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Institut für Sozialmedizin, Epidemiologie und Gesundheitsökonomie
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Habilitationsschrift

Meditationsbasierte Lebensstilmodifikation: Ein Mind-Body-Programm für stressassoziierte Erkrankungen in Psychiatrie, Psychosomatik und Psychotherapie

zur Erlangung der Lehrbefähigung für das Fach

Sozialmedizin mit den Schwerpunkten Psychiatrie und Psychotherapie sowie
Naturheilverfahren/Naturheilkunde

vorgelegt dem Fakultätsrat der Medizinischen Fakultät Charité – Universitätsmedizin Berlin

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Eingereicht: Juni 2023

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1. Gutachter:

2. Gutachter:

Dharmo Rakshati Rakshitah

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Abkürzungsverzeichnis

ACT	Acceptance and Commitment Therapy
CIM	Complementary and Integrative Medicine
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders (Revision IV)
IM	Integrative Medicine
IMH	Integrative Mental Health
MAM	Mantra Meditation
MBCT	Mindfulness Based Cognitive Therapy
MBI	Mindfulness Based Intervention
MBM	Mind-Body Medizin
MBLM	Meditation-based Lifestyle Modification
MBSR	Mindfulness Based Stress Reduction
NCCAM	National Center of Complementary and Alternative Medicine
NCCIH	National Center of Complementary and Integrative Health
PMR	Progressive Muskelentspannung
TAU	Treatment as Usual
TCIM	Traditional, Complementary, and Integrative Medicine
USA	United States of America
WHO	World Health Organization

1. Einleitung

1.1 Integrative Medizin

In der medizinischen Versorgung besteht international und interkulturell ein vielfältiger Theorien- und Methodenpluralismus von Gesundheits- und Krankheitsmodellen, der sich in einem weitgehend unabhängigen Nebeneinander von kulturell und historisch gewachsenen medizinischen Sichtweisen und Praktiken widerspiegelt. So gilt beispielsweise in den westlichen Industrienationen das biopsychosoziale Modell von Krankheit und Gesundheit als der heutige Standard in der medizinischen Versorgung, während in anderen Kulturen auch traditionelle Medizinsysteme wie die Chinesische Medizin oder die Traditionelle Indische Medizin als von der WHO anerkannte Medizinrichtungen in der Breitenversorgung für Milliarden von Menschen eingesetzt werden.¹⁻³ Die in den letzten Dekaden zu beobachtende Emergenz einer Integrativen Medizin stellt möglicherweise im Kern den nächsten, entwicklungslogischen Schritt der Menschheit dar. Integrative Medizin bedeutet allgemein, das weltweit verfügbare medizinische Wissen sinnstiftend zu integrieren.^{4,5} Dabei bedeutet Integration nicht nur eine komplementäre Verwendung von verschiedenen Gesundheitsmodellen, sondern die Entwicklung eines Metamodells, welches die Verortung der subsummierten Modelle beinhaltet, Überschneidungen benennt, Widersprüchliches auflöst und in seiner Gesamtheit erkenntnistheoretisch umfassender wird als seine Bestandteile. Diese Entwicklung wird durch die Globalisierung und die Kapazitätzunahme informationsverarbeitender Systeme, die einen akzelerierten interkulturellen Waren- und Informationstransfer ermöglichen, insbesondere seit der 2. Hälfte des letzten Jahrhunderts katalysiert.^{6,7} In diesem fortschreitenden Prozess hat die Integrative Medizin von heute aus evolutionärer Sicht das Potential, einen wichtigen Beitrag zur *state of the art* Medizin von morgen zu leisten.⁸

Aus Sicht der US-amerikanischen und europäischen Medizingeschichte können nach den großen Erfolgen der Biomedizin insbesondere im Bereich der Infektionskrankheiten und immunvermittelten Erkrankungen sowie der Therapie akuter Erkrankungen durch die Integrativen Medizin neue Aspekte in der medizinischen Versorgung hinzugefügt und wiederentdeckt werden. Angestoßen unter anderem durch Fragestellungen bei der Behandlung von chronischen und funktionellen Erkrankungen,⁹⁻¹¹ wird dabei die biomedizinisch und pathogenetisch geprägte Perspektive wesentlich um salutogenetische Modelle ergänzt, bei denen Verstehbarkeit, Handhabbarkeit und Bedeutsamkeit der eigenen Gesundheit und Krankheit für den Menschen zentral sind.¹² Das daraus entstehende, von A. Antonovsky so genannte Kohärenzgefühl ist dabei zentral für das Individuum in seinem dynamischen Prozess von Gesundheit und Krankheit. Es entsteht, wenn der Mensch Selbstwirksamkeit erfährt, indem er diesen Prozess als verstehbar, handhabbar und sinnhaft erlebt.^{13,14} Die salutogenetischen Prinzipien legen die Notwendigkeit einer Medizin nahe, die nicht nur Therapie von Krankheit, sondern auch Gesundheitserhaltung und Prävention abbilden; die den Menschen nicht auf das körperliche Substrat reduziert, sondern seine

biopsychosoziospirituelle Mehrdimensionalität würdigt; und die Therapien nicht paternalistisch „verordnet“, sondern in dem die Arzt/Ärztin-Patient:innen-Beziehung eine zentrale Rolle in der Unterstützung der Patient:innen zu einem aktiven und selbstbestimmten Gesundheitsverhalten einnimmt.^{8,12,15}

In der zweiten Hälfte des 20. Jahrhunderts hat sich die Integrative Medizin zunächst in den USA und in den letzten 20 Jahren auch in Europa zu einer eigenständigen Disziplin in Wissenschaft, Ausbildung und Gesundheitsversorgung ausgebildet und entwickelt sich zunehmend weiter.^{8,12} Folgt man dem einleitenden Gedanken eines medizinevolutionären Schrittes vom Pluralismus zur Integration, so zeigt sich dieser auch in der historisch gewachsenen Definition der Integrativen Medizin. So definierte das National Center of Complementary and Alternative Medicine des National Institute of Health (NCCAM) um das Jahr 2000 die Integrative Medizin noch als Medizin, die „schulmedizinische Therapien mit Therapien der Komplementär- und Alternativmedizin kombiniert, für die es eine Reihe hochwertiger wissenschaftlicher Nachweise für Sicherheit und Wirksamkeit gibt [eigene Übersetzung des Autors]“.¹² Im Jahr 2014 wurde das Institut in National Center of Complementary and Integrative Health (NCCIH) umbenannt und betont damit bereits in seiner Namensgebung, dass das Nebeneinander („Alternative“) nun der expliziten Ergänzung und Integration Raum gegeben hat. Dass der Weg der Integration noch nicht zu Ende beschritten ist, zeigt dabei deutlich die Übersicht des NCCIH zu den komplementären (und damit zu integrierenden) Gesundheitsansätzen, die dort zwar relativ zueinander positioniert werden, jedoch eine übergeordnete Verortung in ein verbindendes Modell noch vermissen lassen (Abbildung 1). Die aktuellste Definition für Integrative Medizin ist in den USA beim Consortium of Academic Health Centres for Integrative Medicine aus dem Jahre 2015 zu lesen: „Integrative Medizin und Gesundheit bekräftigt die Bedeutung der Beziehung zwischen Arzt/Ärztin und Patient:in, stellt den ganzen Menschen in den Mittelpunkt, stützt sich auf wissenschaftliche Erkenntnisse und nutzt alle geeigneten therapeutischen Ansätze und Lebensweisen, Gesundheitsfachkräfte und Disziplinen, um optimale Gesundheit und Heilung zu erreichen [eigene Übersetzung des Autors].“¹⁶ In Europa findet sich bei Brinkhaus und Esch aus dem Jahre 2020: „Integrative Medizin und Gesundheit‘ bekräftigt die Bedeutung der Beziehung zwischen Arzt/Ärztin und Patient:in, zielt auf die ganze Person ab, wird durch Evidenz informiert und bedient sich aller geeigneten therapeutischen, präventiven, gesundheitsfördernden oder Lifestyle-Ansätze, Fachkräfte und Disziplinen des Gesundheitswesens, um eine optimale Gesundheit und Heilung zu erreichen – Kunst und Wissenschaft des Heilens gleichermaßen hervorhebend. Sie basiert auf einer sozialen und demokratischen sowie natürlichen und gesunden Umwelt.“¹⁷

Der Bedarf und die Nachfrage nach Forschung auf dem Gebiet der Integrativen Medizin haben stark zugenommen, was sich in einer Verdopplung der Zahl der Veröffentlichungen zu diesem Thema in letzten Dekade zeigt.¹⁸ Auf der Seite der Patient:innen besteht ein wachsendes Interesse an komplementärer und integrativer Medizin (CIM), insbesondere wenn sie in einem

integrativen therapeutischen Ansatz angeboten werden.^{19–22} In repräsentativen Untersuchungen nutzten bereits 2002 bzw. 2004 über 60% der Erwachsenen in Nordamerika und in Deutschland CIM-Anwendungen.^{22,23} Die Etikettierung und Separierung von Therapien als CIM begünstigt jedoch die grundsätzliche Problematik einer weiteren Fragmentierung und Spezialisierung von Fachgebieten, die auch zu einer schlechteren Qualität in der Gesundheitsversorgung führen kann.²⁴ Im Gegensatz dazu steht die Integrative Medizin dafür ein, den Patient:innen eine medizinische Versorgungsstruktur aus einer Hand zu bieten, bei der Beziehungszentrierung, ganzheitliche Sichtweise und die interdisziplinär Versorgung von verschiedenen gemeinsam arbeitenden Medizinprofessionen im Zentrum stehen.⁸ Dazu gehört im weiteren Verlauf die schrittweise Überwindung des sich aus dem historischen Prozess heraus ergebene Trennung zwischen „Schulmedizin“ und „komplementärer Medizin“.

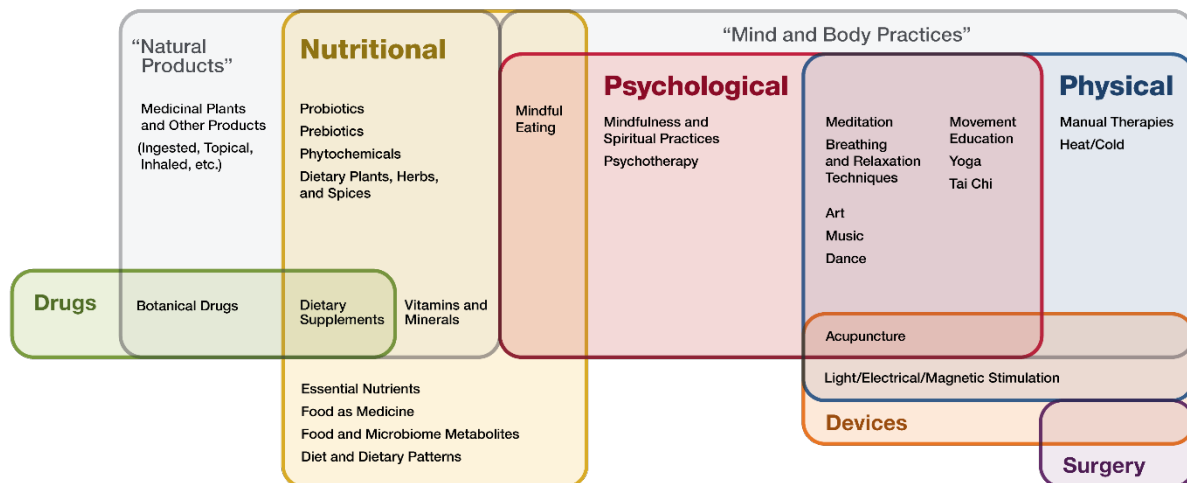


Abbildung 1. Komplementäre Gesundheitsansätze in einer Übersicht des NCCIH. Beispiele für komplementäre Gesundheitsansätze, in einer kategorialen Darstellung (Quelle: NCCIH, 2023).²⁵

1.2 Integrative Psychiatrie, Psychosomatik und Psychotherapie

Vor dem Hintergrund global hoher Prävalenzraten psychischer Erkrankungen^{26,27} und ungedecktem Behandlungsbedarf sowohl in entwickelten als auch in weniger entwickelten Ländern,^{28,29} gepaart mit Limitationen hinsichtlich Wirksamkeit und Sicherheit von psychopharmakologischen Interventionen,^{30–33} hat die Integrative Medizin auch im Bereich der psychischen Gesundheit ihren Einzug gehalten: es besteht weiterer Bedarf an wirksameren, sichereren, kosteneffektiven und leichter zugänglichen Therapieansätzen. Aber auch abgesehen von den genannten Einschränkungen in der aktuellen Versorgung stellen Psychiatrie und Psychosomatik genuin „integrative“ Fächer im Sinne der vorangestellten Definitionen dar, wobei die Einbeziehung von Körper und Psyche, von Individuum und Gesellschaft, die Ausrichtung auf Selbstregulation und Selbstwirksamkeit in der Therapie sowie

die Priorität der therapeutischen Beziehung nur beispielhaft genannt seien. Eine integrative Sichtweise erscheint somit zugleich natürlich als auch vertiefend für diese Fachgebiete.³⁴

In einem ersten Leitfaden zum Thema Integrative Mental Health (IMH) wurden im Jahr 2010 relevante Aspekte der Theoriebildung, der Forschung, der Bildung, der klinischen Leitfäden und der Gesundheitspolitik formuliert.³⁰ Hierzu gehören laut der Autoren in einer stufenweisen Vorgehensweise die theoretische und praktische Etablierung eines bio-psycho-sozio-spirituellen Modells von mentaler Gesundheit und Krankheit, die wissenschaftliche Untersuchung dieses Modells unter Einbeziehung von *mixed-methods designs* und gesundheitsökonomischer Aspekte, die Einbindung von Universitäten in Forschung, Lehre und Klinik, die Einrichtung von IMH-Lehrstühlen, die Aufnahme von Prävention, Gesundheitserhaltung und evidenzbasierten komplementären Therapieformen in klinische Leitlinien, sowie die Einbindung politischer Entscheidungsträger.³⁰ In weiteren Veröffentlichungen wurden beispielsweise klinische Applikationen komplementärmedizinischer Therapien in einem integrativen Ansatz z.B. für affektive Störungen, Angsterkrankungen, psychotische Erkrankungen und Schlafstörungen konkret formuliert,^{35,36} und ein klinisches Curriculum für die Ausbildung in IMH vorgeschlagen.³⁷

Im deutschsprachigen Raum wurde die Integrative Psychiatrie und Psychosomatik als Konfluenz von klassischer Psychiatrie, Mind-Body-Medizin und evidenzbasierter Naturheilverfahren diskutiert.³⁸ Mind-Body-Praktiken umfassen ein breites Spektrum von Therapieformen, die zunehmend evidenz-basiert sind und bei denen die Wechselwirkung von Körper und Geist eine wesentliche Rolle spielen (s. Abb. 1). Historisch entstand die Mind-Body-Medizin aus der US-amerikanischen Stressforschung der 1970er Jahre, die erstmals mentale Techniken einsetzte um Stress auf physiologischer Ebene zu reduzieren (sog. *relaxation response*).³⁹ Im Gegensatz zu der angesichts des Namens zu vermutenden Überlappung mit der im deutschsprachigen Raum als eigenes Fach bestehenden Psychosomatik sind hier vor allem bewusstseinspsychologische Unterschiede herauszustellen.³⁸ Denn während sich beide Disziplinen naturgemäß mit der Interaktion von Körper und Psyche befassen, so liegt der Psychosomatik bzw. Psychotherapie eine grundsätzlich diskursive Herangehensweise an psychopathologische und psychodynamische Inhalte zugrunde, während es in den achtsamkeitsbasierten Verfahren der Mind-Body-Medizin um Desidentifikation von diesen Inhalten geht. Diese entsteht durch das Erreichen eines metabewussten Zustandes: durch Achtsamkeitstechniken wird ein Bewusstseinsraum gezielt geöffnet, in dem ein konstanter Beobachter („innerer Zeuge“) getrennt zu den unaufhörlich wechselnden Bewusstseinsinhalten in Form sensorischer Wahrnehmungen, Emotionen und Gedanken wahrgenommen werden kann.^{40,41} Dabei handelt es sich, wie im nächsten Abschnitt weiter ausgeführt, um einen der zentralen Wirkfaktoren meditativer Verfahren und damit auch der in dieser Arbeit entwickelten und evaluierten Mind-Body-Intervention *Meditation-Based Lifestyle Modification* (MBLM). Mind-Body-Medizin – und so auch MBLM – ist in ihrem Konzept jedoch noch auf

achtsamkeitsbasierte Verfahren im engeren Sinne beschränkt, sondern nutzt durch multimodale Interventionen körperliche, mentale, emotionale, soziale und spirituelle Einflussfaktoren zur mehrdimensionalen Förderung einer individuellen gesundheitlichen Lebensstilgestaltung.

1.3 Meditation: Theorie, Evidenz und Potentiale

Das wissenschaftliche Interesse an der Erforschung von Meditation ist, gemessen an der Anzahl an Publikationen, in den letzten Jahren exponentiell gewachsen.^{42,43} Interessanterweise gibt es dennoch keine einheitliche Definition von Meditation, vielmehr finden sich in der Fachliteratur eine Vielzahl von Beschreibungen mit unterschiedlichem Fokus auf neurobiologische, emotional-kognitive, soziale oder spirituelle Aspekte von Meditation.⁴⁴ Dies mag neben der fachlichen Perspektive der jeweiligen Autoren daran liegen, dass es hunderte von verschiedenen Meditationstechniken gibt,⁴⁵ deren Bandbreite eine geschlossene (und dennoch aussagekräftige) Definition wohl nicht gerecht werden kann. Interessant sind daher auch neuere Ansätze, die Meditation von der eigentlichen Praxis ausgehend dimensional einordnen, z.B. entlang des Ausmaßes an Körperorientierung und der Aktivierung der Meditierenden: aus dieser Herangehensweise ergeben sich Cluster von Meditationstechniken: Kontemplation, Achtsamkeit, Visuelle Konzentration, Körperzentrierte Meditation, Affektzentrierte Meditation, Mantra-Meditation und Meditation mit Bewegung.⁴⁴ Wie in der traditionellen Sichtweise besteht in dieser Aufteilung keine Trennung zwischen Yoga und Meditation (wie sie häufig in der wissenschaftlichen Literatur vorgenommen wird),⁴⁶ sondern Yoga fügt sich als Instanz von „Meditation mit Bewegung“ in die Landschaft der Meditationstechniken ein.

Neben einer einheitlichen Definition fehlt bislang auch eine einheitliche Theorie über die Wirkungsweise von Meditation. Die Sichtweise der westlichen Psychologie vereint jedoch das bereits im vorhergehenden Abschnitt angedeutete Narrativ „Well-Being durch Meta-Bewusstsein“.⁴⁷ In diesem entsteht durch die meditative Technik die Fähigkeit, eine Außenperspektive auf geistige Prozesse der Sinneswahrnehmungen, Emotionen und Kognitionen zu erlangen. Damit geht eine Desidentifikation von diesen Prozessen einher, die eine Distanzierungsmöglichkeit von Schmerz und Leid ermöglicht. Zugleich begünstigt das Metabewusstsein eine geringere Reaktivität auf mentale Prozesse, die häufig problemverstärkend sind.⁴⁸ Auf diese Weise kommt es zu einer Symptomentlastung und erhöhtem Wohlbefinden, ohne sich diskursiv mit der Ursache des Problems befassen zu haben. Zudem kommt es in diesem Bewusstseinszustand auf physiologischer Ebene zur bereits erwähnten *relaxation response*, die den Stresslevel des autonomen Nervensystems und der damit verbundenen endokrinen Antwort reduziert.⁴⁹

Trotz deutlichen Forschungsbedarfs hinsichtlich der theoretischen Grundlagen besteht wissenschaftlich kein Zweifel, dass Meditation eine klinisch relevante, positive Wirkung auf die psychische Gesundheit, auf die körperliche Gesundheit und zu einem geringeren Maße auf das

Gesundheitsverhalten entfaltet, wie unter anderem drei aktuellere Metasynthesen mit Daten von 136 Meta-Analysen zeigen.⁵⁰⁻⁵² Ebenfalls besteht gute Evidenz für die Erkenntnisse, dass die Effekte von Meditation größer als bei reinen Entspannungsverfahren sind^{53,54} und die Effekte von Yoga im Sinne einer Integration von körperlicher Aktivität und Meditationstechniken größer sind als bei anderen Formen der Meditation ohne körperliche Aktivität.^{50,55} Ferner gibt es keine Hinweise darauf, dass Meditation Psychotherapie ersetzen könnte, jedoch sinnvoll in einem therapeutischen Rahmen in Kombination eingesetzt werden können, wie es z.B. bei der *Mindfulness-Based Cognitive Therapy* oder der *Acceptance and Commitment Therapy* bereits der Fall ist.⁴⁷

In der „okzidentalen“ Rezeption von Meditation stehen gesundheitsbezogene Ziele und der Einsatz von säkularisierten Meditationstechniken im Zentrum von Forschung und klinischer Anwendung.⁴⁷ Im „fernöstlichen“ Narrativ stehen indes ganz andere Ziele und Qualitäten im Vordergrund. Meditation wurde in einem subkulturellen bzw. spirituellen Kontext praktiziert, der auf geistige Befreiung („Erleuchtung“) ausgelegt war und Meditationspraktiken waren eingebettet in eine Lebensphilosophie und -praxis, die diese spirituelle Zielsetzung unterstützte.^{47,56-58} Es ist daher möglich, dass z.B. auch gesundheitsrelevante Effekte von Meditation, wie sie traditionell gelebt wurde, der bisherigen Rezeption verborgen blieben und als ungenutztes Potential vorhanden sind.

1.4 Entwicklung und Evaluation der *Meditation-Based Lifestyle Modification*

Leitgedanke der Entwicklung von MBLM war daher die Vertiefung meditativer Erfahrung im klinisch-interventionellen Kontext der Mind-Body-Medizin in Psychiatrie, Psychosomatik und Psychotherapie, um weitere therapeutische Effekte von Meditation zu erschließen.⁵⁹

Dazu sollte Meditation nicht wie im überwiegenden Anteil der bestehenden wissenschaftlichen Arbeiten in einer strikt säkularisierten, aus dem traditionellen Kontext herausgelösten Meditationstechnik vermittelt werden. Vielmehr sollte gerade der Aspekt einer stufenweise sich entwickelnden lebensweltlichen Vorbereitung auf Meditation und auch die genuin spirituelle Ausrichtung von Meditation kultursensitiv angeregt werden. Als theoretischer Hintergrund wurde dabei das klassische Yoga nach Patanjali gewählt, welches – im Gegensatz zum modernen Yoga – zentral auf Meditation und Bewusstseinsentwicklung ausgerichtet ist.^{42,46,60,61} Im diesem klassischen Yoga werden acht Stufen durchlaufen, die Körper und Geist auf immer feiner werdende Formen der Konzentration und Meditation vorbereiten. Ziel des Yoga ist es, die Bewegungen des Geistes (z.B. in Form von Sinneswahrnehmungen, Emotionen oder Gedanken) vollständig zur Stille zu bringen, um so eine Wahrnehmung des beobachtenden Bewusstseins selbst zu ermöglichen.⁶² Die ersten beiden Stufen beziehen sich dabei auf eine ethische Lebenspraxis im Umgang mit anderen und im Umgang mit sich selbst (*yama* und *niyama*), bei der Tugenden wie Gewaltlosigkeit, Wahrhaftigkeit, Maßhalten, Reinheit, Zufriedenheit, Selbstdisziplin, Selbststudium und Hingabe geübt werden. Dies befähigt den Praktizierenden, sich in den weiteren beiden Stufen den Körperpositionen (*asana*) und

Atemübungen (*pranayama*) zuzuwenden, die wiederum für die geistigen Übungen bzw. Zustände der folgenden vier Stufen vorbereiten: Rückzug der Sinne (*prathyahara*), Konzentration auf ein Meditationsobjekt (*dharana*), Verschmelzung mit dem Meditationsobjekt (*dhyana*) und Absorption in das beobachtende Bewusstsein selbst (*samadhi*).⁴⁶ Als ordnungstherapeutischer Rahmen⁴¹ wurde die Traditionelle Indische Medizin gewählt, da diese – kulturell passend zum Kontext des Yoga – gesundheitliche Rahmenbedingungen zu konstitutionsspezifischer Ernährung, Bewegung und gesunder Tagesrhythmik des Praktizierenden ausführt.^{63–65} Auf operativer Ebene wurde das genannte theoretische Konstrukt in ein 8-wöchiges modulares Therapiekonzept mit vergleichbarer Intensität und Dauer des bekannten MBSR-Programmes (Mindfulness-Based Stress Reduction) nach J. Kabat-Zinn übersetzt.^{66,67} Dabei wurde hinsichtlich der spezifischen Inhalte auf eine depressive Symptomatik als häufiger zentraler oder komorbider Anteil psychischer Störungen fokussiert.⁶⁸ MBLM versteht sich jedoch als modulare Intervention, die flexibel auf die Bedürfnisse unterschiedlicher Gruppen von Patient:innen adaptiert werden kann und soll.⁵⁹ Therapeutisch kommen dabei innerhalb von MBLM drei Ebenen in Kombination zum Tragen (Abbildung 2):

1. eine lebensethische Praxis im Sinne der *yamas* und *niyamas*, die in einem Kontext der psychoedukativen bzw. psychotherapeutischen Gruppentherapie vermittelt wird
2. eine körperliche Praxis mit einfachen Yoga-Übungen und Atemtechniken. Ergänzend erfolgt eine konstitutionsspezifische Beratung zu Ernährung und Tagesrhythmus.
3. eine zentrale Meditationspraxis mit spirituellen Mantras (kulturoffen frei wählbar aus Beispielen der fünf Weltreligionen).

