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# A SPIRITUALITY TEACHING PROGRAM FOR DEPRESSION: A RANDOMIZED CONTROLLED TRIAL*

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**ABSTRACT**

*Objective*: This randomized controlled trial assessed the efficacy of a Spirituality Teaching Program to treat unipolar major depression. *Method*: A randomized controlled, assessor blinded trial design was used. A total of 84 individuals aged 18 years or older with unipolar major depression of mild to moderate severity were recruited in Calgary, Canada and randomized to two study arms: 1) Spirituality Teaching Program Group (8 week, home-based Spirituality Teaching Program); and 2) Waitlist Control Group (no intervention followed by Spirituality Teaching Program starting at week 9). Outcome measures (depression severity, response rate, remission rate) were assessed at baseline, 8, 16, and 24 weeks using the Hamilton Depression Rating Scale (HAM-D). *Results*: The two trial groups were similar in their demographic and disease characteristics at baseline. At the 8-week point, the change in depression severity was significantly different between the two groups (change in HAM-D score: 8.5 for the Spirituality Group and 2.3 for the Waitlist Control Group, $p < 0.001$). The Spirituality Teaching Program Group had significantly higher response (36% vs. 4.4%, $p < 0.001$) and remission rates (31% vs. 4.4%, $p < 0.001$) than the Waitlist Control Group. The benefits remained throughout the observation period for the Spirituality Teaching Program Group participants with response rates of 56.4% at 16 weeks and 58.9% at 24 weeks. *Conclusion*: The Spirituality Program significantly reduced depression severity and increased response and remission rates. This non-drug treatment program should be investigated further as a treatment option for depression.

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**Key Words**: depression, spirituality, randomized controlled trial

## INTRODUCTION

Major depression is a widely-spread health problem in Canada with a lifetime prevalence of 11% in men and 16% in women [1, 2]. A recent avenue of research suggests a role for religion/spirituality in the prevention of and recovery from depression [3-5]. It has been hypothesized that religion/spirituality acts as a coping resource in distressing life situations including illness and loss and may address the struggles of depressed patients of feeling separated from their surrounding world, as well as from their inner self [4, 6].

Research investigating the link between religion/spirituality and depression has been challenging because of methodological and ethical challenges to carry out conclusive studies, overlapping definitions between religiosity and spirituality, and the close relationship between spiritual and mental wellness [4]. To navigate these challenges, the majority of research in this field has focused on religiosity and is observational in nature. The evidence from the existing research has been

pooled in two comprehensive meta-analyses and points to a link between religiosity and better mental health with more religiously involved individuals experiencing fewer depressive symptoms and faster recovery from a depressive disorder than those less religiously involved [7, 8]. No conclusions about a causal link can be drawn from these observational studies. However, there are a small number of experimental studies that investigated the use of a spiritually based psychotherapy intervention for depression.

The tested interventions were religiously oriented and incorporated patients' beliefs through prayer and making reference to scriptures [9]. Findings from these studies indicate that faith based approaches to psychotherapy are effective and appear to achieve higher effect sizes than secular psychotherapy [9]. These results are encouraging and support the findings from observational studies. The majority of these studies involved Christian- and Muslim-based interventions. Since a growing portion of the Canadian population identifies themselves as non-religious but spiritual [10], it is pertinent to explore whether there is a role for a non-denominational spiritual intervention as a mental health resource. Moritz et al. addressed this question in a randomized trial that tested a nondenominational Spirituality Teaching Program in individuals with significant mood disturbance based on the Profile of Mood States [11].

In this trial participants were randomized to the Spirituality Teaching Program, a Waitlist Control, or a mindfulness meditation group. Participants in the Spirituality Teaching Program experienced significant improvements in their mood disturbance, most notably a 53% reduction in depressive symptoms. This compared to a 32% reduction of depressive symptoms in the mindfulness meditation group and a 10% reduction in the Waitlist Control Group. Study participants were interviewed 12 months later about how the teachings of the Spirituality Teaching Program may have affected their life and their mood [12]. Interviewees described an expansion of spiritual beliefs, a shift in life perspectives, greater calmness, improved mental well being, and improved relationships, as well as renewed physical energy. These findings point to a possible long-term impact of the Spirituality Teaching Program on mood, specifically on depressed mood.

