups during the group counseling sessions. Another limitation of this trial is an obvious gender bias, because only women were included in this study, thus limiting the informative value related to burnout from this study to women/mothers only. Also, the comparatively large number of participants who refused to participate before and after randomization due to their unwillingness to receive conventional counseling poses another shortcoming and once again suggests an expectation bias related to the effects of Ayurveda. Last but not least the realms of botanical, manual, and cleansing therapeutic options were not included in this trial; however, we intended a pragmatic and applicable Ayurvedic approach that could easily be compared to conventional practice.

The evaluation of prevention and multimodal programs for burnout are at the beginning, e.g. one review evaluated the effectiveness of intervention programs aimed at preventing burnout,[12] including therapies like cognitive behavioral training, psychotherapy, social support and relaxation exercises. About eighty two percent of all person-directed interventions led to a significant reduction in burnout, lasting up to 6 months after the intervention. This review also stated that "even though many studies have examined risk factors for burnout, only relatively few prevention programs have been conducted and even fewer have been evaluated." To date there have been no trials that have examined mothers with burnout-syndrome.

Current treatment options for burnout are limited, so new therapeutic approaches are desirable. Complementary medicine (CAM) and Whole Medical Systems (WMS) like Ayurveda have grown in importance and have become more accepted in public in Western and high-income countries like Germany; on a global scale, Ayurveda is one of the fastest growing CAM systems.[19,46]

Recent studies have mainly evaluated the effectiveness of single components of the originally multi-component Ayurvedic approach, thus the analysis of classical complex Ayurvedic therapies has not yet sufficiently been covered. Moreover, most of these studies (like ours) have been pilot studies, limiting their explanatory power. Overall, studies with higher methodological quality are warranted.[47,48]

The Ayurvedic treatment of stress related disorders has already been investigated in previous studies and suggested effectiveness.[49,50] Furthermore, the usefulness of complex Ayurvedic therapies in the treatment of psychosomatic diseases are currently being discussed.[18,50] In a study on the influence of diet and lifestyle on the pathogenesis of type 2 diabetes showed that in addition to dietary factors, psychological factors (e.g. worries, depressed mood, anger and anxiety) seem to play a role in the pathogenesis. Thus, a reduction of morbidity could be supported through diet and lifestyle modification. Finally, health care costs in Western countries could possibly be reduced by including Ayurvedic nutrition and lifestyle principles elements focusing on prevention and patient empowerment in these fields.[51]

Drawing on the comparison of the interaction processes of the Ayurvedic group with the conventional group, the qualitative part of the study demonstrates how important it is to look at the institutional features of doctor-patient-communication in general. Each form/type of institutional interaction in medicine creates a "unique fingerprint".[52] As John Heritage shows, "the fingerprint being made up of specific tasks, identities, constraints on conduct, and relevant inferential procedures that the participants deploy and are oriented to in their interactions with one another."[53]

A conversation analytic view on medical communication can therefore offer practice implications for practitioners. John Heritage pointed out reasons for so-called "dysfunctions in problem presentation" in primary care consultation and illustrated the nature of dysfunctional practices as well as the roots of it in everyday social life.[54] The aforementioned less asymmetrical conversational style and counseling techniques in Ayurveda offered more opportunities for adequate problem description by patients as well as patient-centered styles of consultation and individual resource-oriented recommendations by the physician. Heritage et al. have shown how general inquiry questions, like "What can I do for you today?" in comparison to symptom confirmation questions, like "You have a cold?" led to significantly longer and more adequate problem presentation by patients, which correlated with patient contentment post evaluation.[55] Similarly, the open-ended interrogative forms used in the Ayurvedic setting facilitated longer and more in-depth problem exposition than was the case in the conventional setting. Furthermore resource-orientation and patient-centered practice was furnished. Ruusuvuori identified in her comparison, that "in general practice, recommendations on patient-centered practice seem not to arise from the (bio)medical theories concerning clinical decision making, but are rather somewhat discrepant with them."[30] Her results coincide with the findings of this study. Furthermore Prüfer et al. concluded that "the need for GP training was identified to improve communication skills" for resource-oriented approaches in general.[56]

The qualitative evaluation emphasizes the importance of conversational practices in doctor-patient-interactions, in particular Ayurvedic counseling concerning the doctor-patient relationship. The lessening of

asymmetrical interactions enables the taking of unique experiences, as well as deeply emotional and spiritual matters of concern for patients into account. The imparting of implicit norms and values as well as the resource-orientation and person-centeredness of Ayurvedic consultation promotes trust and furnishes the possibility of accommodating as well as cultivating an individual doctor-patient relationship.[56,57]

However, this pilot study only focused on two physicians and involved although typical, but nevertheless very selective cases, thereby, significantly limiting the scope for possible generalizations. Further qualitative studies would have to compare several cases of different physicians with both study groups and scrutinize the development of doctor-patient interaction and relationship during treatment over a longer period of time.

## 5. Conclusions

In conclusion, our results suggest that Ayurvedic counseling may be an effective treatment for mothers with burnout-syndrome with respect to a reduction of distress and concomitant psychological symptoms. Yet the data based on this small sample size is still too weak to derive any definite conclusions from it. To better evaluate the impact of Ayurveda on prevention and treatment of lifestyle and stress-related diseases like burnout-syndrome, further studies are needed, which include longer-term follow-ups, male participants and much larger sample sizes. A power calculation revealed a sample size of 142 subjects, based on a moderate effect size ($d = 0.5$), a significance level of $p < 0.05$ and a power of 0.8 for a confirmatory trial. Possible beneficial effects of Ayurveda for burnout-patients would have to be analyzed in such larger trials accordingly. The study has also shown, that it is worthwhile to include a qualitative dimension in further more extensive studies.

## Conflict of interest

The authors declare that they have no conflict of interest related to the content of this manuscript.


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## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.ctim.2017.07.005.

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