Neben wöchentlichen Gruppensitzungen, die inhaltlich und strukturell diese drei Ebenen abbilden, ist eine täglich häusliche Praxis fester und wesentlicher Bestandteil dieser Intervention. Diese wird themenbezogen im wöchentlichen Wechsel vertieft. So wird beispielsweise im Themenkreis der „Gewaltlosigkeit“ die Wahrnehmung eigener körperlicher Grenzen in den Yoga-Übungen und im Alltag gefördert, für negative Selbstattributionen als Form intrapsychischer Gewalt sensibilisiert und eine friedvollere und projektionsreduzierende Kommunikation durch den Ausdruck eigener Bedürfnisse unterstützt.⁶⁹

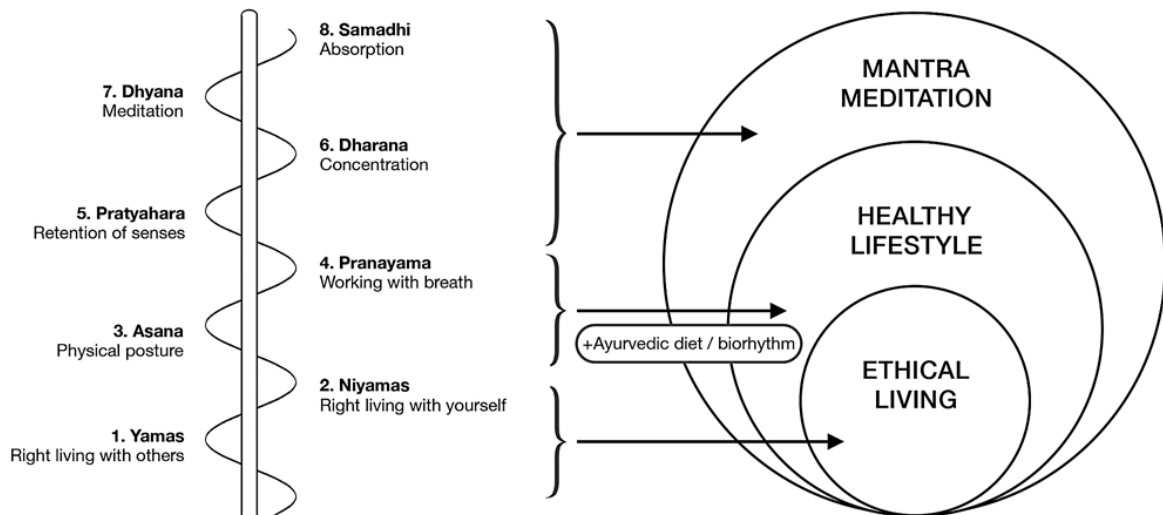


Abbildung 2. Projektion des achtgliedrigen Pfades des klassischen Yoga auf das MBLM-Programm (Quelle: Bringmann et al., 2021).⁵⁹

Für die antidepressive Wirkung der ethisch-spirituellen Komponenten, die eine wesentliche Innovation des MBLM-Programms ausmachen, existieren derzeit jedoch nur wenig empirische Hinweise.^{70–73} Die generelle antidepressive Wirkung von Meditation und den körperorientierten Yoga-Bestandteilen kann jedoch als gesichert angesehen werden.^{50,60,74–81} Die differentielle und integrative Wirkung einzelner Bausteine von komplexen Mind-Body-Interventionen ist noch unzureichend erforscht – es zeichnet sich jedoch wie erwartet ab, dass die Effektivität komplexer Interventionen größer ist als die von Einzelanwendungen.⁵⁵ Aus neurophysiologischer Sicht wirken im klassischen Yoga verschiedene Mechanismen der Selbstregulation zusammen.⁸² Innere Ausrichtung, Zielorientierung und bewusste Handlungsmodifikation wie in der lebensethischen Praxis werden durch cerebrale „top-down Prozesse“ höher-hierarchischer neuronaler Netzwerke abgebildet, die z.B. negative Selbstattribution, emotionale Dysregulation und Rumination inhibieren können. Dem gegenüber stehen neuronale „bottom-up Prozesse“, die durch körperorientiertes Yoga, Atemtechniken und Meditation fasilitiert werden und basale neuronale Netzwerke positiv beeinflussen, die vaso-pulmonale Gefäßkonstriktion, Entzündungsprozesse, Muskelspannung und Schmerzreaktionen positiv beeinflussen.^{82–84}

MBLM versteht sich in seinen zentralen Eigenschaften als Mind-Body-Intervention der so genannten zweiten Generation,⁸⁵ welches bewusst die Operationalisierung eines kultursensitiven und damit auch lebensweltlich eingebundenen Therapiekonzeptes verfolgt. Eine traditionell motivierte Integration spiritueller und lebensethischer Aspekte zur Vertiefung von Meditation war bei der Entwicklung ausdrückliche Intention. Im Sinne eines geordneten Vorgehens (Abbildung 3) entlang der Richtlinien zur Entwicklung, Pilotierung und Auswertung komplexer Interventionen⁸⁶ wurde im Rahmen des Forschungsprojektes zunächst spirituelle

Mantra-Meditation als zentrale Intervention im stationären Setting bei Patient:innen mit majorer Depression untersucht.⁸⁷ Aufgrund der positiven Ergebnisse wurde dann die komplexe Intervention MBLM auf Grundlage von theoretischen und empirischen Ergebnissen maßgeblich vom Autor selbst entwickelt⁵⁹ und im Rahmen einer Machbarkeitsstudie bei ambulanten Patient:innen mit Depression evaluiert.⁸⁸ Um der Frage nachzugehen, ob und welche Komponenten von MBLM synergistisch wirken, wurde ein komplexes Studiendesign in Form einer experimentellen Einzelfallanalyse sowie mehreren Interventionskonditionen eingesetzt.⁸⁹ Mit dem gleichen Studiendesign wurden auch Fragestellungen zum Einfluss von MBLM auf kognitiv-emotionale Prozesse untersucht,⁹⁰ sowie die Frage nach dem Zusammenhang von Persönlichkeitsmerkmalen der Teilnehmer:innen und Effekten des Programms.⁹¹ Weiterer Schwerpunkt waren Untersuchungen an depressiven Patient:innen. Untersucht wurde die klinische Wirksamkeit von MBLM im Vergleich zur psychiatrisch-psychotherapeutischen Standardtherapie,⁹² Effekte von MBLM auf die Herzfrequenzvariabilität⁹³ sowie auf die Spiritualität der Patient:innen. Ergänzt wurden diese Untersuchungen um zwei qualitative Studien, in denen das Erleben der Teilnehmer:innen von MBLM thematisierte⁹⁴ bzw. dieses mit dem Erleben der Standardtherapie untersucht wurde.⁹⁵ Weiterhin erfolgte der Einsatz von MBLM bei Patient:innen mit chronischem Schmerz⁹⁶ und als ein Therapiearm in einer aktuell sich in Durchführung befindlichen, randomisiert-kontrollierten Studie an der Charité bei Patient:innen mit Mamma-CA.⁹⁷

Im Folgenden werden in dieser Habilitationsschrift exemplarisch die randomisiert kontrollierte Vorstudie mit spiritueller Mantra-Meditation bei Major Depression vorgestellt sowie erste Evaluationen von MBLM in unterschiedlichen Populationen unter dem Einsatz von experimentellen Einzelfallanalysen, einer randomisiert-kontrollierten Studie und einer qualitativen Auswertung des Programms.

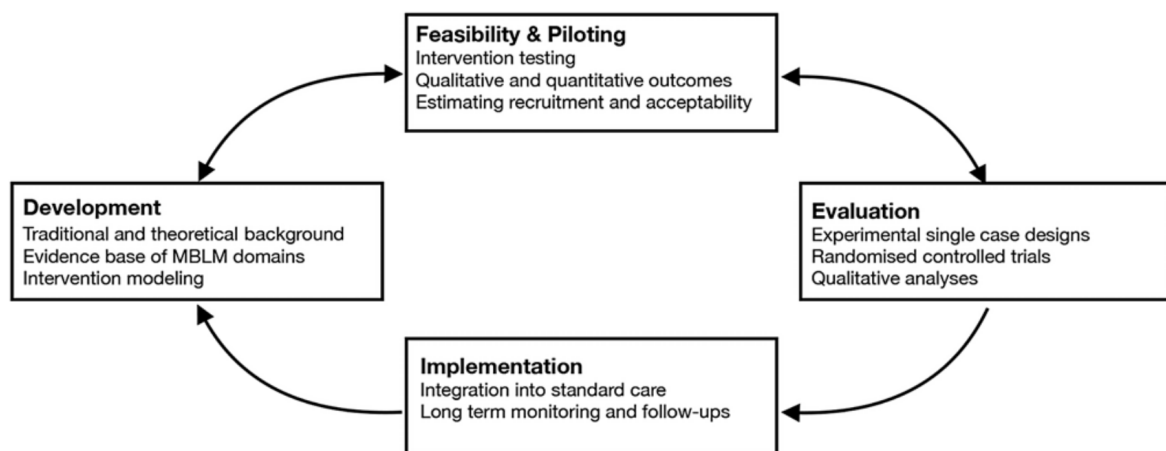


Abbildung 3. Entwicklung, Pilotierung und Evaluation von MBLM (Quelle: Bringmann et al., 2021).⁵⁹

2. Eigene Arbeiten

2.1 Mantra-Meditation als begleitende Therapie bei majorer Depression: Eine randomisierte kontrollierte Studie

Bei dieser Studie handelte es sich um eine Vorstudie zum MBLM-Projekt, in dem spirituelle Mantra-Meditation als Intervention eingesetzt wurde, jedoch ohne eine Integration in einen breiteren Kontext bzw. unterstützende Praktiken im Sinne von MBLM. Untersucht wurde die Wirksamkeit von Mantra-Meditation im Vergleich zu progressiver Muskelentspannung innerhalb einer stationären psychiatrischen Behandlung bei Major Depression.

Übernommen aus der Zusammenfassung der Veröffentlichung:⁸⁷ „Bei dieser Studie handelte es sich um eine zweiarmige, verblindete, randomisierte, kontrollierte Studie mit 123 Patienten einer psychiatrischen Klinik, bei denen eine Major Depression nach DSM-IV-Kriterien diagnostiziert wurde (Januar 2017 bis Juni 2020). Die Behandlungsgruppe praktizierte Mantra-Meditation (MAM, N = 60); die Vergleichsgruppe praktizierte progressive Muskelentspannung (PMR, N = 63). Beide Behandlungen wurden in Form einer einführenden Sitzung durchgeführt, gefolgt von zweimal wöchentlich stattfindenden 30-minütigen Gruppensitzungen als Ergänzung zur üblichen Behandlung depressiver stationärer Patienten (TAU). Der primäre Endpunkt war die Veränderung des vom Arzt bewerteten Schweregrads der Depressionssymptome, gemessen mit dem MADRS-Interview. Sekundärer Endpunkt war der selbst eingeschätzte Schweregrad der Depression, gemessen mit dem BDI-II-Fragebogen. Die *Intention-to-treat*-Analyse wurde anhand linearer gemischter Modelle durchgeführt. Ergebnisse: Die TAU + MAM-Gruppe hatte eine signifikant größere Verbesserung des MADRS-Scores als die TAU + PMR-Gruppe, sowohl beim 3-Monats-Follow-up (Unterschied zwischen den Gruppen = 4,78, 95% CI = [-8,32;-1,42]; d = 0,62) als auch beim 6-Monats-Follow-up (Unterschied zwischen den Gruppen = -6,24, 95% CI = [-9,80;-2,69]; d = 0,79). Nach der Behandlung war der selbstberichtete Schweregrad der Depressionssymptome in der TAU + MAM-Gruppe nicht signifikant niedriger als in der TAU + PMR-Gruppe. Eine explorative Analyse der Unterschiede zwischen den primären und sekundären Ergebnissen zeigte, dass die Mantra-Meditation hauptsächlich die Stimmung und nicht die kognitiven Symptome verbesserte. Schlussfolgerungen: Bei stationären Patienten mit schweren Depressionen führte die begleitende Mantra-Meditation zu einer klinisch relevanten Verringerung der Schwere depressiver Symptome.“



Mantra meditation as adjunctive therapy in major depression: A randomized controlled trial

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ARTICLE INFO

Keywords:

Mantra
Meditation
Major depression
Psychiatry
Mind-body medicine

ABSTRACT

Objective: To investigate the efficacy of add-on mantra meditation compared to progressive muscle relaxation in major depression.

Methods: This study was a two-arm, single-site, raterblinded, randomized controlled trial involving 123 inpatients at a psychiatric hospital diagnosed with major depression according to DSM-IV criteria (January 2017 to June 2020). The treatment group practiced mantra meditation (MAM, $N = 60$); the comparator group practiced progressive muscle relaxation (PMR, $N = 63$). Both treatments were delivered via an introductory lesson followed by 30-minute group sessions twice weekly, adjunctively to usual treatment for depressive inpatients (TAU). The primary outcome measure was change in clinician-rated depression symptom severity, measured by the MADRS interview. The secondary outcome measure was self-reported depression severity, measured by the BDI-II questionnaire. Intention-to-treat was analyzed using linear mixed models.

Results: The TAU + MAM group had significantly greater improvements in MADRS score than the TAU + PMR group, both at the 3-month follow-up (between-group difference = 4.78, 95% CI = -8.32 - -1.42; $d = 0.62$) and at the 6-month follow-up (between-group difference = -6.24, 95% CI = -9.80 - -2.69; $d = 0.79$). Posttreatment, self-reported depression symptom severity was not significantly lower in the TAU + MAM group than in the TAU + PMR group. Exploratory analysis of the differences between primary and secondary outcomes showed that mantra meditation mainly improved mood rather than cognitive symptoms.

Conclusions: In inpatients with major depression, adjunctive mantra meditation led to clinically relevant reduction in depressive symptom severity. Further research would build evidence for the untapped potentials of mantra meditation.

ClinicalTrials.gov Identifier: NCT03004430

1. Introduction

According to the World Health Organization more than 300 million people in the world suffer from depression, which is the single largest factor contributing to global disability. (Smith & De Torres, 2014) During the last three decades, the number of cases of depression worldwide increased by almost 50%, with growing age-standardized incidence rates in regions of any sociodemographic index. (Liu et al., 2019) Depression is and remains a major public health problem.

Antidepressants are a mainstay of treatment for major depression,

but are associated with clinically relevant risks of severe adverse events during both use and withdrawal. (Henssler et al., 2019) To increase the efficacy of treatment, inpatients could potentially benefit from comprehensive, non-pharmacological elements of therapy. (Qaseem et al., 2016, Zaprutko et al., 2020) Among these, relaxation techniques are commonly used to treat depression and have proven effective both solely and adjunctively to standard care. (Af et al., 2010, Jia et al., 2020) Along with the rise of mindfulness-based interventions in mental health care, meditation has received growing attention in research and clinical practice. Meditation, although often used synonymously with

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<https://doi.org/10.1016/j.jadr.2021.100232>

Received 13 July 2021; Received in revised form 26 July 2021; Accepted 7 September 2021

Available online 11 September 2021

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“mindfulness meditation” is an umbrella term for a large variety of techniques and definitions. (Matko & Sedlmeier, 2019) Meditation usually involves sustained attention on an object, which can be external, or a physical or mental process. Meditative techniques exceed the positive psychological effects of mere relaxation techniques in healthy individuals (Sedlmeier et al., 2012, Sedlmeier et al., 2018) and recent meta-syntheses of randomized controlled trials unanimously concede that meditation has substantial beneficial effects on depressive symptoms in clinical populations. (Goldberg et al., 2020, Rose et al., 2020) However, the results so far were quite heterogeneous: depending on type of meditation, population, and outcomes the effects of meditation were not reliable or superiority could not be demonstrated compared to active control groups. (Goldberg et al., 2020, Goyal et al., 2014)

Research on mantra meditation in clinical, but also in other, contexts is still in its infancy. Compared to mindfulness meditation, there are still relatively few studies and these are predominantly characterized by lack of methodological rigor. (Goyal et al., 2014, Ospina et al., 2007) Equally relevant, however, is the fact that there is still no overarching theory on the mechanisms of action of mantras in a scientific context. Such a theory should be informed by the traditional and spiritual contexts of mantra meditation—so far, mantra meditation has mainly been examined in a secularized form by depriving meditation techniques of their traditional background (e.g., relaxation response, (Benson et al., 1974) clinically standardized meditation (Carrington et al., 1980)), or by examining singular techniques in their own context (e.g., transcendental meditation, (Ospina et al., 2007) mantra repetition program (Bormann et al., 2014)).

As an example, a recent mantra meditation program in a clinical setting that is based on the traditional background of classical yoga is Meditation Based Lifestyle Modification (MBLM). (Bringmann et al., 2020, Bringmann et al., 2021) Classical yoga is oriented toward spiritual liberation through meditation. It provides principles and practice of an ethical lifestyle, body-oriented yoga practices, and meditation in order to achieve expanding stillness of the mind and, eventually, self-realization.

Even more important than in yoga, mantra meditation is a key feature of Tantrism. Tantrism is an umbrella term for ancient esoteric traditions of Hinduism and Buddhism, in which highly differentiated mantras (e.g., specific sound formulas) and yantras (e.g., specific geometrical patterns) are used to reproducibly achieve various worldly and transcendent goals. (Feuerstein, 1998, Ramachandra Rao, 1979) In India, a “spiritual science” has developed concerning the employment and utility of mantras, (Ramachandra Rao, 1979) including initiation by a spiritual teacher and specific rules and regulations for practice. (Sivananda and Yoga, 2010) A mantra is described as a “mystical energy encased in a sound structure,” with deep faith in the mantra being paramount to unleash its effects on the body, mind, and soul. (Devananda, 1995, Sivananda and Yoga, 2010) These esoteric and mystical concepts were largely ignored in Western research (e.g., in clinical sciences), or mantras were disregarded as primitive magico-religious practices (e.g., spells or prayers). However, Western scholars predominantly arrived at these interpretations from Christian theology, which led to misleading ideas that have strongly influenced discussions of Indian mantras over the last few decades. (Fárek & Horák, 2021) In contrast, the knowledge on mantra and yantra (Feuerstein, 2012) is more than five millennia old. Traditional practices and their metaphysical assumptions thus deserve serious and open-minded consideration in future research.

While most meta-analyses report on mindfulness meditation, the evidence for the effects of mantra meditation—a common meditation technique among adults in the United States (Burke et al., 2017)—is still scarce. An earlier meta-analysis (Goyal et al., 2014) in 2014 reported either insufficient or low evidence for a positive effect of mantra meditation on anxiety, depression, stress, quality of life, and sleep in clinical populations. However, as only few mantra meditation programs met the inclusion criteria for this analysis, the authors’ ability to draw

conclusions about the effects was significantly limited. Furthermore, the authors reported a likely “floor” effect in selected samples of the general population, if symptom levels of the outcomes were low before the intervention. (Goyal et al., 2014) Another meta-analysis in 2014 on trait anxiety (which is strongly correlated with depressive symptoms), (Knowles & Olatunji, 2020) however, reported transcendental meditation (a mantra-based meditation technique) to be more effective than most active control treatments. (Orme-Johnson & Barnes, 2014) In a recent systematic review of mantra meditation for mental health in the general population, (Lynch et al., 2018) eight of 11 studies reported significant improvements on outcomes of depression (four randomized controlled trials and four other designs).

Overall, the existing reviews illustrate the lack of evidence on the efficacy of mantra meditation in mental health care due to the limited available studies, both in number and methodological rigor. This study aims to add evidence for the effects of mantra meditation in inpatients with major depression compared to progressive muscle relaxation (PMR) by assessing measures of clinician-rated and self-reported depression over six months after discharge from hospital. A Cochrane review has shown variations of PMR to be more effective at reducing self-rated depressive symptoms than no or minimal treatment; (Bringmann et al., 2020) it may add additional efficacy to antidepressant treatment. (Bringmann et al., 2021) Also, we know from meta-analyses of effects of meditation in healthy individuals, that relaxation techniques like PMR are regularly chosen as an active control group. (Sedlmeier et al., 2012, Sedlmeier et al., 2018) Thus, PMR was considered a valid active control group in this study.

2. Methods

2.1. Design

This two-arm, single-site, rater-blinded, randomized controlled trial (ClinicalTrials.gov Identifier: NCT03004430) was conducted at the Clinic for Psychiatry, Psychosomatics, and Psychotherapy, Zschadras, Germany from January 2017 through June 2020. The study was approved by the ethics review board of the Technische Universität Dresden (EK 498,122,016). All participants provided written informed consent after receiving a full explanation regarding the study protocol and before randomized assignment to treatment arms. The study employed open allocation (participants were informed of assignment after randomization) but included blinded assessment of the primary outcome measure before treatment (T0), at hospital discharge (T1), at 3-month follow-up (T2), and at 6-month follow-up (T3).

2.2. Participants

Inclusion criteria were inpatient treatment, a diagnosis of a current episode of major depression as defined by DSM-IV criteria (DSM-IV codes: 296.22, 296.23, 296.32, 296.33. Corresponding ICD-10 codes: F32.1, F32.2, F33.1, F33.2), age ≥ 18 years, a score of 20 or greater in the Beck Depression Inventory (BDI-II), (Beck et al., 1996) and the ability to sit on a chair for at least 20 min.

Patients were excluded for any one of the following reasons: 1. Any psychiatric comorbidity except abuse of or dependence on nicotine, agoraphobia with or without panic disorder, generalized anxiety disorder, posttraumatic stress disorder, specific phobia, social phobia, hypochondriasis, pain disorder, somatization disorder, undifferentiated somatoform disorder, sexual and gender identity disorders or eating disorders; 2. Psychotic symptoms not reconcilable with unipolar depression; 3. acute suicidality; 4. diagnoses affecting cortisol levels such as type I diabetes mellitus, cancer, asthma, chronic hepatitis, chronic fatigue syndrome, or regular use of medication with an immunomodulatory effect (e.g., cytotoxic chemotherapy, corticosteroids, interferons); 5. current practice of other forms of mantra repetition such as the rosary, chanting, or transcendental meditation; 6. current

participation in another clinical trial.

2.3. Primary and secondary outcome measures

The primary outcome measure was the change in the score on the Montgomery and Åsberg Depression Rating Scale (MADRS). (Schmidtke & Moises, 2007) This a clinician-rated, 10-item scale is designed to be sensitive to the change in effects of depressive symptoms during drug therapy. The internal consistency of MADRS is considered very high and the correlation of MADRS has been shown to be generally high or very high with the Hamilton Rating Scale for Depression (HAM-D). (Hamilton, 1960) A score greater than 30 or 35 on MADRS indicates severe depression, while a score of 10 or below indicates remission. To maintain high levels of interrater reliability in this study, trained psychologists used a structured interview guide (SIGMA) (Williams et al., 2008) that has been developed for MADRS.

The secondary outcome measure was the change in the score on the Beck Depression Inventory (BDI-II). (Beck et al., 1996) This is a 21-question multiple-choice self-report inventory, one of the most widely used psychometric tests for measuring the severity of depression. The BDI-II is composed of items relating to symptoms of depression such as hopelessness and irritability, cognitions such as guilt or feelings of being punished, as well as physical symptoms such as fatigue, weight loss, and lack of interest in sex. Cut-off scores: values below 14 can be considered as subclinical depression; 14–19 - mild depression; 20–28 - moderate depression; and 29–63 - severe depression. The present study focuses on depression. Other variables assessed in this research project, including parameters of heart rate variability and measures of spirituality, will be discussed in separate publications.

2.4. Procedure

Patients with suspected depression were screened consecutively at hospital admission by administration of the BDI-II questionnaire. In a personal interview within 72 h of admission, a senior psychiatrist assessed those with a BDI-II score ≥ 20 .

Consenting participants were examined for eligibility, utilizing the Structured Clinical Interview for DSM-IV (SCID) (First et al., 1996) to verify DSM-IV criteria of major depression and exclusionary conditions. Patients meeting the study criteria took part in the MADRS interview and completed questionnaires for clinical measures, demographic data, and medication. They were then enrolled prior to randomization, which was implemented by a software-based minimization algorithm, (O'Callaghan, 2014) stratified for gender, age, diagnosis (first or recurring depressive episode), severity of depression (baseline BDI-II score), and religious affiliation (none vs. any) with 20% randomization. Within these 20%, subjects were randomized 1:1 to either treatment.

Study physicians or psychologists who were trained by standardized procedures to establish interrater reliability gave the MADRS ratings. To assess interrater reliability, 15% of total number of interviews ($n = 65$) were rated by two raters simultaneously. The average intraclass correlation coefficient was 0.99 with a 95% confidence interval from 0.98 to 1.0 ($F(64, 65) = 179, p < .001$), which reflects a high degree of reliability.

2.5. Treatment conditions

The treatment group received training in mantra meditation (MAM, see below), and the control group received training in progressive muscle relaxation (PMR, see below). Both groups did their training in an introductory class, followed by 30-minute group sessions held twice a week. Participants in both groups used standardized manuals, instructor guides, information brochures, and online content with guided audio sessions for personal use. The MAM and PMR therapy facilitators each facilitated only one treatment type. Nursing staff with long-term experience in PMR provided this therapy, and experienced meditation

practitioners led the mantra meditation. Participants were encouraged to practice on their own around 20 min per day and to keep a record of their practice in a diary provided in the study brochure. Both treatments were delivered adjunctively to treatment as usual (TAU), which included an individual program of pharmacotherapy, psychotherapy, ergotherapy, and movement therapy as part of standard inpatient care. After discharge, participants could choose to receive weekly, group-specific emails as a reminder and incentive for continued practice. Participants were asked to refrain from practicing other methods of relaxation or meditation during the study.

2.6. Mantra meditation

In mantra meditation, a spiritually related sound, word, or phrase is silently repeated with one-pointed attention toward the mantra. Participants could choose from mantras from a variety of spiritual traditions during the introductory class. The facilitators advised participants as follows. They were to choose a pleasant-sounding mantra that was compatible with their personal beliefs and easy to remember (e.g., "Ave Maria", "Om mani padme hum", "Om nama shivaya"). During meditation, participants could sit in any, preferably upright, position. The mantra should be recited inwardly with focused attention on the sound rather than its meaning. However, appreciation of the mantra's meaning and belief in it may act as a catalyst for meditative practice. (Wachholtz, 2008) Synchronization with the breath was not part of the technique, but was allowed to occur spontaneously or at will. Arising thoughts should not be judged or followed. With growing meditation practice, concentration on the mantra may become increasingly receptive, sustained, and effortless, allowing for deeper states of experience. (Telles et al., 2016) As an optional technique, participants could choose and visualize a geometrical pattern (yantra) along with the recitation of their mantra, combining auditory and visual concentration (e.g. a symbol of the associated spiritual tradition or simple geometric patterns such as a triangle with a central point in the middle). Also, facilitators encouraged participants to use mantra recitation as a tool for self-regulation in situations of distress in daily life. A more detailed description of the meditation technique, including a list of mantras, yantras, and different systems for classifying meditation is provided in the supplementary material.

2.7. Progressive muscle relaxation

PMR was introduced in 1934 by Jacobson to counter feelings of anxiety and distress mediated by sustained muscle tension. (Jacobson, 1938) The technique involves first tensing and then releasing different muscle groups of the body, with attention being directed toward the differences perceived during tension and relaxation. PMR is considered as an adjunctive therapy for depression and can provide patients with self-maintenance coping skills to reduce depressive symptoms. (Jorm et al., 2008)

2.8. Data analysis

The primary objective was to test differences between groups (active control: TAU + PMR; experimental: TAU + MAM) in total scores of MADRS after inpatient treatment, after 3 months, and after 6 months (time x group interaction). For sample size calculation to detect this interaction parameter, there were no sufficient previous studies we could refer to. Although potentially too limited to be fully reliable, we estimated expected mean values in MADRS scores by taking into account three longitudinal studies on the course of depression over 6 months during psychopharmacological treatment. (Allard et al., 2004, Montgomery et al., 1993, Trick et al., 2004) We calculated the sample size using GLIMMIX, (Wang et al., 2013) resulting in total sample size of $N = 108$, e.g., $n = 54$ within each group with the following assumptions: a α -level of $\alpha = .05$, a power of $(1-\beta) = .80$ and a correlation among

repeated measures of $r = .5$. The resulting estimated difference of means at 3-month and 6-month follow-up was higher or within the range of minimal clinically important difference (MCID) of MADRS, which has been reported to range from 1.6 to 1.9. (Duru & Fantino, 2008) We adjusted the sample size for a 20% attrition rate due to loss to follow-up or dropout. With these assumptions, we calculated a sample size of 130. We did not conduct interim analyses, but recruitment for the study ended in February 2020, due to shortage of care related to the COVID-19 pandemic, prior to reaching the predetermined recruitment goal (final $N = 123$ participants).

To summarize the baseline sociodemographic variables, we used means for quantitative variables and proportions for categorical variables. To check for balance between the study groups, we compared demographic data and other important baseline characteristics with independent-samples t tests for continuous variables and χ^2 tests for categorical variables.