Building on the above research [11, 12] this study was conducted to assess the efficacy of a home-based Spirituality Teaching Program in the treatment of major depression. Specifically, we investigated:

1. whether the Spirituality Teaching Program is efficacious in improving depression severity, response rate, and remission rate; and
2. whether efficacy is maintained long term.

The present study is novel as it explores whether nurturing spiritual coping resources in a non-faith-based way may play a therapeutic role in recovery from depression.

## METHOD

### Recruitment and Sample Size

The trial was conducted at the Canadian Institute of Natural and Integrative Medicine in Calgary, Canada. Participants were recruited between October 2004 and June 2006 from family physician practices, mental health outpatient services, and complementary/alternative therapy clinics. The trial was also advertised through local radio stations and newspapers. A neutral recruitment slogan was used ("*Feeling Down? A non-drug approach to treat depression*") in order to avoid selective recruit of individuals interested in spirituality. Individuals aged 18 and over who met the criteria for major depression with mild to moderate severity (Hamilton Depression Scale score: 18 to 22) were eligible. Individuals were excluded if they were receiving therapy for depression, had uncontrolled medical conditions or other psychiatric conditions, were at high risk for suicide, used mood altering substances or therapies, or had a history of treatment resistance.

A sample size of 78 patients (39 in each study group) was determined to achieve a power of 80% to detect a clinically relevant between-group difference of 30% in the depression response and remission rate between the two study groups (assumptions: $p1 = 0.20$, $p2 = 0.50$).

### Study Design and Variables

The trial received ethics approval from the Conjoint Research Ethics Board of the University of Calgary and was registered with ClinicalTrials.gov (registration number: NCT00322777). The study design employed a parallel-group, randomized, waitlist-controlled, assessor-blinded trial in outpatients with major depressive disorder of mild to moderate severity. A waitlist design was chosen because of the absence of a suitable sham intervention program and because this design is commonly used in the evaluation of psychotherapy for depression [13]. Centralized simple randomization was used to allocate participants with a 1:1 randomization ratio to either a Spirituality Teaching Program Group or a Waitlist Control Group. The randomization list was prepared with the help of computer generated numbers and was kept by an administrator who had no other involvement with the trial. The list was not accessible to any of the trial investigators. Randomization was performed after eligibility was established and consent was received. To receive an allocation the trial coordinator phoned the administrator who noted the name of the newly recruited participant on the randomization list and gave out the corresponding trial identification number and the group allocation.

The trial consisted of an 8-week intervention phase during which the Spirituality Teaching Program Group participated in the trial intervention while the Waitlist Control Group continued normal daily activities. During this phase,

participants were asked not to start any pharmacotherapeutic, herbal, or psychotherapeutic treatments for depression and adherence with this request was monitored. The initial 8-week phase was followed by a 16-week follow-up phase with no restrictions on the use of other treatments for depression. During the follow-up phase, the Waitlist Control Group participated in the Spirituality Teaching Program for 8 weeks while the Spirituality Group had the option to continue utilizing the program at their own discretion. The outcome measures (depression severity, response rate, remission rate) were assessed at baseline, 8, 16, and 24 weeks based on the 17-item Hamilton Depression Rating Scale (HAM-D) through a face-to-face interview conducted by a trained nurse who was blinded to participants' allocation. Response was determined as a reduction in the HAM-D score of at least 50% from baseline and remission as a HAM-D score of no greater than 7. Data on the utilization of the spirituality teaching program were collected through diaries. All trial participants completed weekly diaries while doing the spirituality teaching program intervention (Spirituality Teaching Program Group: week 1 to week 8; Waitlist Control Group: week 9 to week 16). These diaries were used to record how many times participants had listened to the Spirituality Teaching Program CDs and how much time they had spent on the relaxation practice each week. After completion of the Spirituality Program, participants completed monthly diaries on their further utilization of the program.