In the primary analysis, we compared change in depression severity using MADRS and BDI-II scores at the posttreatment and follow-up assessments. First, we used a random-effects linear mixed model (LMM) to examine the overall intervention impact (i.e., overall effect of visits and study treatment group two-way interactions at all post-baseline visits) and then to separately evaluate changes in MADRS and BDI-II scores between treatment groups across four time points from admission to 6 months after discharge from hospital. The model included participants as a random effect, treatment and time as fixed within-subject factors, interaction between treatment and time, and a random intercept. As recommended for longitudinal analysis of RCTs, (Carli et al., 2020) we included baseline scores as covariates with fixed within-subject and

between-subject effects, respectively. We included time as a categorical covariate with baseline as a reference category. In an exploratory analysis, we grouped items of primary and secondary measures across both scales according to three factors presented in an exploratory factor analysis of MADRS, BDI-II, and HAM-D in the larger-scale GENDEP study (observed mood, cognitive, and neurovegetative). (Uher et al., 2008) We used independent-samples t tests to calculate and compare changes from baseline to 6-month follow-up.

All participants, irrespective of treatment compliance, were included in the analysis according to their allocated treatment group at randomization. We computed effect sizes as Cohen's d and an effect size parameter (Westfall et al., 2014) for the LMM. In statistical tests, we used a two-sided benchmark of p -values less than 0.05 as the general error rate for significance. We ran all analyses in R 3.6.

3. Results

3.1. Descriptive analysis

We detected no significant differences between the TAU + MAM and TAU + PMR groups at baseline for any demographic characteristics or clinical measures (Table 1).

The length of inpatient treatment was 39.5 days for the PMR group ($SD: 14.7$), and 40.0 days in the MAM group ($SD: 17.2$). Participants reported practicing an average of 14.85 min per day during the whole study period. The mean amount of practice did not differ between the groups ($\Delta M = 1.69$, 95% CI $(-0.45, 3.83)$, $t(247.30) = 1.56$, $p = 0.120$). Most patients opted for the weekly email reminders after

Table 1
Demographic and clinical characteristics of study participants by group.

Label	N		Levels	Groups		p^a
	Total	Missing		MAM	PMR	
Age	123	0	Mean (SD)	45.0 (14.0)	45.9 (12.5)	0.721 ^b
Gender	123	0	Female	43 (71.7)	40 (63.5)	0.438 ^b
			Male	17 (28.3)	23 (36.5)	
Marital status	121	2	Unmarried	18 (30.0)	20 (31.7)	0.939 ^c
			Divorced	10 (16.7)	8 (12.7)	
			Married	28 (46.7)	31 (49.2)	
			Widowed	3 (5.0)	3 (4.8)	
Current occupation	121	2	Self-employed	1 (1.7)	2 (3.2)	0.423 ^c
			Employed	31 (51.7)	43 (68.3)	
			Unemployed	12 (20.0)	8 (12.7)	
			Pension (disability)	10 (16.7)	6 (9.5)	
			Pension (old-age)	4 (6.7)	4 (6.3)	
Country of Origin	123	0	Germany	59 (98.3)	61 (96.8)	1.000 ^c
			Other	1 (1.7)	2 (3.2)	
			Catholic	0 (0.0)	2 (3.2)	
Denomination	122	1	Protestant	7 (11.7)	10 (15.9)	0.457 ^c
			None	49 (81.7)	49 (77.8)	
			Other	3 (5.0)	2 (3.2)	
			Mean (SD)	5.8 (8.7)	3.5 (6.3)	
Cigarettes per day	78	45	Mean (SD)	1.3 (3.5)	1.7 (3.0)	0.166 ^b
Alcoholic drinks per week	72	51	Mean (SD)	28 (46.7)	32 (50.8)	0.564 ^b
Depression type	123	0	First Episode	28 (46.7)	32 (50.8)	0.782 ^c
			Recurrent episodes	32 (53.3)	31 (49.2)	
ICD-10 F diagnoses	123	0	1	37 (61.7)	43 (68.3)	0.517 ^c
			2	18 (30.0)	13 (20.6)	
			3	5 (8.3)	6 (9.5)	
			4	0 (0.0)	1 (1.6)	
ACE	106	17	< 4	32 (61.5)	42 (77.8)	0.108 ^c
			≥ 4	20 (38.5)	12 (22.2)	
Inpatient treatment (days)	123	0	Mean (SD)	40.0 (17.2)	39.5 (14.7)	0.847 ^b
Max. care after discharge	94	29	Pharmacotherapy	8 (13.3)	6 (9.5)	0.413 ^c
			Psychotherapy	4 (6.7)	4 (6.3)	
			Integrated outpatient care	10 (16.7)	11 (17.5)	
			Day clinic	19 (31.7)	29 (46.0)	
			Inpatient treatment	0 (0.0)	3 (4.8)	

Note. ACE: Adverse Childhood Events; ICD: International Classification of Disease; MAM: Mantra group; PMR: Progressive Muscle Relaxation group.

^a P -value of the comparison between the two groups.

^b independent-samples t -test.

^c χ^2 for independence test.

discharge (115 of 123 participants, 93%) with no significant difference in group.

Attrition after randomization did not differ significantly between the treatment arms, although participants in the MAM group had numerically higher rates of attrition than those in the PMR group at discharge (8% vs. 3%; $\chi^2 = 0.71, p = .398$), at the 3-month follow-up (35% vs. 21%; $\chi^2 = 2.33, p = .114$), and at the 6-month follow-up assessment (42% vs. 27%; $\chi^2 = 2.33, p = .127$). (see Fig. 1)

There were no significant differences in baseline characteristics between study completers and dropouts within each group and between groups (Fig. 2).

3.2. Primary and secondary outcome measures

The baseline-adjusted analysis of the primary outcome revealed significant main effects for time ($F(3, 311.55) = 212.65, p < 0.001$) and group ($F(1, 129.18) = 10.02, p = 0.002$) and, more importantly, a significant interaction between time and group ($F(3, 311.61) = 4.75, p = 0.003$). This interaction was qualified by a mean decline in MADRS score from baseline to 6-month follow-up (baseline unadjusted) of 20.6 points in participants allocated to TAU + MAM treatment, as compared to 15.4 points in the TAU + PMR group. Baseline-adjusted treatment contrasts revealed no between-group difference in mean change from baseline to hospital discharge ($p = .126, 95\% \text{ CI: } -5.61 - 0.69$), but significant between-group differences at both follow-ups (3-month follow-up: $p = .006, 95\% \text{ CI: } -8.32 - -1.42$; 6-month follow-up: $p =$

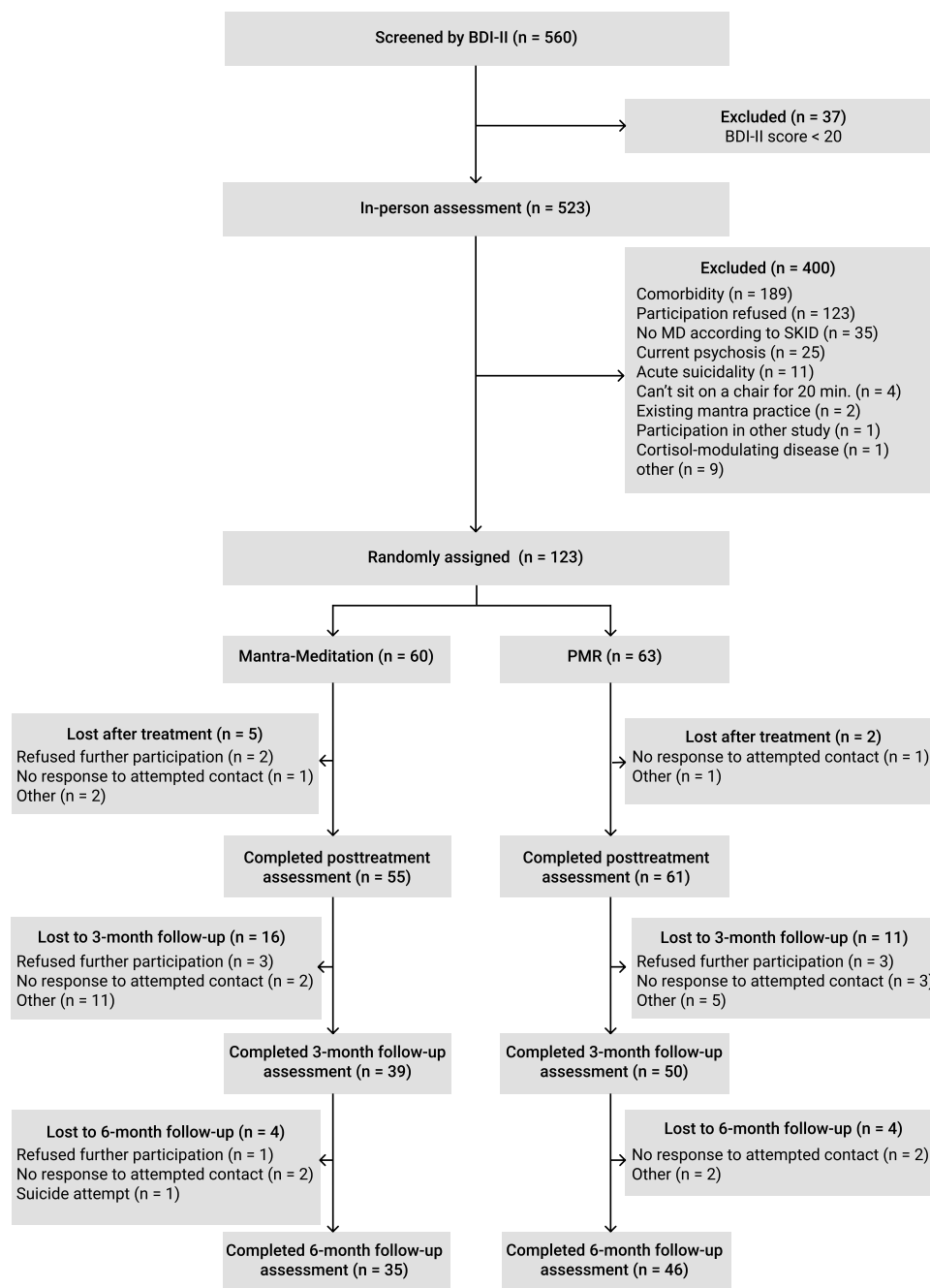


Fig. 1. Participant flow

Note. BDI-II: Beck Depression Inventory; SCID: research version of Structured Clinical Interview for DSM-IV.

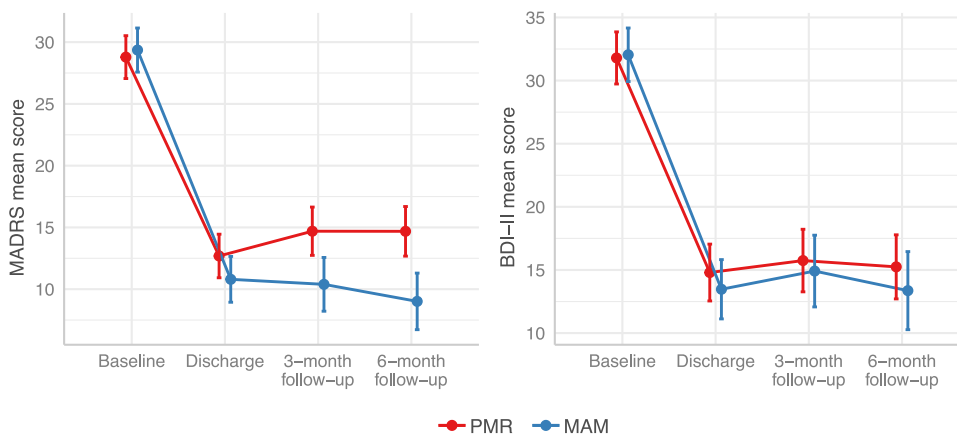


Fig. 2. Marginal effects of primary and secondary outcomes
 Note. Marginal effects of primary outcome (MADRS; left graph) and secondary outcome (BDI-II; right graph) grouped by type of intervention. Error bars represent 95% confidence intervals. BDI-II: Beck Depression Inventory; MADRS: Montgomery-Åsberg Depression Rating Scale score; MAM: Mantra Meditation; PMR: Progressive Muscle Relaxation.

.001, 95% CI: -9.80 - -2.69). The baseline-adjusted analysis of the secondary outcome led to significant main effects for time ($F(3,274.51) = 137.15, p < 0.001$), but not for group ($F(1, 125.55) = 0.80, p = 0.372$) nor for interaction between time and group ($F(3,274.53) = 0.33, p = 0.801$). The mean decline of the change in BDI-II scores from baseline to 6-month follow-up (baseline unadjusted) was 19.6 points in participants allocated to TAU + MAM treatment as compared to 16.6 points in the TAU + PMR group. Baseline-adjusted treatment contrasts revealed no significant between-group difference in changes from baseline to any later visit (hospital discharge: $p = .446, 95\% \text{ CI: } -5.62 - 2.47$; 3-month follow-up: $p = .636, 95\% \text{ CI: } -5.55 - 3.39$; 6-month follow-up: $p = .371, 95\% \text{ CI: } -6.80 - 2.54$). Still, the intervention impact showed in the same direction as for the primary outcome and was estimated to decrease to -2.1 at 6-month follow-up (Table 2 and Fig. 2).

3.3. Exploratory analysis

To further understand the differences between the primary and secondary outcomes, we evaluated pre-post differences (e.g., 6-month follow-up vs. baseline) of each item of both questionnaires (MADRS and BDI-II) by treatment group and with respect to the following factors: 1) observed mood, 2) cognitive, and 3) neurovegetative (Fig. 3). Compared to participants practicing PMR, mantra meditators showed more improvements in observed mood items than in cognitive items ($\Delta M = 0.09, 95\% \text{ CI } (0.04, 0.13), t(12.78) = 3.96, p = 0.002$) and, tended to show more improvements in neurovegetative items ($\Delta M = 0.08, 95\% \text{ CI } (-0.01, 0.16), t(7.53) = 1.98, p = 0.086$). Improvements between cognitive and neurovegetative items did not differ significantly ($\Delta M = 0.01, 95\% \text{ CI } (-0.08, 0.10), t(6.45) = 0.27, p = 0.795$).

Table 2
 Primary and Secondary Outcomes.

Outcome	Time	PMR Mean (SD)	MAM	d _c	Baseline-adjusted models Impact	95% CI	p	d
MADRS	Baseline	28.4 (6.2)	30.2 (5.2)					
	Discharge	12.2 (8.5)	11.4 (7.3)	.11	-2.46	-5.61 - 0.69	.126	.35
	3-month	13.5 (10.1)	10.7 (7.4)	.32	-4.87	-8.32 - -1.42	.006	.62
	6-month	14.0 (11.5)	9.6 (7.8)	.45	-6.24	-9.80 - -2.69	.001	.79
	Overall			.28			.003	.59
BDI-II	Baseline	31.7 (8.9)	32.9 (8.0)					
	Discharge	14.9 (11.7)	13.8 (10.0)	.10	-1.57	-5.62 - 2.47	.446	.19
	3-month	15.3 (12.4)	14.5 (11.2)	.07	-1.08	-5.55 - 3.39	.636	.13
	6-month	15.1 (12.0)	13.3 (12.3)	.15	-2.13	-6.80 - 2.54	.371	.26
	Overall			.10			.801	

Note. BDI-II: Beck Depression Inventory; MADRS: Montgomery-Åsberg Depression Rating Scale score; MAM: Mantra Meditation; PMR: Progressive Muscle Relaxation. Overall: time by group interaction; SD: Standard Deviation; d_c: Cohen's d; Impact: model estimate; CI: Confidence Interval; d: effect size parameter.⁶³

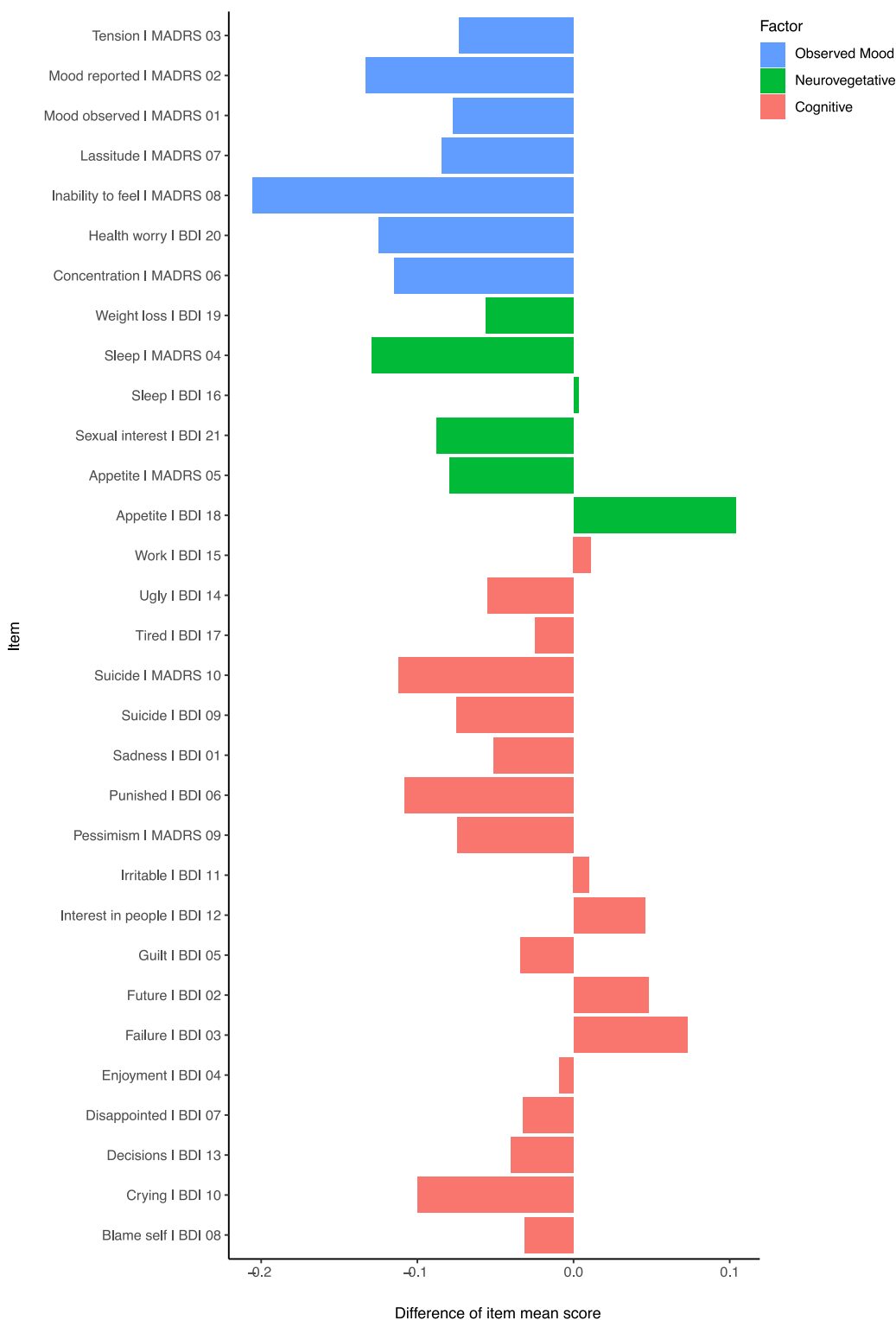


Fig. 3. Difference in pre-post change (6-month follow-up vs. baseline) between treatment groups

Note. Horizontal bar plots show the difference in pre-post change (6-month follow-up vs. baseline) between treatment groups. Negative values favor the TAU + MAM group, positive values favor the TAU + PMR group. E.g., a value of -0.1 means, that mantra meditators performed 10% better on this single item compared to the control group. Items were sorted cross-questionnaire by factors demarking cognitive, mood, and neurovegetative domains. For purposes of comparison, item-mean scores of both questionnaires were normalized by calculating the proportion of points endorsed to points available in each item.

BDI-II: Beck Depression Inventory; MADRS: Montgomery-Åsberg Depression Rating Scale score; MAM: Mantra Meditation; PMR: Progressive Muscle Relaxation; TAU: usual treatment for depressive inpatients.

additional effects of meditation. Follow-up data revealed that the effect of mantra meditation is more stable (or even grows) in the longer term, which is in line with previous findings, that effects of meditation increase with periods of intervention exceeding 6 weeks. (Sedlmeier et al., 2018) Since both groups received the same support for continued practice and the amount of practice did not differ significantly between groups, these effects can be attributed to mantra meditation itself. Effects were clinically important: assuming a conservative MCID of 1.9 for the MADRS, (Duru & Fantino, 2008) improvements in primary outcome

measure are higher than those estimated by the baseline-adjusted model by factors of 1.29 (discharge), 2.56 (3-month follow-up), and 3.28 (6-month follow-up). For the secondary outcome measure, mantra meditation did show numerical improvements compared to the control group, but these remained lower than the statistically significant and clinically important effects reported for BDI-II, (Button et al., 2015) except for the last follow-up (factors of 0.87 at discharge, 0.56 at 3-month follow-up, and 1.13 at 6-month follow-up). Our exploratory analysis revealed that mantra meditation during a study period of 6

months had higher impact on observed mood than on cognitive symptoms. This adds to the literature showing higher effects of concentrative meditation (versus mindfulness meditation) on negative emotions, anxiety, and neuroticism. (Sedlmeier et al., 2012, Sedlmeier et al., 2018) It also supports the understanding of meditation as disengagement of analytic or cognitive processes of the mind, which are often dysfunctional in depressive patients. In this interpretation, disengagement of dysfunctional cognitive patterns leads to better mood as an early effect of meditation, while the long-term goal of meditation would be to completely disidentify with these patterns. (Bryant, 2009) The analysis also demonstrated a tendency to lower effects of mantra meditation on neurovegetative symptoms than on observed mood. Although meditation can be understood as a neurophysiological bottom-up process regulating stress responses, (Gard et al., 2014) this intervention did not include important factors like breathing control and physical postures. Usually, only in long-term practitioners reach deep states of relaxation and absorption, underlining the visibility of early effects of mantra meditation in this study.

In our study design, we addressed frequent methodological issues in mind-body medicine research, including the absence of randomization or an active control group. Strengths of our study included clinician-blinded ratings of depression (the MADRS) and the complementary use of patient-reported BDI-II, clinically and theoretically important exploratory analyses, sequential screening of all admissions to hospital to avoid selection bias, stratification of our randomization by relevant patient characteristics, the inclusion of baseline depression in the linear mixed models, collection of data concerning interrater reliability and frequency of meditation/relaxation practice, and treatments of equal intensity using standardized guidelines. As a side note, the TAU + PMR group was likely to receive even more guided PMR sessions after discharge, if participants were treated in day clinics or other forms of integrated care. Mantra meditation, however, is usually not available in these settings, leading to a potential disadvantage for the TAU + MAM group.

Limitations of this study include a smaller sample size and higher dropout rates than anticipated, a lack of session fidelity assessments, and the use of patient reports to investigate practice frequency over time. Since we did not implement a waiting-list control condition, it is theoretically possible that in this study, the control treatment might have been unintentionally delivered in a less effective way than reported in former studies. (Jorm et al., 2008) This is, however, unlikely, as PMR has been a standardized and well-established therapy for many years at the trial site and was provided by experienced facilitators. Attrition after randomization did not differ significantly between the treatment arms, although participants in the meditation group had numerically higher rates of attrition than those in the control group. However, there were no significant baseline differences among study completers and dropouts in each group and between groups. Also, the linear mixed models used all available data on study completers and dropouts alike to avoid biased results toward the mantra meditation group. Finally, as both interventions were delivered openly to the patients, results may have been biased by patient's expectations.

5. Conclusions

For inpatients with major depression, adjunctive mantra meditation was found to greater and clinically relevant reduction in depressive symptom severity than progressive muscle relaxation. Mantra meditation mainly led to improvements in mood, followed by improvements in neurovegetative and then cognitive symptoms of depression. These promising results, the untapped potential of traditional aspects of mantra meditation, and the current scarcity of methodologically sound trials make further exploration of mantra-based meditation undoubtedly desirable.

CRedit authorship contribution statement

Holger C. Bringmann: Conceptualization, Data curation, Writing – original draft, Investigation, Formal analysis, Funding acquisition. **Aline Sulz:** Data curation, Writing – review & editing. **Philipp Ritter:** Supervision, Writing – review & editing. **Stefan Brunnhuber:** Supervision. **Michael Bauer:** Supervision. **René Mayer-Pelinski:** Formal analysis, Supervision, Writing – review & editing.

Declaration of Competing Interests

The authors declare that there is no conflict of interest.

Acknowledgments

We would like to thank Chief Physician Oliver Somburg for his friendly support for our study at the trial site.

Funding

This project was funded by Karl and Veronica Carstens Foundation under Award Numbers KVC 0/091/2017.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jadr.2021.100232.

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2.2 Unterschiedliche Auswirkungen von ethischer Grundhaltung, körperlichem Hatha Yoga und Mantra-Meditation auf Wohlbefinden und Stress bei gesunden Teilnehmern - eine experimentelle Einzelfallstudie

Diese Studie wurde durchgeführt, um die Wirkung der drei MBLM-Domänen (lebensethische Prinzipien, gesunder Lebensstil, Mantra-Meditation) bei gesunden Probanden zu differenzieren und ihre additiven Aspekte zu untersuchen. Methodisch wurde eine experimentelle Einzelfallanalyse mit Multiple-Baseline-Design⁹⁸ durchgeführt. Die Randomisierung erfolgte in diesem Design zum einen über die Interventionsbedingungen (s.u.). Weiterhin erfolgte spezifisch für eine experimentelle Einzelfallanalyse mit Multiple-Baseline-Design eine Randomisierung über die Zeit. Dies wurde dadurch erreicht, dass die Teilnehmer:innen ihre Behandlung zu zufällig (standardisiert-randomisiert) gewählten Zeitpunkten begannen, was zu unterschiedlichen Baseline-Längen führt (Baseline = Phase in der noch keine Intervention stattfindet, aber Zielparameter gemessen werden). Multiple-Baseline-Designs haben eine große interne Validität, da sie Faktoren im Individuum kontrolliert, die sich über die Zeit verändern. Wenn bei der Auswertung ein starker Zusammenhang zwischen der Behandlung und einem bestimmten Effekt unabhängig davon besteht, wann die Behandlung beginnt, ist dies ein solides Argument für die kausale Wirksamkeit der Behandlung (Abbildung 4). Mehrere Forschungsgruppen haben angemerkt, dass individuelle Unterschiede die Effekte von komplexen Mind-Body-Interventionen maßgeblich beeinflussen könnten.^{82,99–101} Experimentelle Einzelfallanalysen bieten sich hier hervorragend an, um diesen Sachverhalt wissenschaftlich näher zu beleuchten, da die hohe zeitliche Auflösung der Messungen intraindividuelle Veränderungen im Verlauf besser abbilden kann als *pre-post designs*.⁹⁸

Übernommen aus der Zusammenfassung der Veröffentlichung:⁸⁹ „Traditionell ist Yoga eine aus mehreren Komponenten bestehende Praxis, die aus Körperhaltungen, Atemtechniken, Meditation, Mantras und Lebensethik besteht. Bislang haben nur wenige Studien versucht, die Wirkungen jeder dieser Komponenten und ihrer Kombinationen zu differenzieren. Um diese Forschungslücke zu schließen, untersuchten wir die inkrementellen Effekte von ethischer Schulung und körperlichem Hatha-Yoga auf Mantra-Meditation mit Hilfe eines Single-Case Multiple-Baseline-Designs. [...] Siebenundfünfzig gesunde Teilnehmer ohne regelmäßige Yoga- oder Meditationspraxis wurden nach dem Zufallsprinzip drei *Baselines* (7, 14 und 21 Tage) und vier Bedingungen zugewiesen [...]. Die Bedingungen waren Mantra-Meditation allein (MA), Meditation plus körperliches Yoga (MY), Meditation plus ethische Schulung (ME) und Meditation plus Yoga und ethische Schulung (MYE). Alle Interventionen dauerten 8 Wochen und wurden entsprechend der Ausgangsdauer nacheinander durchgeführt. Während der Baseline- und der Behandlungsphase erhielten die Teilnehmer täglich Fragebögen zur Messung ihres Wohlbefindens (WHO-5 Well-Being Index), ihres Stresses (Perceived Stress

Scale) und ihrer subjektiven Erfahrungen. Zweiundvierzig Teilnehmer schlossen die Behandlung ab und wurden in die Analysen einbezogen. Wir analysierten unsere Daten mittels visueller Inspektion, Schätzung der Effektgröße (Tau-U) und *multi-level modelling*. Nahezu alle Teilnehmer zeigten im Längsschnitt einen Anstieg des Wohlbefindens. Was die Unterschiede zwischen den Gruppen betrifft, so zeigten die Teilnehmer, die Ethikunterricht erhielten, den größten Anstieg des Wohlbefindens (Tau-U = 0,30/0,23 für ME/MYE), gefolgt von den Teilnehmern in der MY-Bedingung (Tau-U = 0,12). Umgekehrt zeigten die Teilnehmer in der MA-Bedingung keine Veränderung (Tau-U = 0,07). Es gab eine Tendenz, dass die kombinierten Behandlungen den Stress verringerten. Diese Tendenz war am stärksten in der MY-Bedingung (Tau-U = -0,40) und kehrte sich in der MA-Bedingung um (Tau-U = 0,17). Die Ergebnisse unterstreichen die inkrementellen und differentiellen Effekte der Meditationspraxis in Kombination mit anderen Praktiken des achtfachen Yogaweges. Dieser Forschungsansatz ist daher wertvoll für ein besseres Verständnis der vielseitigen Yogapraxis.“

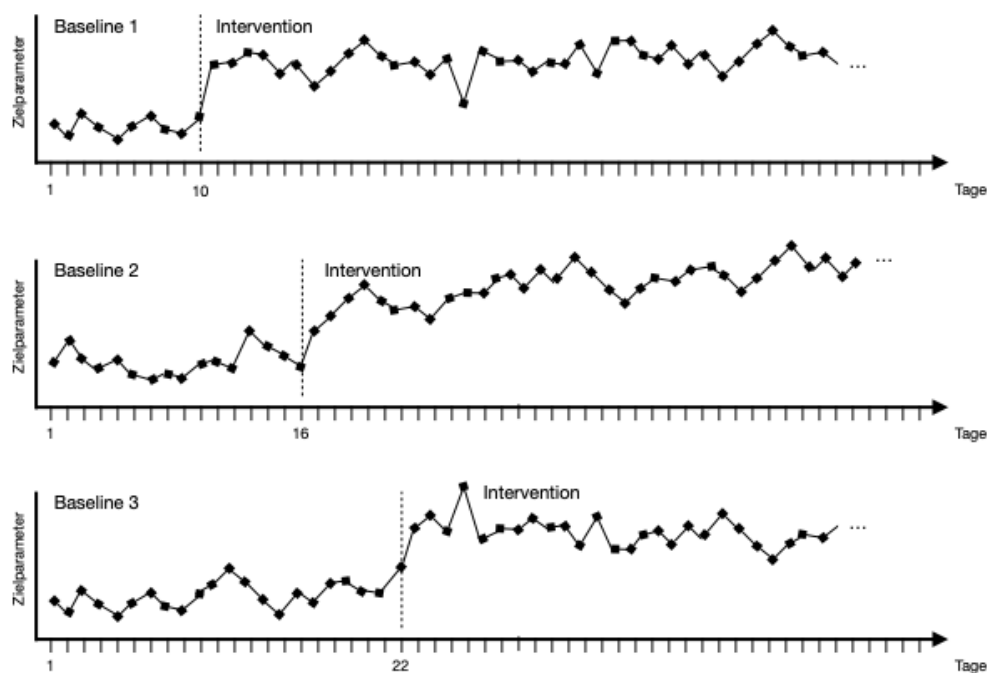


Abbildung 4. Grundprinzipien des Multiple-Baseline Designs. Alle Teilnehmer:innen werden in eine zeitliche Baseline randomisiert. Die Dauer der Baseline ist wie dargestellt unterschiedlich (in diesem Beispiel 10,16 und 22 Tage), während die Dauer der nachgeschalteten Intervention gleichbleibt. Während der Studie werden relevante Zielparameter in einer hohen zeitlichen Auflösung (z.B. täglich) gemessen. Für die statistische Auswertung können robuste, sich ergänzende Methoden eingesetzt werden, um die Effektstärke der Intervention zu bestimmen. Dazu werden die Messpunkte während der Intervention in Relation zu den Messpunkten während der Baseline gesetzt. Jede*r Teilnehmer*in ist dabei seine/ihre eigene Kontrollgruppe (Quelle: vom Autor).



Differential Effects of Ethical Education, Physical Hatha Yoga, and Mantra Meditation on Well-Being and Stress in Healthy Participants—An Experimental Single-Case Study

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Edited by:

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Specialty section:

This article was submitted to
Health Psychology,
a section of the journal
Frontiers in Psychology

Received: 25 February 2021

Accepted: 28 June 2021

Published: 05 August 2021

Citation:

Matko K, Sedlmeier P and
Bringmann HC (2021) Differential
Effects of Ethical Education, Physical
Hatha Yoga, and Mantra Meditation
on Well-Being and Stress in Healthy
Participants—An Experimental
Single-Case Study.
Front. Psychol. 12:672301.
doi: 10.3389/fpsyg.2021.672301

Traditionally, yoga is a multicomponent practice consisting of postures, breathing techniques, meditation, mantras, and ethics. To date, only a few studies have tried to dismantle the effects of each of these components and their combinations. To fill this gap, we examined the incremental effects of ethical education and physical Hatha yoga on mantra meditation using a single-case multiple-baseline design. This study was part of a project evaluating the new mind–body program *Meditation-Based Lifestyle Modification*. Fifty-seven healthy participants with no regular yoga or meditation practice were randomly assigned to three baselines (7, 14, and 21 days) and four conditions using a random number generator. The conditions were mantra meditation alone (MA), meditation plus physical yoga (MY), meditation plus ethical education (ME), and meditation plus yoga and ethical education (MYE). All the interventions lasted for 8 weeks and were run consecutively according to baseline length. During the baseline and treatment phases, participants received daily questionnaires measuring their well-being (WHO-5 Well-Being Index), stress (Perceived Stress Scale), and subjective experiences. Forty-two participants completed the treatment and were entered in the analyses. We analyzed our data using visual inspection, effect size estimation (Tau-U), and multilevel modeling. Almost all participants showed a longitudinal increase in well-being. Regarding between-group differences, participants who received ethical education exhibited the largest increases in well-being (Tau-U = 0.30/0.23 for ME/MYE), followed by participants in the MY condition (Tau-U = 0.12). Conversely, participants in the MA condition showed no change (Tau-U = 0.07). There was a tendency for the combined treatments to decrease stress. This tendency was strongest in the MY condition (Tau-U = -0.40) and reversed in the MA condition (Tau-U = 0.17). These results emphasize the incremental and differential effects of practicing meditation in combination with other practices from the eight-fold yoga path. This approach is valuable for better understanding the multifaceted practice of yoga.

Clinical Trial Registration: www.ClinicalTrials.gov, identifier: NCT04252976.

Keywords: yoga components, mantra meditation, ethical education, differential effects, incremental effects, single-case research, multilevel modeling, mixed-method

INTRODUCTION

Yoga originates from a rich and ancient spiritual tradition that encompasses a variety of diverse practices, such as physical postures, breathing techniques, meditation techniques, mantras, and ethical teachings (Feuerstein, 2012; Telles and Singh, 2013). These practices are designed to promote personal and spiritual growth with the ultimate aim of gaining access to pure consciousness and reaching “enlightenment” (Sedlmeier and Srinivas, 2019). A growing number of studies are acknowledging the positive effects of yoga on alleviating psychological disorders and stress-related diseases (Cramer et al., 2013; Pascoe et al., 2017; Breedvelt et al., 2019) as well as promoting mental and physical health (Büssing et al., 2012; Gothe and McAuley, 2015; Hendriks et al., 2017). However, high heterogeneity among yoga practices and poor methodological quality have limited the generalizability of these findings. Apart from this, previous yoga research has exhibited two major shortcomings. First, yoga incorporates diverse components, which have only insufficiently been investigated and differentiated in the past (Gard et al., 2014; Schmalzl et al., 2015). We know neither how each single component of yoga works nor what impact specific combinations of these components have. Second, the ethical component of yoga has frequently been neglected in the past. In a bibliometric analysis, only 10% of yoga studies explicitly incorporated lectures on yoga philosophy or ethics (Cramer et al., 2014). Yet, traditional yoga experts have advocated that yoga should be practiced in its entirety, including its ethical aspects (Varambally and Gangadhar, 2016).

Traditional yoga dates back over 5,000 years and was originally understood in a much broader sense than is common in Western contemporary settings. Indeed, classical, or *raja* yoga, as outlined by Patanjali (author of the Yoga Sutras; Bryant, 2015), was primarily a system of meditation. Patanjali described the aim of yoga as the stilling of the fluctuations and changing states of the mind that cause suffering (“Yogah chitta vrtti nirodhah,” Yoga Sutras, Chapter 1, Verse 2; Patanjali between 600 BC and 200 AC; Bryant, 2015). The aspiring practitioner could reach this still state through the practice of the eight limbs of yoga, also referred to as the eight-fold yoga path (*ashtanga* yoga). This path comprises the following practices: *yamas* (universal ethics), *niyamas* (individual ethics), *asana* (physical posture), *pranayama* (breath control), *pratyahara* (withdrawal of the senses), *dharana* (concentration), *dhyana* (meditation), and *samadhi* (full meditative absorption; Feuerstein, 2012; Bryant, 2015).

Recent theoretical proposals have taken into account this multitude of yoga practices (Gard et al., 2014; Schmalzl et al., 2015; Sullivan et al., 2017). All of these proposals strongly encourage the empirical investigation of the specific components of yoga and suggest conducting longitudinal, comparative, or dismantling studies. Yet, the multitude of possible “active ingredients” in yoga makes the investigation of its components challenging. Modern styles of yoga have diverted considerably from the “classic” eight-fold yoga path and often reduced its inherent multifariousness. Many styles focus primarily on postures and breathing practices, for example, Ashtanga, Iyengar, or Hatha Yoga in general. There are also yoga styles that comprise

mainly breathing practices (e.g., Surdashaan Kriya), or meditation (e.g., Sahaja Yoga). Some place particular attention to include mantras, chanting and music (e.g., Kundalini Yoga). For an overview on different yoga styles, see McCrary (2013). Just as multifaceted as yoga styles are scientifically investigated yoga interventions. Cramer et al. (2016) reviewed studies investigating 52 different yoga styles and concluded that the proportion of positive outcomes did not vary across styles. However, this analysis did not dismantle the different components of yoga styles.

A recent review summarized comparative studies and meta-analyses of the effects of yoga components (Matko et al., 2021a). The authors concluded that although most of the treatments compared were equal in length, outcomes were better for those that combined several elements of yoga practice. Frequently, combining yoga postures with breathing practices, meditation, or ethical education enhanced the effectiveness of the intervention. This finding was also reported in several meta-analyses (e.g., Gong et al., 2015; Wu et al., 2019). But these studies were very heterogeneous and many findings were inconclusive. Even if combined interventions were mostly more effective, it is not known which specific benefit could be attributed to which component of these interventions.

Often, studies compared rather complex interventions with each other without isolating specific parts of the interventions. For example, Quach et al. (2016) compared a physical yoga program to a mindfulness meditation program, but both programs included breathing exercises and group discussions. Granath et al. (2006) contrasted a physical yoga intervention with a cognitive behavioral therapy program; however, both interventions included psychoeducation and relaxation. Gorvine et al. (2019) compared physical yoga to a meditation program composed of different meditation techniques. Yet, as we know, different meditation techniques produce different effects (Fox et al., 2016; Kropp and Sedlmeier, 2019). Employing such study designs definitely yields interesting insights but makes it hard to uncover how each specific component of these complex programs works. In addition, we found only one study that explicitly examined the effects of adding an ethical education component to a complex yoga intervention (Smith et al., 2011).

Thus, it seems advisable for yoga research to evaluate yoga in its entirety and investigate the specific mechanisms and benefits of each yoga component. There have been repeated calls in this regard to fully understand the underlying mechanisms of yoga (Sherman, 2012; McCall, 2013; Riley and Park, 2015). The investigation of yoga components would facilitate the development of more targeted and efficient programs tailored to the specific needs of respective clinical or healthy populations (Gard et al., 2012; Schmalzl et al., 2015). To date, there have been only a few investigations into this matter. One particularly under researched area of interest is the incorporation of yoga ethics into intervention studies. Furthermore, it remains unclear whether there are specific combinations of yoga practices that yield better effects than others do. Hence, the present study was aimed at bridging this gap. Employing a single-case multiple-baseline design, we compared the relative benefits of adding

ethical education and/or physical postures to a simple mantra meditation intervention.

Almost all meta-analyses and theoretical proposals on yoga criticize the lack of methodological accuracy in previous yoga studies. Longitudinal and dismantling studies have been proposed as an effective means to (1) study mechanisms of mind-body practices/yoga, and (2) provide optimal control groups (Kinsler and Robins, 2013). In addition, conventional research designs reach their limits in yoga and meditation research as there is no overarching theory that would guide systematic investigations, group comparisons cannot capture specific changes over time or individual differences properly, and purely quantitative approaches are limited with regard to participants' individual perceptions of change (Schmalzl et al., 2015; Sedlmeier et al., 2016; Lundh, 2020). Consequently, employing mixed-methods or repeated-measures designs might be more helpful in this respect. Recently, there has been a rise in elaborate studies using daily assessments before, during, and/or after an intervention in experience sampling or single-case research designs (May et al., 2014; Shoham et al., 2017; Lindsay et al., 2018; Singh et al., 2019; Bai et al., 2020). The present study is in line with these research efforts.

In experimental single-case research designs (Barlow et al., 2009) dependent variables are measured very frequently over extended periods of time. Accordingly, they allow for a more detailed examination of individual responses and processes of change and are, thus, more suitable for explorative research questions such as ours. Several authors have suggested that individual differences might tremendously influence the effects of meditation and yoga (Hölzel et al., 2011; Gard et al., 2014; Lippelt et al., 2014). Furthermore, participants are often treated as collaborators rather than "subjects" enabling a closer cooperation and quantitative as well as qualitative insights facilitating a mixed-methods approach. Hence, single-case research does not necessarily require participant blinding. Multiple-baseline designs consist of an A phase (baseline) and a B phase (treatment), but the length of the A phase is varied across different participants creating a staggered introduction of the intervention and making possible horizontal and vertical comparisons (Ferron et al., 2014). In this design, randomization happens over time instead over people producing strong internal validity. If there is a strong contingency between the treatment and a certain effect, irrespective of when the treatment starts, this will be a solid argument for the causal role and effectiveness of the treatment.

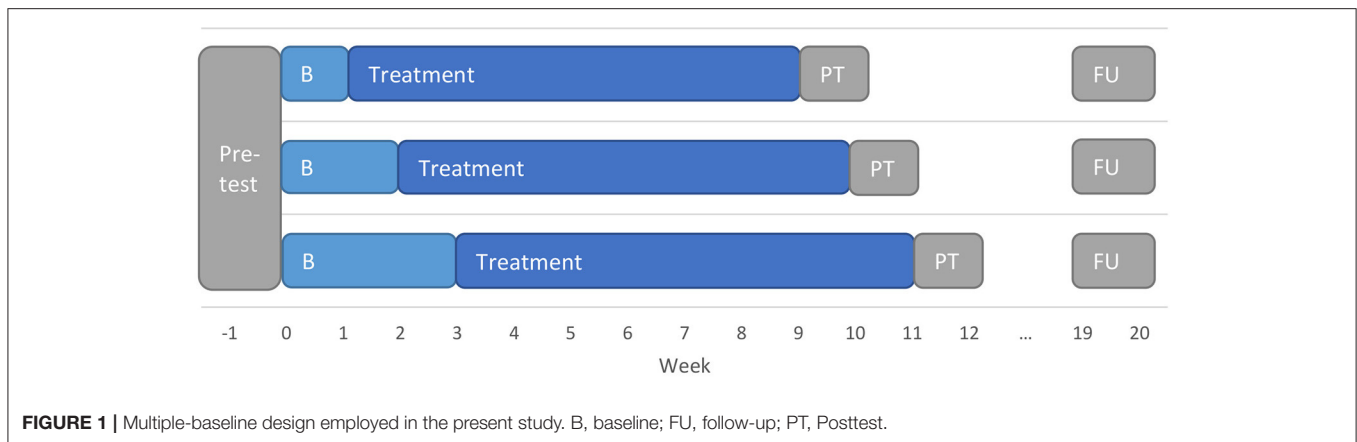
This study was part of a project evaluating a new mind-body program called Meditation-Based Lifestyle Modification (MBLM; Bringmann et al., 2020). This holistic program encourages and empowers participants to adopt a beneficial lifestyle in order to experience sustained eudaemonic well-being, mental health, and human flourishing. Meditation-Based Lifestyle Modification is based on the eight-fold yoga path and covers three main domains that correspond, in short, to (1) yoga's ethical education, (2) postures and breathing practices, and (3) meditation. We describe them in more detail in the Method section. The type of meditation taught is mantra meditation. Previous reviews and meta-analyses substantiated the positive

effects of mantra meditation (Sedlmeier et al., 2012; Lynch et al., 2018). However, they also criticized the poor methodological quality of most studies on mantra meditation and recommended conducting higher quality research into this topic.

We employed MBLM as a test bed for our research. We dismantled the MBLM program and investigated different combinations of its components. At the same time, we evaluated MBLM's efficacy in a healthy population. Although it has been designed as a mind-body therapy for patients with mental disorders, it might be beneficial for preventive purposes, too. Comparable preventive effects have been observed for Mindfulness-Based Stress Reduction (MBSR), which was originally developed for patients suffering from chronic pain (Kabat-Zinn, 1982). Meanwhile, it has become a widespread and widely researched intervention for all kinds of conditions (Grossman et al., 2004). Moreover, yoga was initially designed as a spiritual path for healthy individuals (Feuerstein, 2012). Therefore, we would expect positive outcomes for an intervention that incorporates as many yoga components as MBLM.

Both yoga theory and research literature suggest that combined interventions should be more effective than simple interventions. Yet, research findings were inconclusive on determining what specific combinations were best for what purpose (Matko et al., 2021a). Consequently, we chose an additive design and designed four conditions (see below). From theory, we would expect a small effect for the meditation alone condition, a larger effect for the two conditions including meditation and another component, and the largest effect for the full MBLM program. Conversely, it might be equally reasonable to expect a specific combination of components to be more effective than the full program. The investigation of the ethical component in this study is of particular relevance, as it might have an even bigger impact on participants than physical yoga (Smith et al., 2011). To our knowledge, no other study has contrasted all of these combinations in a comparative study. Moreover, no other study has employed a multiple-baseline design for this purpose. As this field of investigation is relatively new, we combined quantitative and qualitative methods to explore inter-individual differences and differences between conditions.

The present study is part of a larger project in which we measured a wide range of dependent variables commonly associated with the effects of yoga and meditation. Selection of variables was based on theoretical considerations and suggestions found in existing literature (Hölzel et al., 2011; Gard et al., 2014). For this paper, we decided to focus on the most commonly investigated outcomes in the yoga literature: well-being, stress, and life satisfaction. Findings on these variables were not always unequivocal, especially for stress and life satisfaction. Following our considerations above, we would expect favorable effects on all outcome variables, but specifically for the combined conditions. Nevertheless, the present study is exploratory in nature. Thus, we refrained from formulating predefined hypotheses and focused on two central research questions instead. First, what are the incremental effects of ethical education and physical yoga on mantra meditation? Second, what



combinations of components are particularly effective? Is more or is less more?

METHODS

Procedure

This study employed a multiple-baseline design with a priori determined phase lengths. During baseline, participants engaged in their usual daily activities and received no treatment. We randomized participants across three baseline lengths (7, 14, or 21 days) and four treatment conditions. The conditions were mantra meditation alone (MA), mantra meditation plus physical yoga (MY), mantra meditation plus ethical education (ME), and mantra meditation plus physical yoga and ethical education (MYE). Each treatment lasted 8 weeks and participants started according to their baseline condition. The overall study duration varied across participants, ranging from 9 to 11 weeks. Treatments were run on Thursdays (MYE 9:00 to 12:00 a.m.; MA 1:00 to 2:00 p.m.) and Fridays (ME 9:00 to 11:15 a.m.; MY 12:15 a.m. to 2:00 p.m.).

All measurements were taken online. Participants completed an extensive battery of questionnaires (see **Supplementary Material A—Table A1**) during pretest in the week before the baseline measurements commenced. All participants started their baseline measurements on the same day and received daily online questionnaires throughout their entire baseline and treatment phases. After the treatment had ended, participants completed another battery of questionnaires during posttest. Follow-up measures were taken 8 weeks and 12 months after posttest. **Figure 1** depicts the study design.

Participants

We recruited participants via the central experiment server and the university sport mailing list of the Dresden University of Technology and through flyers and handbills distributed in Dresden. All those interested had to complete a short online screening survey. Two hundred thirty-six people completed the screening survey, of whom 128 did not meet our inclusion/exclusion criteria and 51 declined to participate. Participants had to be older than 18 years and had to ensure they

had daily access to web-enabled devices. Exclusion criteria were pre-existing psychiatric conditions, acute psychological issues, or a regular yoga or meditation practice during the last 6 months. Those meeting our criteria were invited to an information event, which was led by KM and HCB. During this event, we fully disclosed the nature of the study to participants, but emphasized that this study was exploratory and we did not know what effects the different conditions might have. Participation was voluntarily and all participants provided written consent to participate in the study. They received no financial or other compensation for their participation in the study, but they had the opportunity to win one of ten €50 gift coupons at the completion of the study. The institutional review board of the Chemnitz University of Technology approved the experimental protocol.

Fifty-seven meditation-naïve participants were randomized to one of 12 subgroups employing simple random sampling without replacement in Excel. Prior to randomization, each subgroup received a number and participants were allowed to indicate a preferred day (Thursday/Friday) without knowing which treatment took place on which day. We used these indications to split the sample into two equal blocks (Thursday/Friday), tossing a coin if participants had not indicated a preferred day. Then, we generated random numbers for each participant within each block and assigned them to one subgroup in ascending order. Their treatment condition was revealed to them directly after randomization, but were not allowed to switch to another group. Seven participants dropped out during the baseline phase before the intervention started and provided no reason for dropping out (see **Figure 2**). Eight participants dropped out during the intervention, mostly because of time issues. Although there was some attrition toward the end of the data collection period (see below), but not during posttest or follow-up, we decided to include all remaining participants in our analysis. Single-case research designs allow for a much closer examination of each case and the statistical methods we employed for data analysis are relatively robust against missing data. The final sample consisted of 42 participants (83.3% female, mean age 26.62 years, $SD = 8.37$). Sociodemographic data differed slightly across conditions (see **Table 1**) and was, therefore, statistically controlled in our statistical analyses.

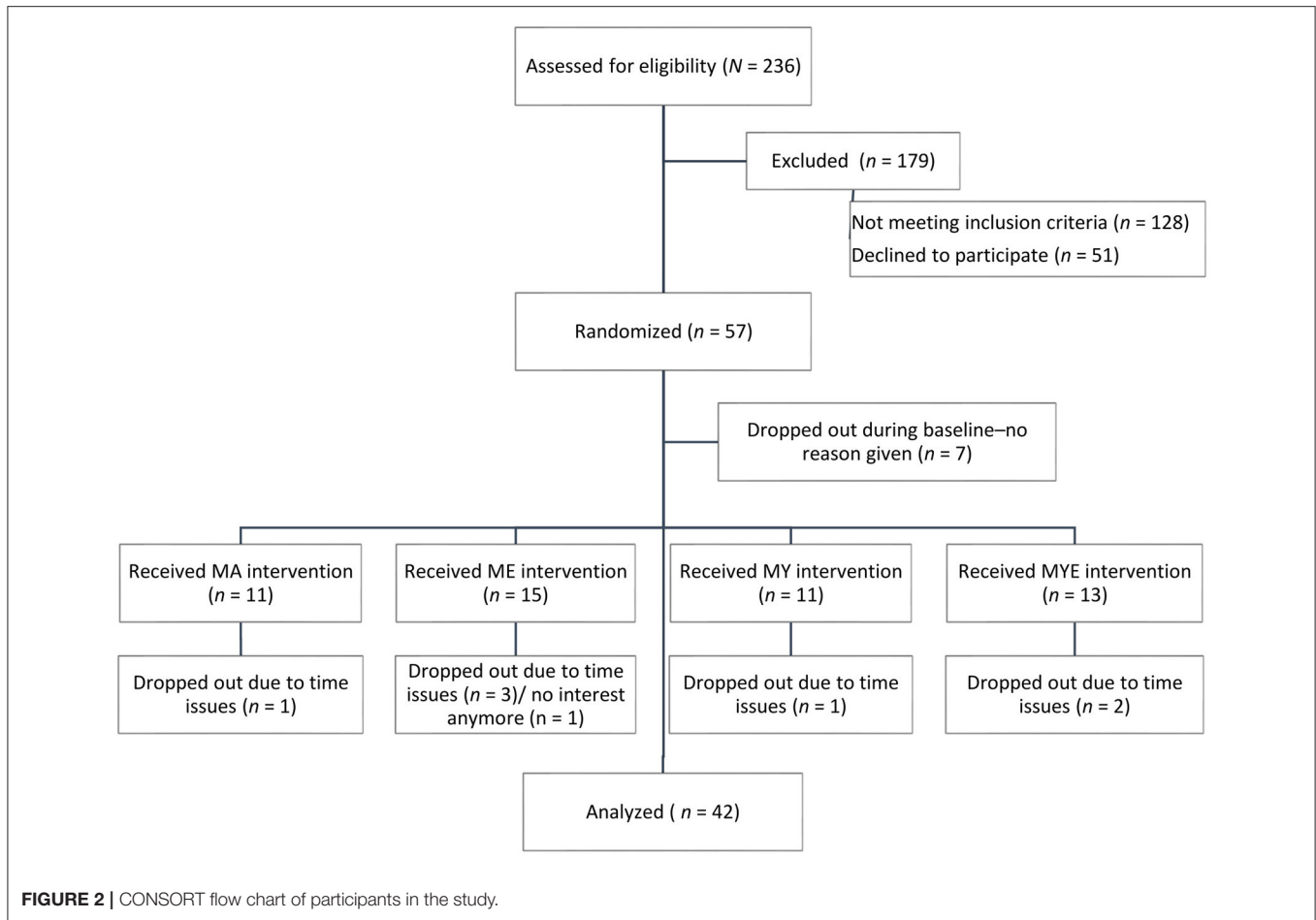


FIGURE 2 | CONSORT flow chart of participants in the study.

TABLE 1 | Sociodemographic data of participants in each condition.