## Study Intervention

The trial intervention (Spirituality Teaching Program) was home-study-based and delivered over 8 weeks through audio CDs. The 8-week duration was chosen because it presents a commonly used length for psychotherapeutic depression interventions and appears sufficient to produce significant improvements [14]. The program was initially developed as a workshop for patients attending an integrative health clinic run by a psychiatrist. The aim of the workshop was to nurture spirituality coping resources. Because of the positive feedback the workshop received, it was taped and an audio CD program was created. The CD program consists of weekly 90-minute teaching sessions that each concludes with a relevant guided visualization practice. In addition there is a 15-minute taped progressive relaxation exercise that is used daily. Using didactic comment and story telling, the program addresses the following spiritual concepts: self-transcendence, connectedness (with others, nature, or the divine), forgiveness, self-acceptance, detachment, compassion, and gratitude. The presented content is non-denominational to ensure compatibility with any beliefs participants may hold. The eight teaching sessions and guided visualization practices introduce concepts that assist the user in developing a more spiritual outlook on life. In addition, the daily progressive relaxation practice creates periods of tranquility. A more detailed description of the program was previously published [11].

### Statistical Analysis

The analysis was performed with the statistical program SAS/STAT 9.1.3. An "Intention to Treat" approach was used. To avoid inflation of the study results, missing values at the 8-week, 16-week, or 24-week time points were replaced with the baseline values. Before hypothesis testing, the two trial groups were compared using descriptive statistics to assess whether randomization resulted in balanced trial groups with regard to depression scores, remission rates, and potential confounding variables at baseline. *F*-tests were used to compare Hamilton Depression Scale scores and their changes for the two study groups. If the *F*-test was significant at the $p < 0.05$ level, *t*-tests were conducted to compare the least square means of the Spirituality Group to the Waitlist Control Group. Two-tailed *t*-tests were used to compare pairs of least square means. The scores and their changes on the Hamilton Depression Scale were analyzed using general linear models including trial group and gender as potential confounding factors. *T*-test and chi-square tests were used to compare depression response rates, remission rates, and mean depression scores between the two groups. Because the trial intervention was deemed safe, no interim analysis was scheduled and no stopping rules were formulated.

## RESULTS

### Study Sample and Eligibility

We received 779 calls in response to our recruitment efforts; 436 of these individuals met basic criteria and agreed to participate in the first eligibility screening step (nurse-conducted telephone screening). Of these 436 individuals, 286 passed the telephone screening and 264 attended the second screening step (i.e., physician-conducted psychiatric assessment). A total of 131 individuals passed the physician screening (major depression was confirmed and other psychiatric illnesses were ruled out). Of these, 84 met the study criteria for mild to moderate depression (Hamilton Depression Scale score of 18 to 22) and were enrolled in the trial after written informed consent was obtained. Figure 1 shows the flow of enrolled patients through the trial. Baseline characteristics of the study population are displayed in Table 1 and show that there were no significant differences between the two trial groups.

### Compliance

Of the 39 participants in the Spirituality Group, 30 (77%) completed the full 8-week Spirituality Program, 3 (8%) completed 4 to 7 weeks, and 6 (15%) participated for less than 4 weeks. The average time spirituality group participants spent on the guided visualization practice over the 8-week intervention duration was 706 minutes. Of the 45 Waitlist Control participants, 26 (58%) completed the