Variable	Condition				Total
	MA	ME	MY	MYE	
<i>n</i>	10	11	10	11	42
Gender (% female)	90.0	72.7	90.0	81.8	83.3
Age (years)					
<i>M</i> (<i>SD</i>)	29.00 (10.40)	25.09 (5.74)	27.60 (12.32)	25.09 (2.95)	26.62 (8.37)
Range	22–57	19–36	18–61	19–30	18–61
Occupation					
% students	80.0	72.7	90.0	100.0	85.7
% employed	20.0	27.3	10.0	0.0	14.3

MA, Mantra meditation; ME, meditation and ethical education; MY, meditation and physical yoga; MYE, meditation, physical yoga, and ethical education.

Treatment: MBLM and Its Components

Weekly training sessions were dedicated to practicing together and discussing emergent questions or difficulties. All treatments were jointly led by KM and HCB, who are both experienced meditation teachers. HCB is an accredited psychiatrist and psychotherapist. KM is a psychologist and certified yoga instructor with 700h of teacher training and 6 years of teaching experience. All treatments took

place in the same seminar room that we rented for the study.

The length of the weekly sessions varied across conditions as each component had different time requirements: 25 min for meditation, 50 min for physical yoga, 75 min for ethical education, and at least 20 min for group sharing, plus time for breaks as required. The overall duration for each condition was as follows: MA = 60 min, MY = 105 min,

TABLE 2 | Set of physical yoga and breathing exercises taught in the physical yoga component including their sanskrit names, short descriptions, and proposed health benefits.

Yoga exercise	Sanskrit name	Description and health benefits
Breathing techniques (<i>pranayama</i>)		
Deep yogic breathing	Dirgha Pranayama	Deeply inhaling and exhaling into abdomen, chest and clavicular region, learning to use full breathing capacity
Victorious breath	Ujjayi Pranayama	“Ocean breath”: Slightly contracting the throat while breathing, learning to inhale and exhale more slowly, more fully, and with more control
Dynamic breathing	Unknown	Standing and taking deep breaths while simultaneously moving the arms and the body in the rhythm of breathing, learning to match movement and breathing, activating effect
Postures (<i>asana</i>) and dynamic exercises (<i>vinyasa</i>)		
Sun salutation	Surya Namaskar	Set of 12 postures practiced subsequently in the rhythm of breathing; engages and warms up the whole body
Mountain pose	Tadasana	Gain sense of stable and good posture
Tree pose	Vrksasana	Improves balance
Eagle pose	Garudasana	Preparatory exercise: rolling shoulders; stretches area between the shoulders, strengthens legs, improves balance
Warrior pose II	Virabhadrasana II	Strengthens and stretches ankles, calves, and thighs, opens hips
Triangle pose	Trikonasana	Stretches and strengthens sides of the body
Wide-legged forward bend with clasp pose	Prasarita Padottanasana C	Opens shoulders and chest, stretches legs and the spine
Knees-to-chest pose	Apanasana	Relaxes back and neck, improves digestion
Supine spinal twist pose	Supta Matsyendrasana	Stretches abdomen and lower back, relaxes shoulders and back
Legs up the wall pose	Viparita Karani	Mild inversion pose, restorative
Boat pose	Navasana	Strengthens abdominal muscles
Cobra pose	Bhujangasana	Strengthens upper back, improves digestion
Child’s pose	Balasana	Relaxes upper back, neck, and arms
Bound Angle Pose	Baddha Konasana	Opens hips
Half-spinal-twist pose	Ardha Matsyendrasana	Relaxes spine and neck, opens chest, tones waist
Deep relaxation in corpse pose	Savasana	Restorative, different relaxation techniques (autosuggestion, body scan)

ME = 135 min, MYE = 180 min. Each training session started with a discussion of participants’ experiences and practice at home since the previous session and ended with another group sharing. All three components are explained in more detail in **Supplementary Material A—Section A2**.

All four conditions involved learning to meditate using mantra meditation. The key practice in this form of mantra meditation is silently repeating the chosen mantra while letting all other thoughts pass by and letting the breath flow naturally. Each weekly session in every condition included a 25-min silent (i.e., non-guided) mantra meditation practice. During the physical yoga practice, each class started with approximately 10 min of breathing exercises, followed by 30 min of postures and dynamic exercises, and concluded with a 10-min guided relaxation (see **Table 2**; for more detailed information on yoga practices, see, e.g., Iyengar, 2009; Stephens, 2011).

Ethical education followed the protocol developed for the MBLM mind–body program (Bringmann et al., 2020). Each week, we introduced one of the 10 *yamas* and *niyamas*, with the last three *niyamas* being grouped together for time reasons into one topic called “transcendence.” After we introduced each topic, we invited participants to discuss its application and relevance for their daily lives and engage in related mindful

living activities (see **Table 3**) during the following week. In the next session, they shared and reflected upon their experiences. Participants received handouts for each treatment component including detailed information and instructions for practicing at home. We asked all participants to practice their respective treatment practices daily, that is, 20 min of mantra meditation, 20 min of yoga exercises, and/or mindful living activities.

Measures

Instruments for daily/weekly measures had to be suited to experimental single-case designs in that they had to be precise, relatively short, and sensitive to changes while not exhibiting floor or ceiling effects. We carried out extensive preparatory work and a pilot study (Quasten, 2019) to test and finalize our selection of instruments. All questionnaires were programmed and implemented with SoSci Survey (Leiner, 2019) and made available to participants on www.sosicisurvey.com. Data were collected between 21 March 2019 and 31 July 2019.

Well-Being

Participants’ daily well-being was measured with the very short and economical World Health Organization Well-Being Index (WHO-5; World Health Organization, 1998). The WHO-5 is a

psychometrically sound self-report measure with high internal consistency and high convergent validity (Brähler et al., 2007). It consists of five items that were rated on a 6-point Likert scale. High scores represent a high state of well-being. As we collected well-being daily in the present study, we adapted the time frame of this measure to “the last 24 h.”

Stress

The Perceived Stress Scale (Cohen and Williamson, 1988) is a widely used self-report measure that we employed weekly in the present study to measure stress. It intends to capture the degree to which people perceive situations in their life as excessively stressful relative to their ability to cope. Respondents rated each of the 10 items on a 5-point Likert scale of 1 (*never*) to 5 (*very often*). It has shown good internal consistency ($\alpha = 0.78$) and moderate convergent validity.

Life Satisfaction

The Satisfaction with Life Scale (SWLS; Diener et al., 1985) has been extensively used as a measure of the life satisfaction component of subjective well-being. We used it in the present study during pre- and post-testing. The SWLS is a very short self-report measure with five items that are rated on a 7-point Likert scale of 1 (*strongly disagree*) to 7 (*strongly agree*). Internal consistency of the scale is high ($\alpha = 0.92$).

Daily Practice

With the beginning of the treatment phase, we asked participants to track their home practice in the daily questionnaire. All participants had to supply information on the length of their daily meditation practice (“How many minutes did you meditate today? Fill in ‘0’ if you did not practice today.”) as well as the time of day they practiced. Furthermore, they were asked to rate their experiences with this day’s meditation practice on a 5-point polarity profile. They were presented with three items to measure (a) experienced difficulty/ease (“Meditating was very difficult ... very easy”), (b) wakefulness (“I was feeling sleepy ... awake), and (c) relaxation (“I was feeling very restless ... very relaxed”). Participants in conditions including physical yoga practice were asked to provide information on their yoga practice in a similar manner. We added one more item to assess experienced coherence of breath during yoga practice (“The practice and my breath were non-coherent ... coherent”). Participants in ethical education conditions were asked only two questions, about (a) engagement in ethical practice (“Did you engage in any of the mindful activities today?”) and (b) experienced difficulty of the current topic of ethical education.

Course Satisfaction

The Client Satisfaction Questionnaire (CSQ-8; Attkisson and Zwick, 1982) was developed to assess global client satisfaction along a single dimension in clinical settings. We used it in this study during posttest to determine participants’ satisfaction with the course they completed. The CSQ-8 has eight items that are rated using a 4-point Likert scale. It is considered a reliable ($\alpha = 0.92$) and valid instrument.

Adverse Events

The posttest included a list of 70 possible adverse events or extraordinary experiences associated with meditation or yoga practice. We gathered this list from several publications on adverse effects of meditation and yoga (Matsushita and Oka, 2015; Cebolla et al., 2017; Lindahl et al., 2017) and categorized all events and experiences into 10 clusters of related symptoms: neurological, somatic, pain, cognitive, emotional, motivational, changes in necessities, difficulties in life, compulsive meditation, and altered states of consciousness (see **Supplementary Material A—Table A4**). Participants were instructed to mark all events and sensations they had experienced during the treatment phase and to rate their severity (mild, moderate, severe) and duration in days (1–2, 3–6, 7–13, 14–20, ≥ 21), respectively.

Special Occurrences

Participants had the opportunity to describe any special events that occurred throughout their day in a free text item in the daily questionnaires.

Data Analysis

Single-case data are usually analyzed using multiple approaches, the most common being visual inspection of dependent-variable-by-time plots (Gage and Lewis, 2013; Lane and Gast, 2014). There are multiple ways how these data can be analyzed statistically, with multifaceted proposals and ongoing debates concerning this issue (Burns, 2012; Evans et al., 2014; Shadish, 2014; Machalíček and Horner, 2018). Various effect size estimates have been proposed, each with their individual advantages and disadvantages (Parker et al., 2011a; Tarlow, 2017; Pustejovsky, 2019). We analyzed data in three ways—by visual inspection, calculating effect sizes using Tau-U, and multilevel modeling. All methods are described below. If all three analyses converged, this would provide strong evidence for our findings. In addition, we enriched our quantitative analyses with qualitative findings, where appropriate, to explore selected single cases and possible reasons for inter-individual differences.

Statistical analyses on the incremental effects of the four conditions were exploratory in nature. We repeated two coding schemes using different dummy variables. To investigate whether there were any general differences between the four conditions, we used three dummy variables to code the four conditions (condition model). We used this model to estimate the overall explanatory power of the dummy variables using the *anova*-function in R. To examine whether there were any differences regarding the inclusion of different program components, we prepared two other dummy variables. These coded the presence vs. absence of ethical education or physical yoga (0 = *without component*, 1 = *with component*) in the respective condition (component model). As our four treatments differed in session length and demographic factors, we included individual practice time, age, gender, occupation, and baseline length in both models to control their influence statistically. To estimate individual practice time, we calculated sum scores of the reported length of each practice participants engaged with at home. For ethical

TABLE 3 | Topics of the ethical education component with corresponding week(s) they were taught in the study, sanskrit names, and sample mindful living exercises.

Week	Topic	Sanskrit name	Sample mindful living exercises
Yamas—universal ethics/right living with others			
1 and 9	Non-violence	Ahimsa	Practice praising instead of criticizing (also of myself) Practice respecting my boundaries (e.g., taking breaks)
2 and 10	Truthfulness	Satya	Write down how I really think and feel Practice being truthful instead of “nice”
3	Non-stealing	Asteya	Recognize inner and outer abundance in my life Practice giving when I receive something
4	Self-restraint	Brahmacharya	Enjoy eating/working/watching TV before excess or inertia sets in
5	Non-hoarding	Aparigraha	Clear things out that I don't need Recognize expectations I have concerning myself and others
Niyamas—individual ethics/right living with yourself			
6	Cleanliness	Sauca	Practice bodily cleansing (e.g., intermittent fasting) Recognize and enjoy moments of purity
7	Contentment	Santosha	Practice being thankful for things that happened today Refrain from chasing or avoiding specific things I like/dislike
8	Transcendence	Tapas (self-discipline) Svadhaya (self-study) Ishwara pranidana (devotion)	Practice faculty of discrimination (“Is this conducive to my goals?”) Read a spiritual text Try to connect to the miracles of life

practice, we multiplied participants' entries (1/0) by 20 min to get a comparable estimate of practice duration. As we expected combined interventions to have stronger effects than the simple meditation intervention, we applied one-tailed tests of significance by dividing the resulting p levels by two. We considered $p < 0.05$ to be statistically significant.

All statistical analyses were performed using R 3.6.3 (R Core Team, 2020). Plots were generated with the statistical packages lattice (Sarkar, 2008) and ggpubr (Kassambara, 2020). Tau- U estimates were calculated and analyzed using the package scan (Wilbert and Lueke, 2019), and multilevel models were conducted using the package nlme (Pinheiro et al., 2020). Proportion of explained variance in multilevel models was calculated using the R-based online application mimosa (Titz,

2020). All scripts and data that support the results can be found at osf.io/n7y64/.

Visual Analysis

We kept our visual analysis relatively simple for pragmatic reasons as our sample was exceptionally large for an experimental single-case study. We used the R packages scan and lattice to generate individual dependent-variable-by-time plots with according level and trend lines. Following common visual analysis standards (Kratochwill et al., 2010), we then assessed whether there were perceivable trends in the baseline or the treatment phase, and whether there were differences between the means and the variability of data in each phase. Furthermore, we analyzed the immediacy of the effect after the onset of the treatment and the consistency of data patterns across individuals. Finally, we compared all individuals in one condition to individuals in the other conditions to see whether the observed patterns differed between conditions.

Tau- U

To provide a nuanced measure of phase non-overlap we calculated Tau- U . Parker et al. (2011b) initially proposed Tau- U as a non-parametric estimate of effect size in single-case research designs that allows controlling trends observed in both phases. Tau- U is a family of non-parametric rank correlation indices that, as such, are relatively robust to autocorrelation and have shown good statistical power. In this study, we calculated Tau- U coefficients for each participant and each dependent variable. We assumed trends in the data to be theoretically probable, both in response to repeatedly filling out questionnaires in the baseline phase and in the form of a continuous improvement in the treatment phase. Therefore, we corrected trends in both phases if they were statistically significant, larger than 0.40, or visually prominent. Accordingly, we chose and reported corrected effect size estimates for these individuals (Tau- $U_{A \text{ vs. } B-\text{Trend } A}$, Tau- $U_{A \text{ vs. } B+\text{Trend } B}$, or Tau- $U_{A \text{ vs. } B+\text{Trend } B-\text{Trend } A}$). If no trends were evident, we reported Tau- $U_{A \text{ vs. } B}$. We applied the interpretative benchmarks provided by Solomon et al. (2015) where an effect size of less than 0.28 indicates a small effect; 0.29–0.47 a moderate effect; 0.48–0.57 a large effect; and 0.58 or above a very large effect.

We explored possible differences between conditions by first generating and comparing boxplots of Tau- U s for the four conditions. Second, we conducted two multiple regression analyses predicting Tau- U estimates by the different dummy variables described above. Analyzing the effects of condition or component on effect size estimates resembles cross-level interactions in multilevel modeling.

Multilevel Modeling

Multilevel modeling (also known as hierarchical linear modeling) is a powerful tool for modeling correlated data in which observations are nested within individuals and for examining both individual change and group differences (Dedrick et al., 2009; Hox, 2010). It has been proposed as a suitable method for analyzing multiple-baseline data (Ferron et al., 2009). In this study, we modeled changes over time within each

individual on one level and differences between individuals on a second level. Prior to all analyses, we standardized all variables to obtain standardized regression coefficients and reliable interaction terms.

For each dependent variable, we estimated several models with increasing levels of complexity. However, as we were primarily interested in the cross-level interactions, we report only the final models. The full estimation procedure can be found in **Supplementary Material B (Tables B1, B2)**. We modeled a cross-level interaction between time and dummy variables to determine whether any condition or component had an incremental beneficial effect on participants in this study. The following equation shows the final component model:

$$y_{ij} = \gamma_{00} + \gamma_{01}ethical\ education_j + \gamma_{02}physical\ yoga_j \\ + \gamma_{03}age_j + \gamma_{04}gender_j + \gamma_{05}baseline\ length_j + \gamma_{10}time_{ij} \\ + \gamma_{11}ethical\ education_j * time_{ij} + \gamma_{12}physical\ yoga_j * time_{ij} \\ + u_{0j} + u_{1j}time_{ij} + r_{ij}$$

where y_{ij} refers to the dependent variable, all γ variables refer to fixed effects, and all u and r variables refer to random effects.

Time was a contrast-coded Level 1 variable representing the expected slope of change that occurred from baseline to treatment phase. It was coded with zero for the baseline phase as we expected no systematic change in this phase, and a logarithmic trend starting at the beginning of the treatment phase. We applied the logarithmic curve as this is a type of growth commonly observed in psychology (Jones et al., 2005), and it provides a better conceptual fit than a linear trend. If we observed substantial variation in individual slopes during visual inspection, we modeled time as a random slope. Furthermore, we applied one-tailed tests of significance to the time variable as we expected all treatments to exert a positive effect on our participants.

Data were screened and corrected for (illegitimate) outliers due to data-entry errors. Other (legitimate) outliers were hard to identify. Hence, we treated them conservatively by not excluding them. Following a proposal of Nakagawa and Schielzeth (2013), we used two effect size estimates to assess the proportion of explained variance in each model, namely, marginal R^2 (variance explained by fixed factors), and conditional R^2 (variance explained by both fixed and random factors). All models were estimated using the restricted maximum likelihood estimation procedure.

Missing Data

Because of the admittedly high response load with daily questionnaires over a period of 71–85 days, we did have some missing data in the present study, specifically toward the end of the data collection period. Some data points were missing because some participants simply forgot to respond to the questionnaire on some days, or because a few participants reported (during class) stressful life events that kept them from responding. Mean amount of missing data across participants was 18.5% (range 2.8–45.9%). We performed all analyses with the data available bearing in mind the limitations of this approach (Peng and Chen, 2021).

Only one participant failed to respond at posttest and follow-up and another one failed to respond at follow-up. We excluded these two participants from the analysis of life satisfaction.

RESULTS

In this section, we first report on participants' adherence to our treatment. Then, we present the results on our three main outcome variables: well-being, perceived stress, and life satisfaction. For the two continuously measured variables, we first present individual plots for each participant and report the results of our visual inspection. Second, we report on our statistical analyses of these variables employing Tau- U effect size estimates and multilevel modeling. In the final part of the Results section, we explore possible moderator variables that might help explain the effects found for our main outcomes. These moderator variables are course satisfaction, adverse, or extraordinary events experienced during the treatment, and subjective experiences with the daily practice.

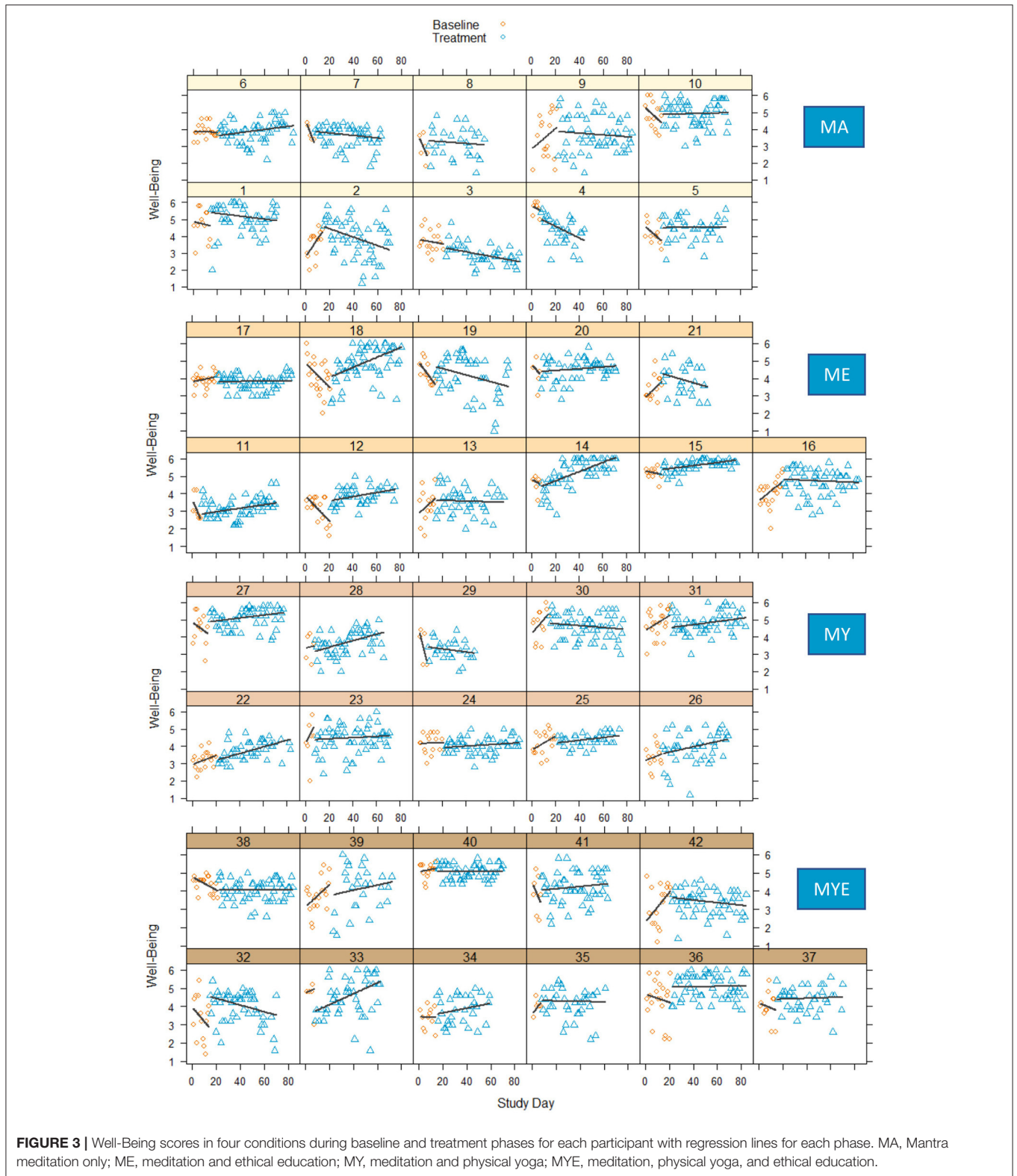
Adherence

First, we looked at whether participants actually engaged in their respective daily home practice. Compared to all other conditions, participants in the meditation-only condition reported significantly higher daily meditation practice durations, $M_{MA} = 18.2$, $SD = 9.7$; $M_{ME} = 14.7$, $SD = 9.3$; $M_{MY} = 14.0$, $SD = 9.8$; $M_{MYE} = 13.1$, $SD = 10.2$; $F_{(3, 1,908)} = 23.45$, $p < 0.001$. This might be because, in contrast to the other conditions, this was the only home practice participants were supposed to engage with. We plotted the engagement in all three home practices over time and examined the respective plots (see **Supplementary Material C—Figures C1–C3**). For meditation practice, we observed a decline in practice duration across all conditions toward the end of the study. Remarkably, participants in the MYE condition reported higher average practice duration/frequency in Hatha yoga and mindful living activities, compared to participants in the ME or MY conditions, yoga: $M_{MYE} = 15.7$, $SD = 13.1$; $M_{MY} = 12.6$, $SD = 12.2$; $t_{(959)} = -3.81$, $p < 0.001$, and ethics: $M_{MYE} = 0.74$, $SD = 0.44$; $M_{ME} = 0.68$, $SD = 0.47$; $t_{(1,046)} = -2.18$, $p = 0.030$. However, practice times may be underestimates, as participants may have engaged in home practice on days for which they did not complete the daily questionnaire.

Course adherence was moderate to high. Apart from four participants who attended only one, two, or three group sessions but consistently practiced at home, the majority of participants attended at least six of the eight group sessions. Adherence was a bit higher in conditions that involved ethical education ($M_{ME} = 6.09$; $M_{MYE} = 6.64$) than in the other two conditions ($M_{MA} = 5.50$; $M_{MY} = 5.20$).

Well-Being Visual Analysis

Figure 3 depicts the well-being scores of each participant over the course of time. It is subdivided into four plots, one for each condition. As can be seen from this figure, well-being scores show strong fluctuation and variation over time



and the amount of daily fluctuation varies inter-individually. Some points in this figure stand out as days with especially low well-being. Most of these days correspond to life events

participants experienced as very challenging, for example, exams, illnesses, or a separation, and reported during the weekly sessions.

For most participants, the baseline phase cannot be considered to be stable. Around half of the participants showed a decline in their well-being scores during the baseline phase and a third showed an increase, the reason for this finding being unclear. Comparing both phases, some participants showed no observable changes in level and/or slope (e.g., Participants 9, 23, 31, 40), whereas most profited from the treatment, some more obviously (e.g., Participants 14, 15, 22, 36) than others (e.g., Participants 11, 26, 27, 28). Strong positive effects seem to be present predominantly in the ME condition. On the other hand, some participants exhibited a decline in well-being over the course of time, especially toward the end of the treatment. This might indicate an increasing fatigue with the intervention, which might be particularly true for those participants who prematurely stopped responding to the daily questionnaires (e.g., Participants 4, 21, 29). Yet, the decline was most pronounced in the group of participants who were practicing mantra meditation only (e.g., Participants 1–4).

For most participants, well-being increased gradually either from the beginning of the treatment or after a small delay of 1 or 2 weeks. Quite a few participants reported having mastered the meditation technique after initial difficulties at 2 weeks after the beginning of the treatment. After a few more weeks, however, participants reported getting bored or feeling stuck with meditating. While some of them found ways to revive their motivation or find deeper meaning in meditating, others resigned, or tried to uphold their meditation practice without connecting it to a deeper meaning. We observed the latter more frequently in the MA condition and less frequently in the other conditions. These qualitative findings correspond to our analysis of experienced meditation difficulty over time, which we report at the end of the Results section. Intriguingly, it seems that the experiences during the process of learning meditation were closely related to daily well-being.

Overall, these results strengthen the impression that people respond quite differently to meditation interventions. There seem to be discernible differences between the four treatment conditions, too, indicating a negative effect of the meditation-only intervention. To further explore and validate our visual analysis we conducted two distinct statistical analyses.

Statistical Analysis

Tau-U

The *Tau-U* statistic was calculated to assess the effect size of the intervention for each participant (see **Supplementary Material B—Table B3**). Most effect size estimates ranged from 0.20 to 0.40, indicating a small to moderate improvement of well-being for the majority of participants. We observed the largest positive effect sizes (0.42–0.46) for Participants 14, 15, and 22. Three participants (3, 4, and 38) had a substantially lower well-being following the treatment (−0.30 to −0.51). These results correspond to our visual analysis.

Next, we looked at potential explanations for the strong negative effects. Participant 3 (MA) had an especially hard time trying to learn mantra meditation. She almost always rated her meditations as being very hard. Participant 38 (MYE) deeply appreciated her course but reported having elevated

levels of stress due to beginning work on her master's thesis, which coincided with the beginning of the treatment. We had considered excluding Participant 4 (MA) from the analysis as she attended only the first two sessions of her meditation course and stopped responding to the daily questionnaires in Week 5 of the treatment. However, she had meditated very conscientiously at home for 20–30 min nearly every day. Unfortunately, we do not know whether there were other reasons that caused her to drop out of the study. When we contacted our participants after 12 months, she stated that the course had a very positive impact on her and that meditation proved to be a valuable resource in her life. Participant 3 had stopped meditating soon after the course had ended, whereas Participant 38 used meditation and yoga practice regularly as a means to cope with tension or establish mental calm. The latter stated that the topics of ethical education were often present in her mind.

To allow for better comparison, we also looked at the qualitative statements of the three participants with the highest positive effect sizes. For Participants 14 and 15, the participation in the course (both ME) had led to profound changes in perspective. Specifically, the ethical education component had informed their actions and thoughts in their daily lives up to 12 months after the study had ended. They both continued to meditate: Participant 14 meditated daily and Participant 15 once or twice a week. The former also enthusiastically described how the course had inspired her to follow a spiritual path and form a group of like-minded people to regularly meditate and exchange. Participant 22 (MY) described how she had dived into an intensive yoga practice after the course, which she continued up to the present. She did not continue to meditate. Interestingly, Participants 14 and 15 found meditating very easy from the very beginning of the treatment. All three participants reported meditation becoming increasingly easy over the course of time.

After this qualitative evaluation, we grouped all *Tau-U* effect size estimates by condition and generated according box plots (**Figure 4**).

The box plots in **Figure 4** reinforce our impression from visual inspection. On average, the MA condition had no effect on participants' well-being [$Mdn = 0.07$, interquartile range (IQR) = 0.30]. All other conditions, however, enhanced participants' well-being. This was particularly pronounced in the two conditions involving ethical education, ME ($Mdn = 0.30$, IQR = 0.22) and MYE ($Mdn = 0.23$, IQR = 0.22), and less pronounced in the MY condition ($Mdn = 0.12$, IQR = 0.35).

We further statistically explored these differences using multiple regression analysis. We entered the effect size estimates as the dependent variable and the abovementioned dummy and control variables as predictors (see **Supplementary Material B—Table B4** for a correlation matrix of all variables). The aggregated effect of all four conditions was $F_{(3,33)} = 2.78$, $p = 0.028$, pointing to existing differences between them. The condition model indicated a significant effect for the ME condition, $\beta = 0.56$, $p = 0.006$, the MYE condition, $\beta = 0.51$, $p = 0.028$, and, pointed to an effect of the MY condition, $\beta = 0.30$, $p = 0.066$ (see **Supplementary Material B—Table B5** for the full regression table). The component model provided evidence for the effectiveness of the ethical education, but not

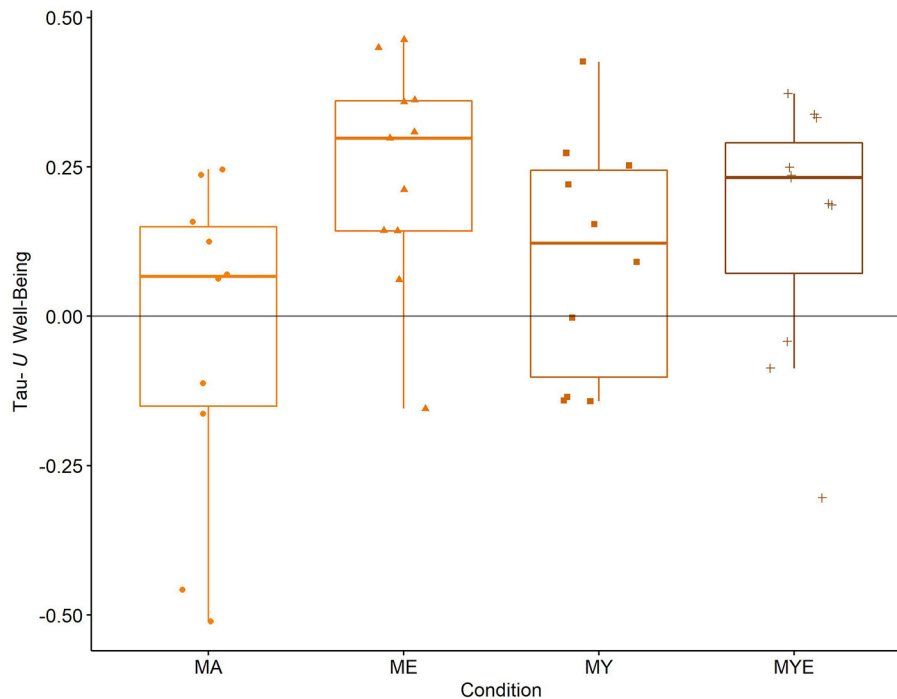


FIGURE 4 | Box plots for averaged Tau-*U* well-being estimates in each condition. Individual well-being estimates are scattered across the box plots. MA, Mantra meditation only; ME, meditation and ethical education; MY, meditation and physical yoga; MYE, meditation, physical yoga, and ethical education. Whiskers represent the largest and lowest values within a distance of 1.5 times the interquartile range.

TABLE 4 | Regression model for Tau-*U* well-being estimates as dependent variable and effective component, age, gender, and baseline length as predictors ($df = 36$).

Variable	<i>b</i>	β	<i>SE</i>	<i>t</i>	<i>p</i>
(Intercept)	0.32	0.00	0.21	1.55	0.131
Ethical education (yes/no)	0.20	0.44	0.09	2.33	0.013
Physical yoga (yes/no)	0.08	0.17	0.09	0.93	0.179
Total practice time	0.00	-0.28	0.00	-1.36	0.183
Age	-0.01	-0.24	0.01	-1.12	0.270
Gender	0.03	0.06	0.10	0.36	0.723
Occupation	0.05	0.07	0.14	0.32	0.755
Baseline length	0.00	-0.08	0.01	-0.48	0.635

the physical yoga component in improving subjective well-being (Table 4).

Neither practice time, age, gender, occupation nor baseline length significantly predicted changes in well-being over time in any model. The multiple R^2 was 0.22, indicating that there was still unexplained variance in this model. In summary, it seems that the ethical education component had a positive effect on well-being whereas MA or in combination with physical yoga did not. Conversely, yoga seemed to buffer the negative effect of meditation alone.

Multilevel Modeling

We used a similar procedure for multilevel modeling. Time slopes were modeled as random effects. When we estimated

the effect of all dummy variables taken together, that is, the effect of the group factor, we found a significant effect of time, $F_{(1,2,492)} = 6.73$, $p = 0.005$, and a significant cross-level interaction between time and condition, $F_{(3,2,492)} = 3.53$, $p = 0.007$. The significant effect of time indicates that well-being did not change during the baseline phase, but gradually increased over the course of the treatment for the majority of participants irrespective of their condition. The significant interaction, on the other hand, suggests differential improvements, such as some conditions yielding stronger improvements than others. In the condition model, there was a significant effect of time, $\beta = 0.08$, $SE = 0.03$, $p = 0.004$, indicating a global improvement across all treatments. However, all three interaction terms were significant, too, ME: $\beta = 0.13$, $SE = 0.04$, $p = 0.001$, MY:

TABLE 5 | Multilevel regression estimates for well-being scores as dependent variable and time, effective component, age, gender, and baseline length as predictors.

Variable	β	SE	df	t	p
Time	0.08	0.03	2493	2.45	0.007
Ethical education (yes/no)	-0.01	0.12	34	-0.11	0.912
Physical yoga (yes/no)	-0.07	0.12	34	-0.61	0.547
Total practice time	0.15	0.12	34	1.24	0.222
Age	0.07	0.12	34	0.53	0.600
Gender	0.08	0.10	34	0.84	0.407
Occupation	-0.17	0.13	34	-1.31	0.198
Baseline length	0.00	0.10	34	0.01	0.993
Time * Ethical education	0.07	0.03	2493	2.09	0.018
Time * Physical yoga	0.03	0.03	2493	0.92	0.178

$\beta = 0.09$, $SE = 0.04$, $p = 0.011$, MYE: $\beta = 0.09$, $SE = 0.04$, $p = 0.011$ (see **Supplementary Material—Table B6**). This speaks to the supplementary benefit of all three combined interventions and suggests that well-being scores in the combined conditions, particularly in the ME condition, showed a steeper upward slope in the treatment phase. The component model is depicted in **Table 5**.

There was a significant effect of time as well as a significant interaction between time and ethical education. None of the moderators was a significant predictor of well-being. Thus, it seems that the treatment had an overall positive effect on participants' well-being, but conditions involving ethical education produced stronger enhancements than those that did not. Marginal R^2 of this model was 0.05, and conditional R^2 was 0.45, indicating that only 5% of the variance could be explained by the fixed effects time, components, practice time, age, gender, occupation, and baseline length, whereas 45% was attributable to individual differences.

All three analyses converge, suggesting a generally positive effect of all four treatments on our participants' well-being. Additionally, all analyses show that the combined interventions were more effective than the simple meditation intervention, and that the ethical education component was particularly beneficial in this regard. This effect was independent of the accumulated amount/length of all home practices participants completed. We explore possible explanatory and moderator variables for these findings at the end of the Results section.

Stress

Visual Analysis

Figure 5 displays weekly stress scores for each participant over the course of the study.

Compared to well-being, perceived stress seemed to fluctuate a lot less. Again, there was substantial variation in participants' general stress levels, their weekly fluctuations as well as their response to the treatment. It was hard to make reliable inferences on baseline trends as there were too few data points in the baseline phase. Cautiously comparing both phases, most treatment curves show a slight to considerable downward trend, indicating reduced stress levels. Only a few participants exhibited unchanging stress levels from baseline to treatment phase (e.g.,

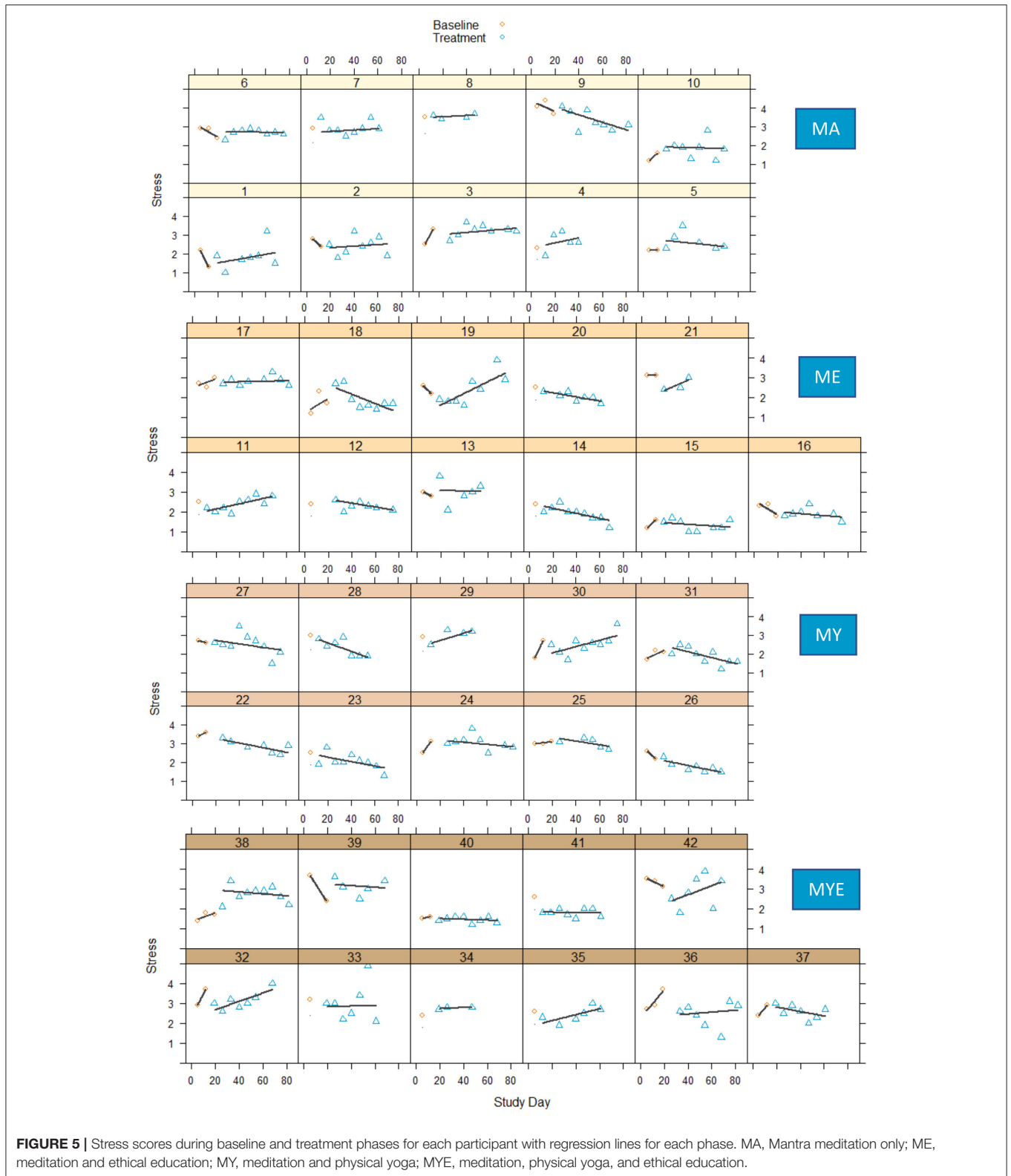
Participants 7, 33, 39). However, corresponding to our analyses of well-being, some participants experienced an increase in perceived stress. This might possibly have been due to the heightened effort required to participate in our indeed quite demanding study. It seems that the treatment was particularly demanding for participants in the most extensive condition MYE as well as for participants in the MA condition. Conversely, most participants in the MY condition exhibited a consistent reduction in perceived stress. This was also true for a large proportion of participants in the ME condition.

Statistical Analysis

Tau-U

We had to rely on far fewer measurements for this calculation of effect sizes. Particularly estimates for participants with a baseline length of 7 days need to be interpreted with care. On average, effect size estimates are markedly larger than effect size estimates of well-being and range from -1.00 to 0.87. Yet, most effect sizes range from -0.74 to 0.40, indicating moderate to very large effects on perceived stress. A reduction of perceived stress was desirable—thus, a negative sign in effect sizes represented a change in the expected direction. Whereas the stress level increased for 16 participants, it decreased for 22 participants. Only three participants had an effect size close to zero. The full Tau-U table can be found in **Supplementary Material B (Table B7)**.

Six participants exhibited large decreases in perceived stress over time, and Participant 41 showed a very large decrease. Three of these received the MY treatment. Indeed, the majority of participants in the MY condition reported decreased levels of stress throughout the treatment, in contrast to most other conditions. Participants 34 and 38 (both MYE condition) showed very large increases in perceived stress over time. The latter had already been identified as experiencing significant decreases in well-being (see above). This was not true for Participant 34, but, she had only very few measurement points in total, indicating an overestimation of the effect. Again, it seems as if the MA condition had the least favorable effect, as half of the participants in this condition exhibited moderate increases and only two moderate decreases in stress. We further explored these apparent



differences between conditions by generating box plots for each condition (Figure 6).

The box plots in Figure 6 underpin our impression from the visual inspection and qualitative evaluation. On average,

meditation alone (MA) slightly increased perceived stress ($Mdn = 0.17$, $IQR = 0.38$). In contrast, the treatment helped reduce stress a little in the MYE condition ($Mdn = -0.11$, $IQR = 0.62$) and to a moderate amount in the ME

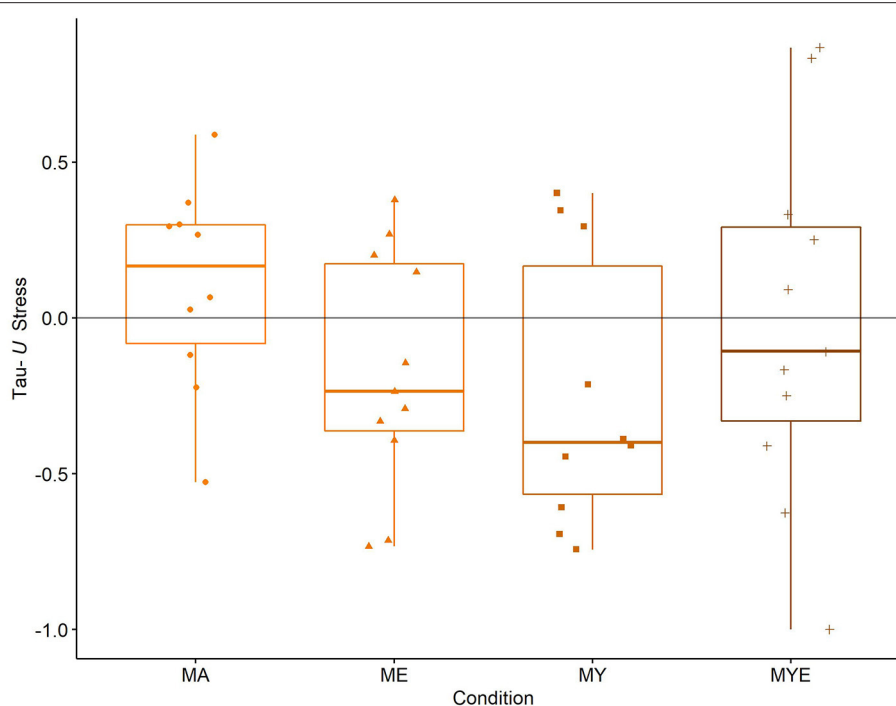


FIGURE 6 | Box Plots for averaged Tau-*U* stress estimates in each condition. Individual stress estimates are scattered across the box plots. MA, Mantra meditation only; ME, meditation and ethical education; MY, meditation and physical yoga; MYE, meditation, physical yoga, and ethical education. Whiskers represent the largest and lowest values within a distance of 1.5 times the interquartile range.

condition ($Mdn = -0.24$, $IQR = 0.54$) and the MY condition ($Mdn = -0.40$, $IQR = 0.73$).

Furthermore, we performed the same regression analyses as for well-being. When we estimated the total effect, we found no differences between conditions, $F_{(3, 33)} = 1.20$, $p = 0.161$. This was true also for the condition model (see **Supplementary Material B—Table B8**) and the component model (**Table 6**). Neither practice time, age, gender, occupation nor baseline length significantly predicted perceived stress in either model. Multiple R^2 of the component model was 0.07.

Apparently, the trends we observed during visual analysis were not as substantial. Nevertheless, the slightly negative effect of the MA condition corresponds to the results we found for well-being. As we expected, Tau-*U* estimates of well-being and stress correlated considerably ($r = -0.41$).

Multilevel Modeling

Time was modeled as a random slope. Results differed from those we found with effect size estimates. Overall, there was no significant effect of time, $F_{(3, 331)} = 1.69$, $p = 0.097$, nor a significant cross-level interaction, $F_{(3, 331)} = 0.97$, $p = 0.205$. This also applied to the component model (see **Table 7**).

Interestingly, accumulated practice time was a significant predictor in this model, indicating that the more participants engaged in a regular home practice the more their stress decreased, independent of the condition they were assigned to. Obviously, total practice time was longer in more extensive conditions, but still varied across participants.

In the condition model (see **Supplementary Material B—Table B9**), the cross-level interaction between time and the MY condition was significant, $\beta = -0.09$, $SE = 0.06$, $p = 0.051$, suggesting that this condition led to the greatest reductions in perceived stress. The magnitude of change was comparable to results obtained for well-being. Yet, two variables had an even greater impact on perceived stress. Practice time was, again, a significant predictor of stress reduction, $\beta = -0.42$, $SE = 0.14$, $p = 0.006$, whereas being employed (compared to being a student) significantly predicted an increase of stress, $\beta = 0.37$, $SE = 0.15$, $p = 0.023$. In this model, marginal R^2 was 0.22 and conditional R^2 was 0.64.

In sum, findings on stress are inconclusive. Whereas the visual analysis of the line graphs and box plots indicated a stress-relieving effect of all combined treatments, but especially the MY condition, both types of regression analyses did not uncover a significant effect of time or meaningful differences between conditions. Contrary to well-being, engagement in home practice significantly predicted stress reduction in multilevel modeling. It seems that the total amount of home practice was more relevant for a successful stress reduction than the actual treatment participants completed.

Life Satisfaction

A mixed two-way ANOVA yielded a significant effect of time, $F_{(2, 72)} = 3.46$, $p = 0.037$, with a small effect size, $\eta^2 = 0.01$. The four groups did not differ in their overall life satisfaction, $F_{(3, 36)} = 1.27$, $p = 0.301$; nor was there a significant interaction

TABLE 6 | Regression model for Tau-U stress estimates as dependent variable and effective component, age, gender, and baseline length as predictors ($df = 36$).

Variable	<i>b</i>	β	SE	<i>t</i>	<i>p</i>
(Intercept)	-0.12	0.00	0.44	-0.27	0.786
Ethical education (yes/no)	0.03	0.04	0.18	0.18	0.430
Physical yoga (yes/no)	-0.02	-0.02	0.18	-0.12	0.452
Total practice time	0.00	-0.15	0.00	-0.66	0.512
Age	0.01	0.10	0.01	0.44	0.664
Gender	0.21	0.18	0.20	1.03	0.310
Occupation	-0.02	-0.02	0.30	-0.07	0.947
Baseline length	0.00	-0.01	0.01	-0.04	0.972

TABLE 7 | Multilevel regression estimates for stress scores as dependent variable and time, effective component, age, gender, and baseline length as predictors.

Variable	β	SE	<i>df</i>	<i>t</i>	<i>p</i>
Time	-0.06	0.05	332	-1.19	0.117
Ethical education (yes/no)	0.02	0.14	34	0.13	0.900
Physical yoga (yes/no)	0.30	0.14	34	2.09	0.044
Total practice time	-0.37	0.15	34	-2.45	0.020
Age	-0.19	0.15	34	-1.24	0.224
Gender	-0.09	0.12	34	-0.76	0.453
Occupation	0.29	0.16	34	1.82	0.078
Baseline length	0.07	0.12	34	0.59	0.556
Time * Ethical education	0.01	0.05	332	0.13	0.447
Time * Physical yoga	-0.04	0.05	332	-0.82	0.207

between time and group, $F_{(6, 72)} = 0.51$, $p = 0.796$. The mean life satisfaction across all groups was $M_{pre} = 4.99$ ($SD = 1.16$) before the study, $M_{post} = 5.24$ ($SD = 1.12$) at completion of the study, and $M_{fu} = 5.24$ ($SD = 1.14$) 2 months later. Thus, life satisfaction increased from pre- to posttest for all participants from our study, and this increase remained stable until follow-up. This increase did not depend on the specific treatment they received. Accordingly, learning how to meditate seems to be sufficient to experience increased life satisfaction.

Potential Explanatory Variables

We now explore a few variables that might help explain some of the inter-individual variance we observed in the main analyses. For this analysis, we employed mainly exploratory and descriptive methods, such as figures, correlations, and frequency tables.

Course Satisfaction

Apart from one participant (Case 4) in condition MY who attended class only once and primarily practiced on her own, class ratings were high in all conditions (the maximum rating being 4)—MA: $Mdn = 3.44$; ME: $Mdn = 3.75$; MY: $Mdn = 3.38$; MYE: $Mdn = 3.62$. Participants in the two conditions that involved ethical education reported a somewhat higher satisfaction with their course, $F_{(1,39)} = 3.99$, $p = 0.053$, which might explain the higher course adherence in these two groups.

Adverse or Extraordinary Events

We required participants to mark all symptoms they had experienced throughout the study that were directly related to their practice. These symptoms could be positive (strong positive emotions during meditation), negative (fear, emotional distress), or neutral (feeling hot or cold). Unfortunately, we did not assess whether participants rated their experiences as adverse or not. We transformed duration ratings numerically to resemble comparable intervals. For each cluster of symptoms, we summed up number, severity, and duration ratings to calculate cluster scores. Two participants reported no symptoms, but this could as well represent a lack of diligence. Therefore, we excluded them from the following analyses.

All symptoms were mentioned by at least one participant. The five most common symptoms were exhaustion (54%), impression that something is missing in life (41%), inner tension (39%), strong positive feelings during meditation (33%), and the feeling of oneness with all that is (33%). The six least common symptoms, mentioned by only one participant each, were fainting, redness of the skin, sweating, losing interest in one's surroundings, impression that not meditating is a waste of time, and impression that only people who meditate are valuable people. The most affecting symptoms in terms of number, severity, and duration were reported in the cluster of somatic symptoms (mean affecting score $M = 7.98$), followed by emotional symptoms ($M = 5.92$), and altered states of consciousness ($M = 5.33$). On average, participants reported

experiencing 11.8 symptoms ($SD = 9.57$, range 1–44) with a mild severity ($M = 1.42$, $SD = 0.35$) for around 6.2 days ($SD = 4.26$). No adverse events necessitated referral to a health professional.

Participants in the MYE condition reported the most symptoms (altogether 138), followed by those in the MA condition (127) and the ME condition (117). The fewest symptoms were reported by the MY group (77). We tested all symptom clusters for significant differences between conditions employing one-way ANOVAs. Thereby, we found potentially meaningful differences in the number and severity of emotional symptoms, $F_{(3, 35)} = 2.48$, $p = 0.077$, and $F_{(3, 35)} = 2.81$, $p = 0.054$, respectively, and the duration of neurological symptoms, $F_{(3, 35)} = 2.77$, $p = 0.056$. Pairwise t -tests revealed that participants in the MY and ME conditions experienced significantly fewer emotional symptoms than those in the MA condition, and, furthermore, participants in the MY condition experienced them as less severe. On the other hand, the ME group experienced significantly longer neurological symptoms than the other groups, but, specifically the MY group. A detailed analysis revealed that these neurological symptoms were predominantly a numbness of body regions, a shaking of the body, and involuntary body movements. It seems, thus, that practicing physical yoga prevents some of the possibly adverse symptoms associated with the practice of mantra meditation and ethical education.

Daily Practice

Throughout the treatment, we daily asked participants to rate their experiences with their respective home practice/s. We now present a qualitative review of the changes and differences between conditions that we observed during visual inspection (see **Supplementary Material C—Figures C4–C11**). For all variables, we observed substantial variation between participants as well as strong day-to-day fluctuations within participants.

For perceived *meditation ease*, we detected a clear upward trend over time, indicating that for most participants meditation got easier over the course of the intervention. This trend was most evident in participants in the ME condition. For some participants, meditation ease stayed more or less the same over time. These participants mainly belonged to the MA and MY conditions. Three participants in the MYE condition experienced increased difficulty in meditating toward the end of the treatment. The visual analysis of perceived *relaxation during meditation* revealed a transition from restlessness to a more relaxed state over time for the majority of participants. Still, ratings of perceived relaxation varied strongly from day to day, suggesting that meditation quality strongly depended on mood and daily form. There were no apparent differences between conditions. *Wakefulness during meditation* showed a similar pattern. The majority of participants experienced a shift from being tired during meditation to being more wakeful, particularly participants from the MY condition.

For *yoga experience* variables, there were no perceivable differences between the two conditions that received physical yoga as a treatment. Wakefulness and relaxation during

yoga exercises were consistently high to very high for most participants. In contrast, perceived ease of yoga exercises and their coherence with the breath increased over time for most participants. There were no consistent findings regarding perceived *ease of ethical exercises*. This might have been due to the heterogeneity of weekly topics participants were supposed to engage with. During our weekly meetings, participants repeatedly reported that some topics were more challenging for them than others. To test this assumption, we conducted a simple regression analysis with ease of ethical practice as dependent variable and topic of ethical education as predictor. We set the hardest topic as the reference category (truthfulness) and found that only two topics were significant predictors of perceived ease—non-stealing, $b = 0.50$, $SE = 0.14$, $p < 0.001$, and contentment, $b = 0.62$, $SE = 0.16$, $p < 0.001$. Furthermore, we found substantial correlations between the subjective experience variables, indicating that on “good” days participants perceived all of their home exercises as easier and were more relaxed and awake during meditation and/or yoga (for more details see **Supplementary Material A—Section A5**).

Dose–Response and Experience–Response Relations

We evaluated the effects of dosage and subjective experience on the daily fluctuations in our dependent variables during the treatment phase by adding four predictor variables on Level 1 (daily meditation practice duration, perceived meditation ease, relaxation, and wakefulness) to the component models described above. Similar to in other studies (Fredrickson et al., 2017), we used unstandardized values in our models and person-mean centered the meditation variables. In the following, we point out main findings; for full multilevel regression tables see **Supplementary Material B (Tables B10, B11)**. All of these models take into account only measurement points from the treatment phase. Thus, they do not allow for comparisons between baseline and treatment phases.