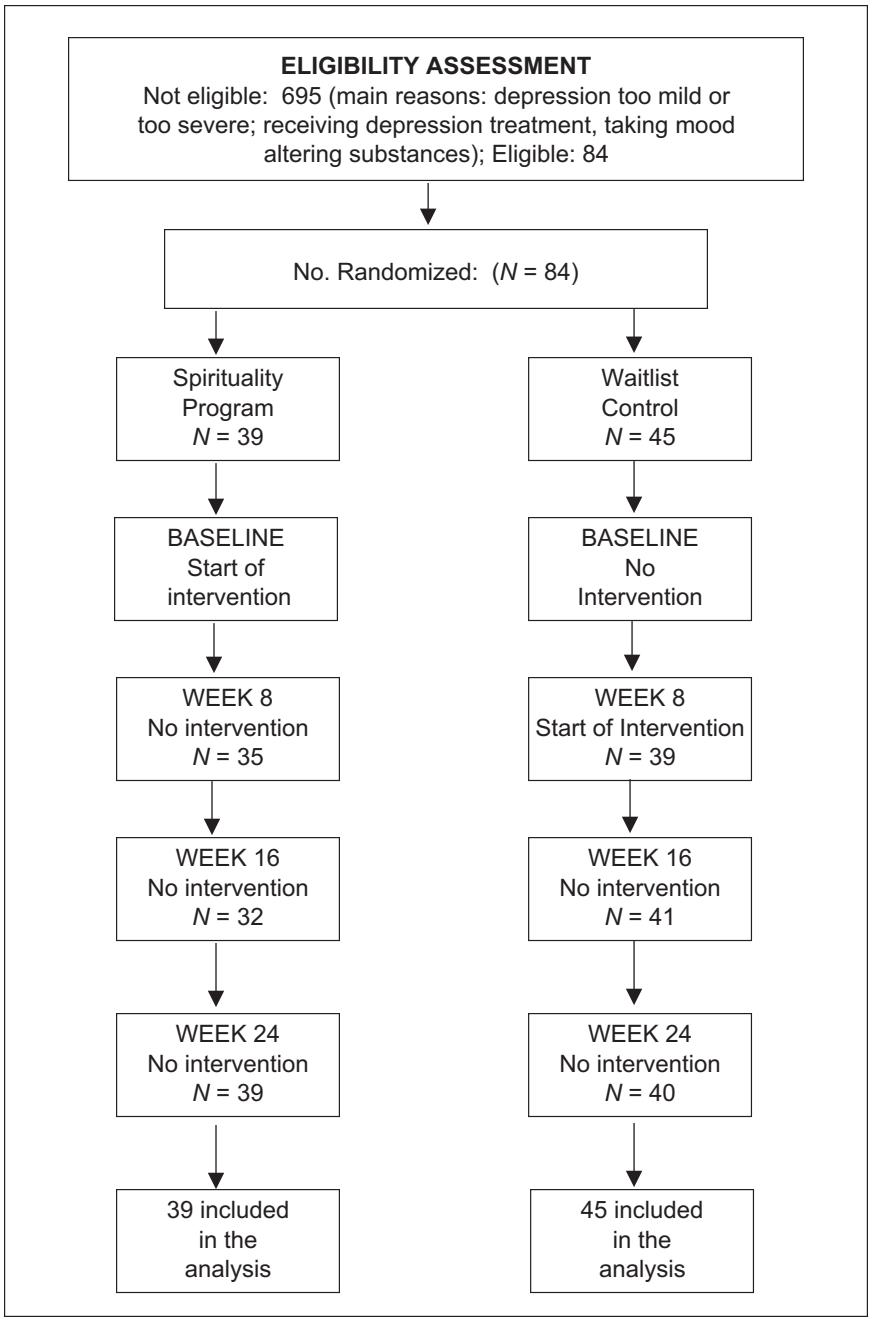


Figure 1. Study flow chart.

Table 1. Baseline Characteristics of Study Participants

| | Control Group (*N* = 45) | Spirituality Group (*N* = 39) | *p*-Value |
|---|---|---|---|
| Age (mean) | 44.0 | 44.1 | 0.95 |
| Gender | | | |
| Males | 9 (20%) | 10 (25.6%) | 0.54 |
| Females | 36 (80%) | 29 (74.4%) | |
| Marital status | | | |
| Married/common law | 22 (48.9%) | 27 (69.2%) | 0.06 |
| Not married | 23 (51.1%) | 12 (30.8%) | |
| Education | | | |
| ≤ High school | 7 (15.6%) | 5 (12.8%) | 0.55 |
| Some college or university | 8 (17.8%) | 9 (23.1%) | |
| Graduated from college or university | 24 (53.3%) | 22 (56.4%) | |
| Postgraduate or professional degree | 6 (13.3%) | 1 (5.1%) | |
| Not available | | 1 (2.6%) | |
| Employment status | | | |
| Paid work | 33 (73.3%) | 31 (79.5%) | 0.51 |
| No paid work | 12 (26.7%) | 8 (20.5%) | |
| Religion | | | |
| No religion | 16 (35.6%) | 14 (35.9%) | 0.98 |
| Christian | 25 (55.6%) | 22 (56.4%) | |
| Other | 4 (8.9%) | 3 (7.7%) | |
| Interest in spirituality | | | |
| A little interested | 3 (6.7%) | 4 (10.3%) | 0.81 |
| Quite interested | 12 (26.7%) | 11 (28.2%) | |
| Very interested | 30 (66.7%) | 24 (61.5%) | |
| Hamilton Depression Scale | | | |
| Baseline Score (mean) | 20.3 | 20.4 | 0.70 |

Spirituality Teaching Program when it became available, 7 (16%) completed 4 to 7 weeks, and 12 (27%) completed less than 4 weeks. The average time Waitlist Control Group participants spent on the guided visualization practice over the 8-week intervention duration was 604 minutes.