For well-being, we found significant positive effects for all subjective meditation experience variables (all $p < 0.02$ to $p < 0.001$), but not for meditation practice duration. This means that participants who experienced meditation as easier and were more relaxed and awake during meditation on a given day, compared to their own typical level of daily experience, reported higher levels of well-being on that day. Surprisingly, this effect was independent of the duration of their meditation practice. Unfortunately, we cannot tell from our data whether participants experienced higher well-being because of their meditation, or whether their meditation was easy because they were feeling well. For stress, only relaxation during meditation predicted lower stress levels on a given day ($p < 0.05$).

We were able to explore the direction of these effects tentatively by considering the time of meditation practice that participants reported. We found that meditating in the morning positively influenced well-being on that day and that participants meditated less on days when they were feeling well and more when they were feeling less stressed (for more details see **Supplementary Material A—Section A6**).

DISCUSSION

The present study provides the first in-depth insights into the incremental impact of ethical education and physical Hatha yoga on mantra meditation in healthy participants. At the same time, it dismantled and investigated diverse combinations of the components of the new MBLM mind–body therapy (Bringmann et al., 2020), which is based on the yoga path. The single-case multiple-baseline design gave detailed access to individual responses and trajectories of change. Participants in all four conditions enjoyed their course and established a regular home practice, indicating that MBLM is a feasible and helpful intervention for a predominantly young and healthy population. Course satisfaction and adherence was a bit higher in conditions that involved ethical education. Ethical education also had the greatest impact on increasing participants' well-being. While results on well-being were quite strong and unambiguous, findings on stress were inconclusive. Overall, the majority of participants experienced an increase in well-being and a decrease in stress over time. However, for both variables, the combined interventions had more positive effects on participants than the simple meditation intervention.

For stress, changes could not be consistently attributed to the inclusion of a specific component. The MY condition was the most efficient in reducing stress, tentatively speaking to a stress-relieving effect of physical yoga. The MA condition was the least effective as some participants showed a decrease in well-being and/or an increase in stress over time. The positive effects of ethical education on well-being were independent of the total amount of home practice participants completed, suggesting a benefit specific to this yoga component. These results provide evidence for the differential effects various combinations of yoga components can elicit.

Interestingly, life satisfaction significantly improved across all conditions from pre- to posttest and had continued to improve when measured at 2 month follow-up. Thus, participating in any of our four interventions, whether simple or complex, seemed to be beneficial for contentment in life. This might be an effect specific to mantra meditation, as all conditions involved this practice. Alternatively, it might be due to unspecific factors common to all conditions, such as group dynamics, social support, or attention from study staff. Yet, the latter might be unlikely as the effect persisted until follow-up. From a eudaemonic perspective, decreased hedonic well-being, as reported above for the MA condition, is not inconsistent with increased life satisfaction (Ryan and Deci, 2001). Even if participants felt more stressed during the treatment, they might have gained profound insights during meditation that significantly affected their perspective and satisfaction with life.

Overall, we observed high inter- as well as intrapersonal variability in responses emphasizing the potential relevance of personality factors in this regard. While some participants benefited strongly from their treatment, others did not change much, and still others experienced a deterioration in their well-being or an increase in perceived stress. Similarly, for some participants meditating was really easy from the beginning, for most it got easier as they practiced, and for some it remained

difficult throughout. The different dimensions of subjective experience during home practice were interrelated, suggesting that meditation or yoga exercises were easier when participants felt relaxed and awake. Physical yoga might be helpful in this regard as participants in the MY condition experienced the most prominent increase in wakefulness during meditation. Ethical education, on the other hand, can be quite challenging or unsettling and thus can impair relaxation during meditation. From our observations of the different classes, the transition to meditation was much smoother and quieter in the conditions where meditation was preceded by physical Hatha yoga (MY and MYE) than in the ME condition. Nonetheless, the latter showed the greatest improvement in perceived meditation ease. As this condition also showed the greatest increases in well-being, it appears to have been a very effective combination. The combination of physical yoga and meditation (MY), though, seems to have been particularly beneficial in reducing stress and adverse events associated with the treatment.

Framing Mantra Meditation Enhances Its Effects

It is not easy to compare our findings to results of earlier studies. Although there have been some comparative or dismantling studies (Matko et al., 2021a), no study employed an additive design comparable to ours. Most studies compared rather complex interventions with each other, and only a few actually dismantled or added program components (e.g., Smith et al., 2011; Hunt et al., 2018). Only one study compared a complex Kundalini Yoga program (including meditation, breathing, and some movement) to a meditation program entailing mantra and breathing meditation (Shannahoff-Khalsa et al., 2019) and found that the complex yoga program¹ outperformed the simple meditation program. This is in line with the results of our study. Conversely, it is not quite clear why the mantra meditation condition in our study elicited no changes or even negative effects. Mantra meditation has been shown to have a strong impact on negative emotions, stress, anxiety, and depression, but not necessarily well-being (Sedlmeier et al., 2012; Lynch et al., 2018). However, there are to date only a few investigations into the effects of mantra meditation on healthy participants that are methodologically sound and more research into this matter is needed.

Interestingly, our mantra meditation intervention differed significantly from earlier investigations. The format of teaching mantra meditation might not have been optimal. Participants received only minimal instructions and were then “thrown in at the deep end” with instructions to immediately begin practicing 20–25 min of silent meditation. Research has shown that letting participants engage in a guided meditation practice resulted in greater improvements than letting them engage in silent

¹We acknowledge that both groups in the respective study were classified as meditation and our labeling might divert from the traditional Kundalini Yoga (as taught by Yogi Bhasan) view. Yet, as the Kundalini Yoga group also entailed breathing and movement practices (contrary to the Relaxation Response) and, thus, more components from the classical yoga path, we decided to label it a “complex yoga program”.

meditation (Trivedi et al., 2020). Mantra meditation has been proposed as a suitable practice for both beginners and advanced meditators (Devananda, 1999), and also for patients with mental disorders (Orme-Johnson and Barnes, 2013). Nevertheless, individual factors might influence the liking of and coping with a specific meditation technique and, therefore, its effects (Hölzel et al., 2011). We assessed a multitude of personality factors in the larger project this study belongs to, and will explore possible interactions in future publications. Another factor could have been that participants were fully informed about the experimental procedure and might have been disappointed at receiving only the minimal treatment. Accordingly, comparing equally extensive interventions, for example, diverse meditation techniques, might lead to different effects.

Furthermore, interventions in other mantra meditation studies were embedded in a spiritual framework and enriched by rituals, additional exercises, or a sense of secrecy or sacredness. Most mantra meditation programs follow a specific spiritual teacher or lineage (Kirtan Kriya, Mantram Repetition, Passage Meditation, and Transcendental Meditation). Research has shown that spirituality is a critical ingredient in mantra meditation and can tremendously enhance its effects (Wolf and Abell, 2003; Wachholtz and Pargament, 2005). Although we employed spiritual mantras in this study, we did not provide any additional information on the belief systems or spiritual entities behind these mantras. Thus, our mantra meditation intervention was rather technical and less devotional than other programs. This might have impaired its effectiveness.

Indeed, providing participants with some kind of framework, such as physical yoga or ethical education, reversed the negative effect of mantra meditation in this study. While ethical education provided a philosophical framework to contextualize the practice of mantra meditation as well as experiences made during meditation, physical yoga offered a bodily or embodied framework. Yoga postures and breath work help people calm body and mind and develop a better connection to and understanding of their own bodily processes (Schmalzl et al., 2015; Kishida et al., 2018). Traditionally, postures and breathing were considered preparatory exercises that preceded meditation and helped the yogi reach the “stilling of the changing states of the mind” described in the *Yoga Sutras* (Bryant, 2015). Likewise, the ethical practice of the *yamas* and *niyamas* was supposed to ground and permeate all other yogic practices, such as postures or meditation (Feuerstein, 2012).

Following these assumptions, the full MBLM program (MYE) should have led to the greatest effects, but this was not the case. It seems, rather, that certain combinations of practices were more helpful than others and effects could not be reduced to simple dosing effects. Indeed, in this sample of healthy adults, a bit more was better than much more as the ME and MY treatments outperformed the MYE treatment. One reason for this finding might be the substantially longer class duration in the MYE condition as well as the larger amount of assigned home practice. Interestingly, in a systematic review, effect sizes did not change in shortened vs. original MBSR treatments, and shorter assigned practice time was associated with larger effect sizes (Carmody and Baer, 2009). In our

study, the total amount of home practice participants completed was not related to well-being outcomes, but was related to stress outcomes. This indicates that less extensive interventions are probably easier to integrate into people's lives, but more practice helps to reduce stress more. Furthermore, the eight-fold yoga path was designed as a lifelong journey for spiritual seekers on their way to enlightenment (Feuerstein, 2012). Participants in scientific studies (and meditators in general) are usually motivated to meditate for much more mundane reasons (Sedlmeier and Theumer, 2020). Thus, providing participants with a less extensive set of practices might give them more time to adjust and assimilate.

Specific Combinations of Practices Yield Different Effects

In this context, which component of the yoga path or, rather, which combination of components is most effective? We cannot give a comprehensive answer to this question, as we investigated only four possible combinations of practices, but will tentatively discuss our findings in the following. The intensive ethical confrontation in the ethical education groups invited participants to reconsider some of their maladaptive cognitive, emotional, and behavioral habits and divert them to a more adaptive direction. Essentially, this is one of the core principles of cognitive-behavioral therapy and stress reduction programs (Lehrer et al., 2007; Powers et al., 2017).

The ethical education component of MBLM might help attendees gain a deeper awareness of their goals and values in life, empowering them to make adaptive choices and switch off the “automatic pilot” of daily actions. Acting in accordance with personal values has positive effects on well-being and quality of life (Brunstein, 1993; Franquesa et al., 2017). Likewise, the importance of value-related behavior has become increasingly popular in psychotherapy, for example, in acceptance and commitment therapy (Hayes et al., 2004), and in positive psychology in general (Seligman, 2004). It has been suggested as a potential mechanism of mindfulness (Kocovski et al., 2009) and yoga (Sullivan et al., 2017) interventions. Our findings are also in line with research demonstrating that incorporating ethical practice into yoga or mindfulness interventions increased their efficacy (Smith et al., 2011; Chen and Jordan, 2020). Remarkably, engagement in intergroup discussions was strongest in the ME condition, even after the class had ended. In contrast to all other conditions, these participants also formed an informal meditation group and continued to meet after they finished the study. It might well be that this group initiated a self-reinforcing process that boosted the treatment's efficacy.

Engaging in physical Hatha yoga practice and simple breathing exercises might have initiated an upsurge in resilience to stress (Hartfiel et al., 2011; Manincor et al., 2016). Perceived stress decreased most in this condition and participants reported the fewest and the mildest emotional and other adverse symptoms during the treatment. This speaks to the protective effects of physical yoga practice. Findings from other studies support the positive effect of (physical) yoga on psychological well-being and stress (Bhat et al., 2012; Gard et al., 2012;

Gorvine et al., 2019). Conversely, some studies found no effect on stress (Quach et al., 2016; Park et al., 2020). Admittedly, the yoga interventions under investigation in these studies varied greatly, making it hard to draw reliable conclusions. Yet, many of the abovementioned studies used psychological as well as physiological measures of stress. Thus, a multimodal assessment and use of more standardized intervention protocols (Sherman, 2012) in future studies might provide more support for the stress-relieving effect of physical yoga.

Possibly, physical yoga might have enhanced non-judgmental metacognitive monitoring, as the yoga instructor repeatedly encouraged participants to observe their bodily sensations and thoughts in an accepting and non-judgmental manner. This process has been proposed as a central mechanism in yoga-based practices (Schmalzl et al., 2015) and mindfulness meditation (Lindsay et al., 2018). This accepting stance might have broadened to include the meditation practice, making it easier for participants to meditate. Moreover, physical yoga and breath work have been found to decrease sympathetic response and increase vagal/parasympathetic activity (Gard et al., 2014; Riley and Park, 2015), thereby intensifying the calming effect of yoga. In contrast to participants in the other conditions, participants in the MY condition were the least talkative during and after class and developed the least group cohesion. Our impression was that the MY condition provided participants with a valid opportunity to increase self-care but did not lead to the profound reorientation and reconsideration of values that we observed in the two ethical education conditions.

Limitations and Future Directions

The single-case multiple-baseline design enabled us to monitor changes in well-being, stress, and subjective experience continuously and with a high time resolution. However, a few features of the study might limit the generalizability of its outcomes. First, we recruited a convenience sample of young healthy participants from the general public, which consisted mainly of students. The majority of participants were 18–36 years old, with two exceptions—two women who were 57 and 61 years old. Nonetheless, age did not significantly predict any of the outcome variables. Still, this sample cannot be considered representative of the general public. Moreover, as participants received no financial compensation for their participation, we have to assume that they were intrinsically motivated to participate in this study and shared an inherent interest in or openness to yoga and meditation. The lack of financial compensation might explain the relatively high number of dropouts and high amounts of missing data and attrition toward the end of the study. Future studies should consider providing financial or other compensation to increase commitment in studies that employ intense data-gathering periods. Furthermore, this approach might also attract individuals who are less intrinsically motivated.

In single-case research, a sample of 42 participants is considered exceptionally large. With up to 85 measurements per participant for daily measures, findings, and effect size estimates should be very robust. This applies less to measures of stress. Usually, single-case research manuals recommend taking

at least three to five baseline measurements (Barlow et al., 2009; Kratochwill et al., 2010). Unfortunately, this could not be achieved in all cases in this study. Thus, results on perceived stress should be interpreted with care. Future studies should either increase baseline lengths for all participants or try to capture perceived stress more often. The latter could be achieved by including simple questions in daily assessments, such as “How stressed have you felt throughout the day?”

The sample size was somewhat small for multilevel modeling and pre–post comparisons, though. Multilevel modeling is usually applied to much larger data sets with a large number of data points at both levels. However, simulation studies performed with multiple-baseline data have included fewer participants and measurements occasions and reported satisfactory results (Ferron et al., 2009; Moeyaert et al., 2017). Nevertheless, more research is needed to validate our findings. Likewise, subgroup samples for the four conditions were comparatively small for drawing reliable conclusions through ANOVAs. Nonetheless, we were able to comply successfully with one of the main limitations of yoga and meditation research, that is, finding suitable control groups. The meditation-only condition served as an appropriate baseline group for depicting the effect of meditation as well as factors common to a group setting (Kinser and Robins, 2013; Stein and Witkiewitz, 2020). Intriguingly, our study showed that these factors were maybe not as important and could not outweigh the partially negative effects of mantra meditation.

A couple of improvements could be made to make the treatment and the data collection more feasible and enjoyable for participants. First, it would be advisable to give participants more guidance on mantra meditation. Second, daily questionnaires could be shortened and at the same time be made more specific (see above). Alternatively, experience-sampling methods or ecological momentary assessment (Shiffman et al., 2008) provide an intriguing means to capture immediate experiences at different time points in one day. Furthermore, participants should be encouraged to make journal-like entries in the daily questionnaire and reliably report challenging situations, such as exams. This would enable researchers to understand the fluctuations in their daily experience better. We did provide a field for exceptional experiences in our questionnaire, but not all participants regularly made use of this.

Finally, future studies could dismantle the effects of the eight-fold yoga path in an even more detailed way. Accordingly, studies could compare the effects of combined practices to treatments incorporating only ethics, only physical yoga, in addition to only meditation. Alternatively, they could examine the effects of diverse meditation techniques in this context. Current research has revealed a multiplicity of meditation techniques (Matko and Sedlmeier, 2019; Matko et al., 2021b), most of which are under researched at present. Furthermore, yoga incorporates a collection of diverse breathing techniques that can have quite different, sometimes even opposing effects on practitioners (Raghuraj et al., 1998; Peng et al., 2004). Thus, future studies should examine different combinations of ethical education, postures, breathing practices, and meditation techniques. Dosing questions should be paid special attention in this context. The four conditions we investigated in this study differed in session

length, which might have influenced their outcomes. However, the assigned and reported home practice was comparable across the various components and could not account for differences in well-being change. Furthermore, as we mentioned above, the longest treatment was not the most effective. Nevertheless, more studies are needed to truly understand the multifaceted practice of yoga in its entirety. In the end, these research efforts could contribute to the development of a profound theory of yoga.

DATA AVAILABILITY STATEMENT

All scripts and data that support the results can be found at the Open Science Framework (osf.io/n7y64/).

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the institutional review board of the Chemnitz University of Technology. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

KM designed and executed the study, analyzed the data, and wrote the first draft of the manuscript. PS collaborated on the study design and data analysis. HB conceptualized and supervised the interventions and collaborated with the study

design and data analysis. All authors worked on the final version of the manuscript.

FUNDING

This project was funded by Karl and Veronica Carstens Foundation under Award Number KVC 0/098/2018. The publication of this article was funded by Chemnitz University of Technology.

ACKNOWLEDGMENTS

We thank Christin Block and Felix Neuhaus for assisting in the execution of the study. We also acknowledge their and Annika Sternkopf's help in preparing and screening the data. We thank Ulrich Ott for the fruitful discussions concerning the clustering of adverse events. Thank you to Philipp Kanske for giving us access to the central experiment server of the Dresden University of Technology. Moreover, our thanks go to Anita Todd for her valuable comments on a previous version of this paper.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpsyg.2021.672301/full#supplementary-material>

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2.3 Meditationsbasierte Lebensstilmodifikation bei leichter bis mittelschwerer Depression - eine randomisierte kontrollierte Studie

Bei dieser Studie handelt es sich um eine erste, confirmatorische Evaluationsstudie innerhalb des MBLM-Projektes: Die Arbeit wurde 2022 mit dem Holzschuh-Preis der Hufelandgesellschaft für Integrative Medizin ausgezeichnet.¹⁰²

Aus der Zusammenfassung der Veröffentlichung:⁹² „Zielsetzung: Depressionen stellen weltweit eine der größten Herausforderungen in der psychischen Gesundheitsversorgung dar. Die Einführung wirksamer, risikoarmer und kosteneffizienter Interventionen zur Verringerung der Krankheitslast ist daher eine Notwendigkeit. Ziel dieser Studie war es, die Wirksamkeit des neuen Programms Meditation-Based Lifestyle Modification (MBLM), einer achtsamkeitsbasierten Intervention der "zweiten Generation", bei ambulanten Patient:innen mit Depression zu untersuchen. Methoden: Einundachtzig Patient:innen mit leichten bis mittelschweren Depressionen wurden nach dem Zufallsprinzip in drei Gruppen eingeteilt: die Interventionsgruppe (MBLM), die Kontrollgruppe (CONTROL) und die Gruppe mit der Standardbehandlung (TAU). Das primäre Ergebnis war die Veränderung der depressiven Symptome, die mit dem Beck Depression Inventory-II (BDI-II) nach 4 und 8 Wochen gemessen wurden. Zu den sekundären Ergebnissen gehörten die Brief Symptom Checklist-18 und die Perceived Stress Scale-10. Es wurde eine 6-monatige Nachuntersuchung durchgeführt. Ergebnisse: Bei den MBLM-Teilnehmern wurde im Vergleich zu den CONTROL-Teilnehmern eine stärkere Verringerung der depressiven Symptome festgestellt ($p < .001$, $\eta^2 = 0,11$, $d = 0,70$) und TAU ($p < .001$, $r = 0,10$, $r = 0,67$) mit einer Reduzierung des BDI-II-Scores um 13,15 Punkte gegenüber 1,71 Punkten (CONTROL) und 3,34 Punkten (TAU) nach 8 Wochen. Post-hoc-Tests zwischen den Gruppen für alle sekundären Ergebnisse und bei der Nachuntersuchung ergaben ebenfalls signifikante Unterschiede zwischen den Gruppen mit mittleren bis großen Effektstärken zugunsten von MBLM. Schlussfolgerungen: Die Studienergebnisse zeigten positive Auswirkungen der MBLM bei ambulanten depressiven Patienten. Weitere hochwertige kontrollierte klinische Studien, einschließlich qualitativer Forschung, sind erforderlich, um die spezifischen und unspezifischen Auswirkungen des MBLM-Programms bei Depressionen und anderen Erkrankungen zu untersuchen.“

Meditation-based lifestyle modification in mild to moderate depression—A randomized controlled trial

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Funding information

Karl und Veronica Carstens-Stiftung, Grant/Award Number: 0/901/2017

Abstract

Objective: Depression is a global key challenge in mental health care. The implementation of effective, low-risk and cost-effective interventions to reduce its disease burden is a necessity. The aim of this study was to investigate the efficacy of the new Meditation-Based Lifestyle Modification (MBLM) program, a “second-generation” mindfulness-based intervention, in depressive outpatients.

Methods: Eighty-one patients with mild to moderate depression were randomized into three groups: intervention group (MBLM), control group (CONTROL), and treatment as usual group (TAU). The primary outcome was the change of depressive symptoms as administered by the Beck Depression Inventory-II (BDI-II) after 4 and 8 weeks. Secondary outcome variables included the Brief Symptom Checklist-18 and the Perceived Stress Scale-10. A 6-month follow-up was conducted.

Results: A greater reduction of depressive symptoms was found in MBLM participants compared to CONTROL ($p < .001$, $\eta_p^2 = 0.11$, $d = 0.70$) and TAU ($p < .001$, $\eta_p^2 = 0.10$, $d = 0.67$) with a 13.15 points reduction of BDI-II score versus 1.71 points (CONTROL) and 3.34 points (TAU) after 8 weeks. Between-group post hoc tests for all secondary outcomes and at follow-up also yielded significant between-group differences with medium to large effect sizes in favor of MBLM.

Conclusions: Study results showed beneficial effects of MBLM in depressed outpatients. Further high-quality controlled clinical studies including qualitative research are needed to investigate the specific and unspecific effects of the MBLM program in depression and other medical conditions.

KEYWORDS

depression, ethical living, mantra, meditation, yoga

1 | INTRODUCTION

Depression is a complex disorder determined by biological factors, the environmental milieu, life events, and multilayered interactions between the aforementioned (Malhi & Mann, 2018). People with depression suffer from depressed mood, loss of interest or pleasure, thought disorders, diminished ability to concentrate, loss of energy, feelings of worthlessness or guilt, and suicidal ideations (American Psychiatric Association, 2013). The prevalence of depression has been growing in the last two decades, and with a 12-month prevalence of 6%, it has been recognized as the leading cause of disability in the world combined with a significant socioeconomic burden for the health systems (Malhi & Mann, 2018). Especially in regions with a high sociodemographic index, the age-standardized incidence rate has increased (Liu et al., 2019). This underscores the role of depression as a global key challenge in public health and the necessity of implementing cost-effective interventions to reduce its disease burden (Ferrari et al., 2013; Friedrich, 2017).

Conventional treatment includes pharmacological options, brain stimulation, and psychotherapeutic interventions. First-line pharmacotherapy commonly uses drugs that affect cerebral monoamine levels. The monoamine hypothesis in the context of depression has persisted for over 50 years and may be one of the reasons for a lack of innovation in the field of depression research and treatment. In this context, the efficacy of drugs that increase cerebral serotonin or norepinephrine levels is being debated increasingly and controversially (Bschor & Kilarski, 2016). In addition, adverse effects of antidepressive pharmacological interventions can be severe regarding both their utilization and discontinuation (Henssler et al., 2019). Brain stimulation treatments such as electroconvulsive therapy, repetitive transcranial magnetic stimulation, or deep brain stimulation for passive induction of neuronal plasticity can only be considered for the treatment of specific cases (Synofzik et al., 2010) and may not be used on a widespread basis due to ethical considerations, high technical requirements, and associated expenses.

In psychotherapy, several waves of behavioral therapy have been distinguished on the basis of historical, theoretical, and practical considerations (Kahl et al., 2012). The first wave focused methodologically on the principles of classical conditioning and operant learning, in which the behavior of the individual was supposed to be altered through exposure to specific stimuli. In the second “cognitive” wave, the central focus shifted to information processing, in which interrelations between thoughts, emotions, and behavior were analyzed and altered through cognitive reappraisal. The third wave of behavioral therapy is characterized by multifaceted methods in which mindfulness, acceptance, and cognitive defusion, among others, are implemented therapeutically (Kahl et al., 2012). These methods overlap with treatments that have found their way into integrative psychiatry (Sarris et al., 2015) through mind-body medicine (National Center for Complementary and Integrative Health, 2017). Unlike first- and second-wave cognitive behavioral therapy (and other classical psychotherapies), the primary focus of these techniques is not on verbally processing biographical events,

developmental traumas, conflicts, or dysfunctional conditioning (Kahl et al., 2012). Embedded mindfulness-based applications focus on a disidentification of inner experience and states of consciousness, which lead to greater serenity, improved emotion regulation, and a decrease in symptoms. In depression treatment, for example, Mindfulness-Based Cognitive Therapy for Depression (MBCT-D) (Finucane & Mercer, 2006; Segal et al., 2002) and Acceptance and Commitment Therapy (ACT) (Hayes et al., 2006) have been developed in this context and have been shown to be effective. Whether these therapies are more effective than the second wave therapies has not yet been fully established, but mindfulness-based interventions are superior to cognitive theory in terms of consciousness psychology and epistemology, since they adopt a metaperspective on cognitive and emotional processes (Brunnhuber & Michalsen, 2012). Recent developments in psychotherapy and mind-body medicine go even one step further. In these approaches, flourishing and eudaimonic well-being (Ryff & Singer, 2008) are the main focuses of therapy rather than a mere correction of mental health symptoms. In this “fourth-wave” psychotherapy, approaches include positive psychology interventions and spiritually informed therapies that have evolved from existential and humanistic backgrounds (Petee, 2018). In mind-body medicine, “second-generation” mindfulness-based interventions overtly include psychospiritual (e.g., mindfulness) or spiritual (e.g., belief or faith) elements and feature ethical aspects as a key component of the intervention (Van Gordon & Shonin, 2020). A central feature of these approaches is that they intend to support the suffering individual in developing to his or her fullest potential. In a systematic review of research from 1872 till 2010, the large majority of studies found that religious involvement is related to greater well-being and happiness, and more than the half of studies found less depression or faster recovery from depression in spiritually active people (Koenig, 2012). Spiritual practices and experiences mediate positive psychological traits that in turn affect emotions, cognitions, behavior, and coping styles that may lead to better mental (and physical) health (Koenig, 2011). Across different studies, spiritual meditation had a greater impact than the secular forms of meditation on psychological variables (Wachholtz & Austin, 2012).

The new Meditation Based Lifestyle Modification (MBLM) (Bringmann et al., 2021b) therapeutic program can be attributed beneficially to these recent developments. MBLM is an 8-week mind-body intervention designed for mental health care settings, which is based on classical yoga. According to classical yoga texts, yoga implements ethical living, yoga exercises, breathing practices, and meditation to still the mind in a way that allows for self-realization (Bryant, 2015). In MBLM, the thematic exploration of the ethical principles of yoga takes place in an educational and group-psychotherapeutic setting and forms the basis for a lifestyle change that incorporates both the physical and the meditative levels. In a feasibility study without a control group, depressed patients showed increased eudaimonic well-being in addition to significantly improved depressiveness after participating in MBLM (Bringmann et al., 2021b). Furthermore, participants reported an increased capacity for self-reflection, mindfulness, and self-regulation. These results could be

confirmed in a subsequent qualitative analysis, in which the high relevance of the ethical aspects for the participants and the associated reappraisal of their lives became apparent (Bringmann et al., 2021). Various components of MBLM also increased well-being and reduced stress in psychologically healthy participants (Matko et al., 2021).