## Depression Severity, Response Rate, and Remission Rate

In the Spirituality Teaching Program Group, the mean Hamilton Depression Scale (HAM-D) score decreased significantly ($p < 0.0001$) from 20.4 (95% CI: 19.9 to 20.9) at baseline to 11.9 (95% CI: 10.2 to 13.5) at the 8-week point following the trial intervention and decreased further to 10.7 (95% CI: 8.5 to 13.0) at 16 weeks and 10.4 (95% CI: 8.0 to 12.7) at 24 weeks. In the Waitlist Control Group, the HAM-D score decreased slightly from 20.3 (95% CI: 19.8 to 20.8) at baseline to 18.0 (95% CI: 16.4 to 19.7) at the 8-week point (see Figure 2). After the Waitlist Control Group received the intervention, the baseline score decreased significantly to 12.0 (95% CI: 9.8 to 14.2) at 16 weeks and to 10.1 (95% CI: 7.8 to 12.4) at 24 weeks. The decrease of depression severity from baseline to 8 weeks between the two groups was statistically significant (8.5 for Spirituality Teaching Program Group HAM-D score vs. 2.3 for Waitlist Control Group HAM-D score, $p < 0.0001$). For the Spirituality Teaching Program Group, the depression response rate at 8 weeks of 35.9% increased to 56.4% and 64.1%, respectively, at 16 and 24 weeks. The Waitlist Control Group showed a response rate of 4.4% after the waitlist period at 8 weeks which then rose to 51.1% at 16 weeks and 66.7% at 24 weeks following the intervention (see Figure 3). The response rate at 8 weeks was significantly higher for the Spirituality Group than that for the Control Group ($p < 0.001$).

At the 8-week, 16-week, and 24-week point the remission rates were 30.7%, 38.5%, and 41.0% for the Spirituality Group, and 2.2%, 31.1%, and 53.3% for the Waitlist Control Group, respectively (see Figure 4). At 8 weeks there was a significant difference in the remission rate ($p < 0.001$) between the Spirituality Group and the Control Group.

## Utilization of Depression Treatments and Adverse Events

During the first 8 weeks of trial participation, use of pharmacotherapeutic, herbal, or psychotherapeutic treatments for depression were not permitted and there were no violations. Following the intervention participants were free to utilize depression therapies but their use was monitored. In the Spirituality Teaching Program Group, one patient started antidepressants. Among the Waitlist Control Group participants, one patient started antidepressants. No adverse events were reported by study participants during their trial participation.

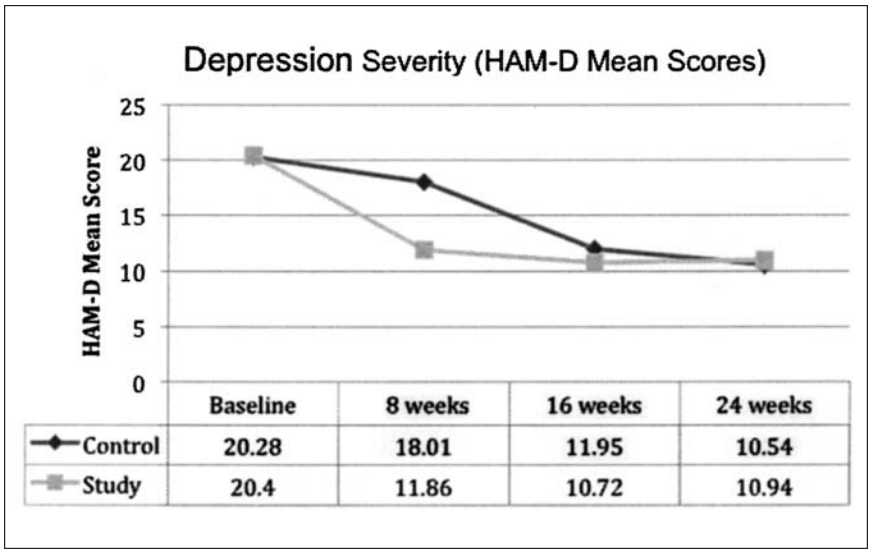


Figure 2. Depression severity.

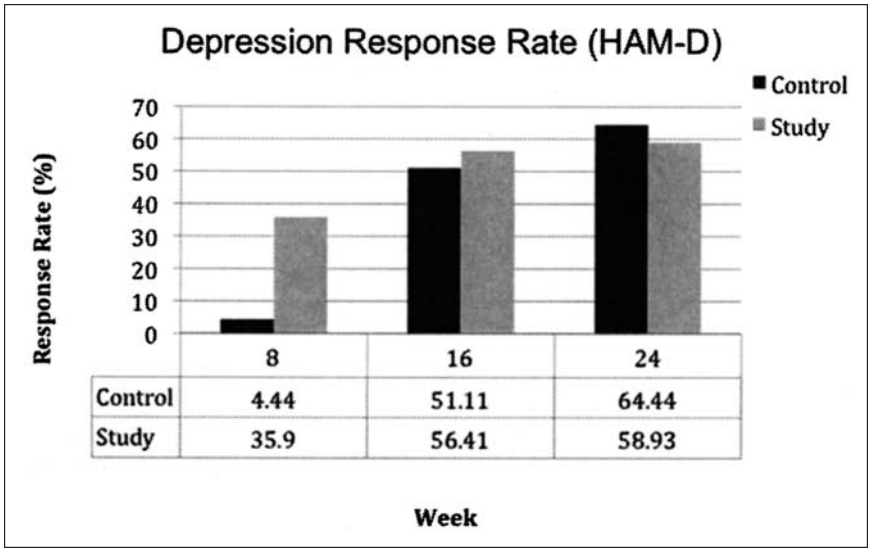


Figure 3. Depression response rate.

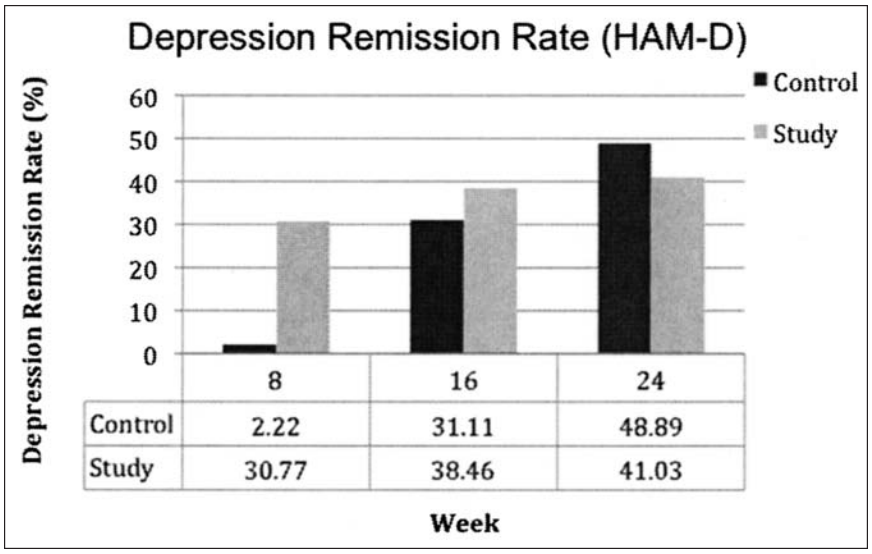


Figure 4. Depression remission rate.

## DISCUSSION

This randomized trial demonstrated that the Spirituality Teaching Program significantly decreased depression severity and increased depression response and remission rates. The benefits were sustained for at least 6 months.

While the achieved response rate after completion of the intervention was moderate, this rate increased further over time, reaching 56% and 64%, respectively, at the 4- and 6-month point. Although participants were free to utilize depression treatments after the 2-month follow-up point, only one patient in each trial group chose to do so and it is thus unlikely that the 4- and 6-month follow-up results were impacted.

This suggests that participants improved further while implementing the perspectives and practices they learned from the Spirituality Teaching Program. These response rates are in the range for pharmacological and psychological interventions which range from 44% to 71% for antidepressants, according to a systematic review [15], and from 36% to 44% for cognitive behavioral therapy-based psychotherapy [16]. Antidepressants appear to reduce depressive symptoms more rapidly; however, relapses, adverse events, and drug discontinuation are common [16-18]. Psychotherapy is a non-pharmacological treatment option without side effects, but its utilization is limited because of waiting times for publicly-funded therapy and patients' concerns about cost [19].

The Spirituality Teaching Program is in some way similar to cognitive behavioral therapy: it attempts to influence how patients think and act. However, while cognitive behavioral therapy does so by pointing out dysfunctional thinking patterns and offering strategies to correct these [20], the Spirituality Teaching Program provides a new, larger context for understanding and integrating all aspects of one's life. It does this by offering spiritual guidance cognitive on concepts such as self-transcendence, connectedness, wholeness, self-acceptance, and detachment. In contrast to faith-based cognitive behavioral therapy [21], the exploration of these spiritual concepts is not rooted in the patient's beliefs system. Rather, the program introduces new perspectives to the patient and suggests ways to implement these. Participation in the Spirituality Teaching Program additionally required active engagement in the practice of progressive relaxation. The intervention focussed on the development of patient's own connection to what the program content termed "universal energy" and the cultivation of spiritual qualities. It is likely that the daily practice of progressive relaxation deepened over time and allowed patients to make more productive use of the spiritual teachings to which they listened.

Because the spirituality teaching program is designed for self-study, appeal and willingness to utilize the program is important. It is thus encouraging that study participants showed active and consistent participation. This is notable because the program is demanding and participants had to act on their own motivation with minimal professional support. This strong engagement supports the possibility that the program could be successfully implemented in a clinical setting. Other studies also show a high level of participation in home based depression programs and it has been suggested that this delivery format may be particularly suited for a depressed population with little energy and motivation to venture out [22-25].

The Spirituality Teaching Program is a low-cost, self-study intervention. It could appeal to patients interested in a non-pharmacological intervention because of concerns about taking antidepressants, fears the medication could cause harm, concerns about addiction to the medication, or beliefs that their illness cannot be treated with medication. Compared to psychotherapy, there are no waiting times to accessing therapy and patients are spared the troubles of travel time and taking time off work for appointments. Furthermore, given that the majority of physicians frequently encounter patients who raise issues of religion or spirituality, a spirituality intervention for depression may be a welcome treatment option for patients and a welcome resource for physicians [26].

Because of the early stage and nature of this research, a simple study design was warranted and we were unable to include a placebo comparison group. Therefore, the Spirituality Teaching Program was evaluated against a Waitlist Control Group only, with no comparison to a placebo or an active treatment. Another limitation of this study relates to attrition and incomplete follow-up data for some participants. We handled missing data in a conservative way, by

replacing missing values with baseline values; thus we are likely to have underestimated efficacy of the intervention.

Trial participants were predominantly middle-aged, educated females and thus generalizability is limited. The reported demographics are likely related to the higher depression prevalence rates in middle-aged females [15], but may also be a reflection of a greater willingness of educated women to participate in an intervention for depression. However, both genders may benefit from the presented program given the social interest in spirituality in general and the increasing prevalence of depression being reported among men.

Although a neutral advertising slogan ("*Feeling Down? A non-drug approach to treat depression*") was used to recruit for the trial, it cannot be ruled out that self-selection of participants with an open attitude to spirituality may have impacted the composition of our study population. The reported interest in spirituality expressed by mental health patients is also likely to have played a role [26].

In conclusion, our results indicate that the evaluated spirituality education program can significantly reduce mild to moderate depression in the short and long term. As a non-drug treatment, the program allows patients to avoid the side effects commonly observed with antidepressants. The high level of active engagement is encouraging and supports the possibility that such a program could be successfully implemented in a clinical setting with minimal professional support. Furthermore, the home study design is highly accessible and less costly than psychotherapy. Our findings suggest that spirituality approaches to treating depression are promising and worthy of further development.

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