Evidence of efficacy of MBLM in depressed patients has not yet been established in a prospective randomized study with active control groups. Therefore, in this study, we investigated the efficacy of MBLM in comparison to two conventional therapy programs, as they are common in clinical practice. We considered a multimodal therapy, including pharmacotherapy, psychotherapy, movement therapy, occupational therapy, and relaxation techniques as a “state-of-the-art” treatment as usual (TAU). On the other hand, we considered the mere administration of antidepressant medication as minimal therapy (CONTROL).

2 | METHODS

2.1 | Design

This three-arm, single-site, randomized controlled trial (ClinicalTrials.gov Identifier: NCT03652220) was registered before the inclusion of the first patient and conducted at the Clinic for Psychiatry, Psychosomatics, and Psychotherapy, Zschadraß, Germany from August 2018 through June 2020. All participants provided written informed consent after receiving a full explanation regarding the study protocol and before randomized assignment to treatment arms. Participants were informed of the assignment after randomization (open allocation). The study was approved by the Ethics Review Board of the University of Chemnitz University of Technology (V-276-15-PS-MBLM-D-14062018). In this study, two steps of randomization were implemented (Phases 1 and II, see also Figure 1). In Phase I (8 weeks), participants were randomized 1:1:1 into three groups: intervention group (MBLM), control group (CONTROL), and TAU. In Phase II (16 weeks), participants of CONTROL and TAU groups were randomized to TAU or TAU + MBLM (ratio 3:1 to target equal group sizes in phase II), whereas all participants previously randomized to MBLM were allocated to TAU + MBLM. In this phase, participants of all groups began or continued TAU as described above. Patients allocated to TAU + MBLM additionally participated in the 8-week MBLM program (if they had not done so during the first 8 weeks). The streamlining of the study design to two groups for Phase II was chosen primarily for clinical reasons: it was necessary to enable the patients from the CONTROL group to undergo intensified therapy after 8 weeks. In addition, due to the a priori unknown effectiveness of the program, patients from the MBLM group should also be given TAU after 8 weeks. With this design, we were able to (A) compare clinical outcomes at follow-up of patients who had received MBLM as part of their multimodal therapy and those who had not. Additionally, we could (B) compare a subgroup of patients from the prior CONTROL group who received either TAU or TAU + MBLM treatment (augmentation effect).

2.2 | Participants

Outpatients of the Department of Psychiatry, Psychosomatics, and Psychotherapy, Diakoniekliniken Zschadraß, Colditz, Germany were recruited via their attending psychiatrist and via flyers posted in the waiting room of the clinic's outpatient department. The study included outpatients who were at least 18 years old, who had been diagnosed with mild or moderate depression according to the International Classification of Diseases, Tenth Revision criteria assessed by their attending psychiatrist during a consultation, and who achieved a total score of at least 10 points in the Beck Depression Inventory (BDI-II) (Beck et al., 1996). The BDI functioned as a screening instrument before the clinical interview and did not necessarily determine the diagnosis of a mild or moderate depression. As a prerequisite, participants were asked if they were physically able to do gentle yoga exercises and to sit still for 20 min. Patients with obsessive-compulsive disorder, cerebral organic diseases, or addictive disorders, psychotic symptoms, or acute suicidality were excluded. After providing informed consent, participants completed the baseline survey including sociodemographic and psychosocial questionnaires.

2.3 | Primary and secondary outcome measures

Participants were asked to complete standardized questionnaires at four time points: at baseline before the intervention (T_0); after 4 weeks (T_1); after 8 weeks, immediately following the intervention (T_2); during follow-up, 6 months after the intervention had started (T_3).

The primary outcome measure was the change in the score of the BDI-II at T_1 and T_2 (Beck et al., 1996). The BDI-II is a 21-question multiple-choice self-report inventory, one of the most widely used psychometric tests for measuring the severity of depression. It is composed of items relating to symptoms of depression such as hopelessness and irritability and cognitions such as guilt or feelings of being punished, as well as physical symptoms such as fatigue, weight loss, and lack of interest in sex. Cut-off scores: values of 13 and less can be considered as subclinical depression; 14–19 as mild depression; 20–28 as moderate depression; and 29–63 as severe depression. The minimum clinically important difference of the BDI is reported in the literature to be a 17.5% reduction from baseline (Button et al., 2015).

Secondary outcome variables included (1) the Brief Symptom Checklist-18 (BSI-18) (Franke et al., 2017) to assess complementary information about the change in somatization, depression, and anxiety and (2) the Perceived Stress Scale-10 (PSS-10) (Cohen et al., 1983) for measuring the perception of stress. Further, secondary outcome variables assessed in this study project, including 24-h heart rate variability, qualitative data (in-depth interviews with a subset of participants), and a range of measures of spirituality (for details see the study's registry at ClinicalTrials.gov), will be discussed in separate publications. Due to the novelty of the MBLM program, we chose to extend our research questions beyond the evaluation of

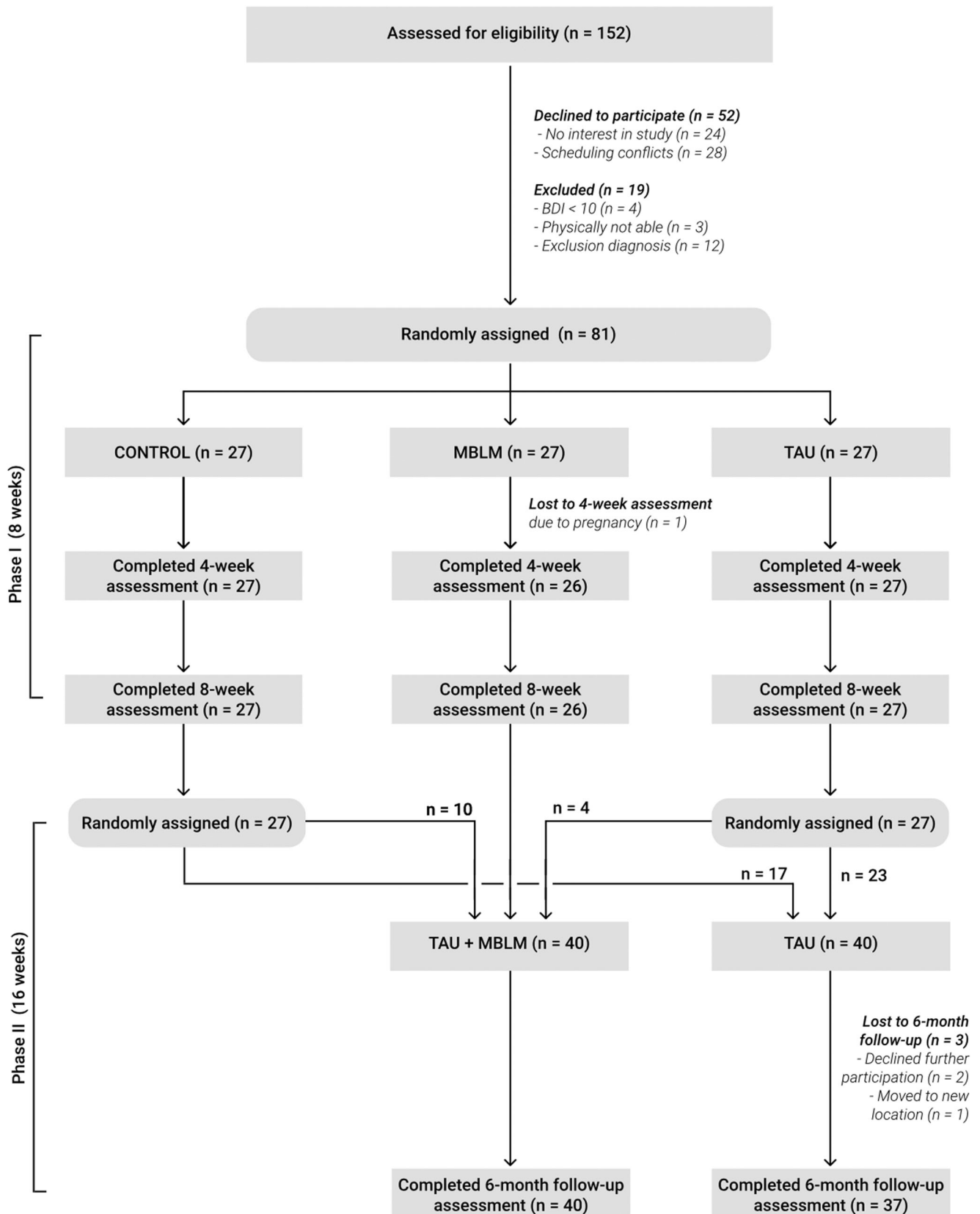


FIGURE 1 Participant flow. BDI-II, Beck Depression Inventory-II; CONTROL, drug continuation therapy; MBLM, meditation-based lifestyle modification; TAU, treatment as usual

primarily clinical parameters, which are, however, beyond the scope of this article. Adverse effects were assessed by prespecified questionnaires with a list of common problems related to yoga and meditation practice (Kessler et al., 2017; Matsushita & Oka, 2015) to be filled in at T_2 by the participants of MBLM and TAU group (see Supporting Information [Material](#) for a complete list of items). In the questionnaire, participants could retrospectively state how many days the adverse event was present (days per week, number of weeks). Adherence to home practices related to MBLM (mantra meditation, yoga, ethical living) were assessed by prestructured patient diaries that were collected on a weekly basis. Participants were asked to fill in minutes of daily practice (yoga and meditation, respectively) and to keep a diary of exercises associated with ethical living. Blinded research assistants collected patient-reported data, and research personnel blinded to group allocation entered and monitored the data.

2.4 | Study interventions

Patients were asked to participate over a period of 8 weeks (Phase I) and consecutively for another 16 weeks (Phase II) according to their allocated treatment. All involved physicians and therapists were specialists in their respective fields and had multiple years of professional experience.

2.5 | Meditation Based Lifestyle Modification (MBLM)

Participants in the MBLM group were allowed to continue their antidepressant medication (if any) and participated in the 8-week MBLM program. The MBLM program is a mind-body intervention, which includes three domains of practice, based on the eightfold path of classical yoga (Bringmann et al., 2021b): ethical living, healthy lifestyle, and mantra meditation. It consists of eight consecutive, weekly group sessions of 180 min each, and 45 min of recommended, daily home practice. Each group session (as well as training at home) includes the three domains of practice. In the first part, ethical living, the therapists introduce major aspects of yoga practice concerning virtue-based ethics, including constraints (nonviolence, truthfulness, nonstealing, nonexcess, and nongreed) and spiritual observances (purity, contentment, and transcendence). During the second part, healthy lifestyle, the participants learn breathing exercises and gentle yoga postures suitable for people with depression and anxiety. Participants also receive individualized healthy lifestyle advice based on basic Ayurvedic recommendations before the course (see Appendix A in Supporting Information [Material](#)) (Kessler et al., 2017). The third part of each group session is a mantra meditation period where participants silently recite a mantra, which they have chosen themselves from a list and learned to apply in an introductory session before the course. A detailed description of MBLM and its feasibility for

depressive disorders have been published elsewhere (Bringmann et al., 2021a, 2021b).

2.6 | Multidisciplinary psychiatric outpatient care (TAU)

During the whole study period, participants in the TAU group received an individually tailored multimodal therapy based on the national guidelines for the treatment of unipolar depression (DGPPN et al., 2015), including pharmacotherapy, psychotherapy, and accessory therapies (e.g., relaxation techniques, movement therapies, psychotherapy, and occupational therapy; for details, see Supporting Information [Data](#)). Although international standards may vary in what is considered as "TAU," we labeled the multidisciplinary psychiatric outpatient care as TAU, as it was the standard care for outpatients in the study center.

In addition to psychiatric and psychotherapeutic treatment, the multidisciplinary approach included therapies conveyed by specially trained nurses, occupational therapists, movement therapists, art therapists, and social workers. Body-oriented yoga, therapies related to mindfulness-based stress reduction (Rusch et al., 2018), and mantra meditation were excluded from the portfolio of therapies available for study participants. For analysis of therapy hours and to reduce complexity, we did not distinguish whether psychotherapy was carried out in a group setting or in single sessions. Psychotherapy was delivered nonmanualized according to the professional training of the therapists. Similarly, we did not distinguish between different types of movement therapies, occupational therapies, and relaxation techniques. Patients were allowed to switch between therapy modules during the treatment phases if indicated by their consulting psychiatrist. Exercises at home were not part of the protocol.

2.7 | Drug continuation therapy (CONTROL)

In the control group, the participants received medical advice from their psychiatrist as needed, but at least one time during the period of 8 weeks. Participants of this group were excluded from all nonpharmacological therapies. Any pre-existing antidepressant medication was continued. Adjusting the dose or changing the medication was possible to prevent or respond to severe adverse events.

2.8 | Sample size and data analysis

The primary objective was to compare the efficacy of MBLM, TAU, and CONTROL in total scores of BDI-II after 4 weeks (T_1) and after 8 weeks (T_2). As we did not have any data at the time to estimate what difference to expect between the treatment conditions, we elected to power the study to be able to detect a moderate effect size difference of $d = 0.5$ between the groups, based on reported effect sizes for yoga in depression (Cramer et al., 2013; Klatt et al.,

2016). Sample size calculation with G*Power 3.1 (Faul et al., 2007) has been performed for a repeated-measures (e.g., T_0 , T_1 , and T_2) analysis of variance (ANOVA) with an α -level of $\alpha = .05$, a power of $(1 - \beta) = 0.90$, resulting in a total sample size of $N = 72$. We expected a rather low level of 10% dropouts, considering missing side effects of intervention and extensive efforts to support patient's adherence (weekly classes, working sheets). We, therefore, planned to recruit a total of $N = 81$ patients into the study, or 27 patients for each group, respectively. For both steps of randomization and concealment of allocation, MinimPy (Saghaei & Saghaei, 2011), which implements a software-based minimization algorithm (O'Callaghan, 2014; Scott et al., 2002) was used to create homogeneous subpopulations with respect to age, gender, BDI-II score before the intervention, recurrence of depression, and adverse childhood events.

To check for balance between the study groups, we compared demographic data and other important baseline characteristics with ANOVA or χ^2 tests where applicable.

To compare the effectiveness of interventions, a repeated-measures analysis of covariance (ANCOVA) was conducted to analyze time-by-group interactions, with group allocation as the independent variable and (in subsequent models) BDI, BSI-18, and PSS-10 as the dependent variables. For the primary outcome (BDI), three time points were available for analysis (T_0 , T_1 , and T_2). For the secondary outcomes (BSI-18, PSS-10), two time points were available (T_0 and T_2). As recommended for longitudinal analysis of RCTs, all analyses were adjusted by including baseline outcome values as covariates in the model (Committee for Medicinal Products for Human Use, 2015). Before the analysis, we made sure that the specific assumptions for normality and homogeneity of variance for the ANCOVA were met.

For follow-up analyses after 6 months (T_3), we performed an exploratory analysis with the same statistical methods on subgroups of interest. We report p values and the respective partial η^2 /Cohen's d as effect size. Exploratory post hoc t tests were conducted for treatment contrasts of interest, reporting corresponding p values and Cohen's d as effect size. Bonferroni-Holm correction was used where applicable. We used R 3.6 for all our quantitative analyses and p values $< .05$ were considered significant. Outcomes were analysed on an intention-to-treat basis. Missing data were imputed using Multivariate Imputations by Chained Equations algorithm (van Buuren & Groothuis-Oudshoorn, 2011). No restrictions were imposed on the value range of the imputed results. The data that support the findings of this study are available from the corresponding author upon reasonable request.

3 | RESULTS

3.1 | Descriptive analysis

Recruitment took place from August 2018 till January 2020. The last follow-up measurements took place in June 2020. Demographic and clinical characteristics at baseline are stated in Table 1. One

participant was lost during the study during Phase I, and three participants during Phase II (Figure 1). Dropped-out participants did not differ in baseline characteristics as shown in Table 1, except for a higher rate of adverse childhood events ($p = .02$). Overall, 2.0% of all questionnaire items were missing completely at random (Little's missing completely at random test, $p = .55$) and were imputed before analysis.

3.2 | Phase I results

The baseline-adjusted analysis of the primary outcome revealed a significant interaction between time and group, $F(2,2) = 7.45$, $p < .001$, $\eta_p^2 = 0.11$, $d = 0.70$. Significant interactions were also found for MBLM vs. CONTROL, $F(1,2) = 9.91$, $p < .001$, $\eta_p^2 = 0.11$, $d = 0.70$, and MBLM versus TAU, $F(1,2) = 9.42$, $p < .001$, $\eta_p^2 = 0.10$, $d = 0.67$. This interaction was qualified by a mean decline in BDI score from baseline to 8 weeks (baseline unadjusted) of 13.1 points in participants allocated to MBLM treatment, as compared to 3.3 points in the TAU group and 1.7 points in the CONTROL group (Table 2 and Figure 2). Differences between groups for each time point are shown in Table 3.

On average, patients in the TAU group received more program hours of therapy per week than the MBLM group (MBLM: 3.0 h, $SD = 0.0$ vs. TAU: 4.0 h, $SD = 1.2$; $p < .001$). Weekly treatment in the TAU group was delivered on average as 1.4 ($SD = 0.7$) h of psychotherapy, 1.0 ($SD = 0.9$) h of movement therapy, 0.9 ($SD = 0.9$) h of occupational therapy, and 0.7 ($SD = 0.6$) h of relaxation therapy.

Participants in the MBLM group practiced daily on average 20 min ($SD = 8.95$ of mantra meditation and 22 min ($SD = 14.43$) of yoga at home. Exploratory post hoc analysis indicated a large effect of MBLM after eight weeks compared to CONTROL, whereas TAU and CONTROL did not differ significantly (Table 3). Similarly, secondary outcomes revealed significant time-by-group interactions in favor of the MBLM group for both BSI-18, $F(2,1) = 7.29$, $p < .001$, $\eta_p^2 = 0.9$, $d = 0.63$, and PSS-10 scores, $F(2,1) = 18.30$, $p < .001$, $\eta_p^2 = 0.19$, $d = 0.97$. Again, significant interactions were also found for MBLM versus CONTROL (BSI-18: $F(1,1) = 9.91$, $p < .002$, $\eta_p^2 = 0.09$, $d = 0.63$; PSS-10: $F(1,1) = 33.68$, $p < .001$, $\eta_p^2 = 0.25$, $d = 1.15$) and MBLM versus TAU (BSI-18: $F(1,1) = 11.45$, $p < .001$, $\eta_p^2 = 0.10$, $d = 0.67$; PSS-10: $F(1,2) = 19.17$, $p < .001$, $\eta_p^2 = 0.17$, $d = 0.91$). Further details and post hoc analyses are depicted in Tables 2 and 3.

3.3 | Phase II results

In analysis A, we contrasted patients who had received MBLM as a part of their treatment regime within 6 months with patients who had received any therapy but not MBLM ($N = 81$). Due to the different time courses of the therapies, we only compared T_0 with T_4 . In the 6 months till follow-up, patients in the non-MBLM group

TABLE 1 Demographic and clinical characteristics of study participants by group

Label	N		Levels	Groups		
	Total	Missing		MBLM	CONTROL	TAU
Age	81	0	Mean (SD)	49.1 (11.1)	51.0 (12.7)	45.0 (11.1)
Gender	81	0	Female	21 (77.8)	21 (77.8)	23 (85.2)
			Male	6 (22.2)	6 (22.2)	4 (14.8)
Marital status	81	0	Unmarried	2 (7.4)	5 (18.5)	7 (25.9)
			Divorced	4 (14.8)	5 (18.5)	3 (11.1)
			Married	20 (74.1)	14 (51.9)	17 (63.0)
			Widowed	1 (3.7)	3 (11.1)	0 (0.0)
Current occupation	78	3	Employed	13 (48.1)	15 (55.6)	12 (44.4)
			Unemployed	6 (22.2)	3 (11.1)	8 (29.6)
			Pension (disability)	5 (18.5)	6 (22.2)	6 (22.2)
			Pension (old age)	1 (3.7)	3 (11.1)	0 (0.0)
			(Missing)	2 (7.4)	0 (0.0)	1 (3.7)
Denomination	78	3	Catholic	1 (3.7)	0 (0.0)	0 (0.0)
			Protestant	7 (25.9)	11 (40.7)	5 (18.5)
			None	17 (63.0)	14 (51.9)	21 (77.8)
			Other	1 (3.7)	0 (0.0)	1 (3.7)
			(Missing)	1 (3.7)	2 (7.4)	0 (0.0)
Cigarettes per day	81	0	Mean (SD)	2.7 (6.0)	6.0 (7.7)	4.2 (6.8)
Alcoholic bev. per week	79	2	Mean (SD)	1.1 (1.6)	1.8 (3.3)	1.2 (1.8)
Depression type	81	0	First episode	10 (37.0)	11 (40.7)	10 (37.0)
			Recurrent episodes	17 (63.0)	16 (59.3)	17 (63.0)
Years since the first episode	81	0	Mean (SD)	6.4 (7.9)	8.2 (8.1)	10.1 (8.5)
ACE \geq 4	74	7	No	19 (73.1)	19 (76.0)	17 (73.9)
			Yes	7 (26.9)	6 (24.0)	6 (26.1)
Months of psychotherapy	81	0	Mean (SD)	25.1 (27.0)	24.1 (29.1)	30.4 (29.7)

Abbreviations: ACE, adverse childhood events; CONTROL, drug continuation therapy; MBLM, Meditation-Based Lifestyle Modification; TAU, treatment as usual.

received more hours of therapy per week than the patients who received MBLM (MBLM: 2.1 h, SD = 1.2 vs. non-MBLM: 3.2 h, SD = 1.1; $p < .001$). Significant differences regarding BDI, BSI-18, and PSS-10 were found with medium to large effect sizes for time-by-group interaction (BDI: $F(1,1) = 14.86$, $p < .001$, $\eta_p^2 = 0.09$, $d = 0.63$; BSI-18: $F(1,1) = 8.74$, $p < .001$, $\eta_p^2 = 0.05$, $d = 0.46$; PSS-10: $F(1,1) = 14.37$, $p < .001$, $\eta_p^2 = 0.08$, $d = 0.59$) and large effect sizes for post hoc differences after 6 months (Table 4 and Figure 3).

In analysis (B), we measured the differences between a small subgroup of patients from the prior CONTROL group who were

either randomized to TAU or TAU + MBLM ($n = 27$). In the 4 months between T_2 and T_3 , patients in the TAU group received more hours of therapy per week than the patients in the TAU + MBLM group (TAU: 3.5 h, SD = 1.1 vs. TAU + MBLM: 2.0 h, SD = 0.6; $p < .001$). A significant difference was found only for PSS-10 with a large effect size for time (T_2 vs. T_3) by group interaction, $F(1,1) = 9.09$, $p < .001$, $\eta_p^2 = .16$, $d = 0.87$, as well as for post hoc difference after 6 months (Table 4 and Figure 3). Mean levels of depression at baseline of Phase II (T_2) were lower in these groups compared to baseline of Phase I (mean BDI score of 21.53 vs. 25.36).

Outcome	Group	Baseline (T_0)	4 weeks (T_1)	8 weeks (T_2)	ΔM	p	η_p^2
BDI-II	CONTROL	23.30 (8.40)	20.89 (8.14)	21.59 (9.67)	-1.71	<.001	0.113
	TAU	26.04 (8.12)	24.33 (7.78)	22.70 (9.26)	-3.34		
	MBLM	26.74 (9.46)	16.81 (10.65)	13.59 (10.63)	-13.15		
BSI-18	CONTROL	24.44 (11.99)		23.04 (12.72)	-1.4	<.001	0.086
	TAU	22.70 (11.52)		21.74 (11.39)	-0.96		
	MBLM	21.70 (11.71)		12.48 (11.11)	-9.22		
PSS-10	CONTROL	27.52 (4.59)		27.15 (4.58)	-0.37	<.001	0.191
	TAU	28.26 (4.93)		27.07 (6.41)	-1.19		
	MBLM	28.04 (4.60)		20.11 (5.34)	-7.93		

TABLE 2 Effect of intervention on primary and secondary outcomes after 4 and 8 weeks; mean (SD), intention-to-treat population ($N = 81$)

Abbreviations: BDI-II, Beck Depression Inventory; BSI-18, Brief Symptom Index-18; ΔM , change of mean score between 8 weeks and baseline; η_p^2 , partial squared eta for baseline-adjusted model; p , p value; PSS-10, Perceived Stress Scale-10.

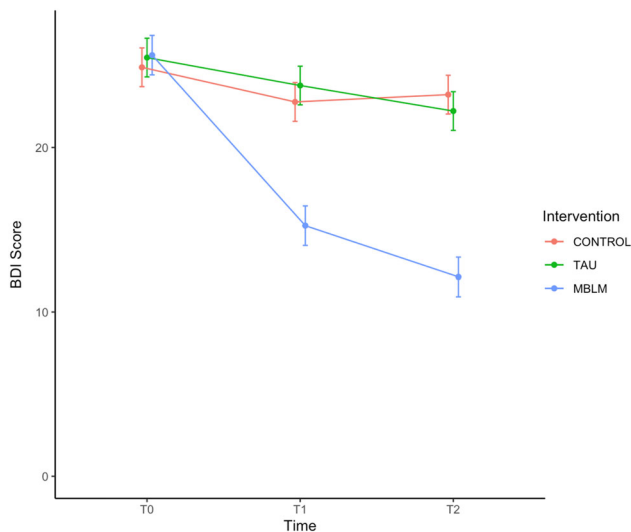


FIGURE 2 Effects of primary outcome after 4 and 8 weeks. Effects of primary outcome grouped by type of intervention at baseline before the intervention (T_0); after 4 weeks (T_1); after 8 weeks, immediately following the intervention (T_2). Error bars represent standard errors (SE). BDI-II, Beck Depression Inventory-II; CONTROL, drug continuation therapy; MBLM, Meditation-Based Lifestyle Modification; TAU, multimodal treatment

3.4 | Adverse events

The most common adverse events experienced by the participants during Phase I of the study are detailed in Table 5 (for a complete list, see Supporting Information Data and Table 2). No serious adverse events occurred. The pattern of adverse events differed between the MBLM and TAU groups. More participants of the TAU group expressed symptoms compared to the MBLM group (on average, 4.8 vs. 3.3 participants per symptom; $p < .001$). Also, the mean duration of adverse symptoms in the TAU group lasted longer than in the MBLM group (0.9 vs. 0.5 days, $p < .001$).

4 | DISCUSSION

Patients who participated in the MBLM program during the 6-month study period showed higher improvements in self-rated depression, psychosomatic symptoms, and stress at 4 weeks, 8 weeks and 6 months, compared with the other group(s). The improvement in the primary outcome (self-rated depression levels) was of clinical relevance at both time points, both within-group and between-group comparisons. After 8 weeks, we saw a clinically important reduction of depression levels in the MBLM group of 49% versus 13% in the TAU group. This difference was still clearly visible after 6 months (47% vs. 19% reduction).

MBLM showed greater effects than body-oriented yoga (Brinsley et al., 2020; Cramer et al., 2017; Gong et al., 2015; Klatt et al., 2016) and meditative movement (Zou et al., 2018) compared to the existing literature. This is in line with previous findings that combined interventions incorporating multiple components usually outperform simpler yoga or meditation interventions (Matko et al., 2021). On the other hand, this study also showed larger effect sizes than found in a meta-analysis of MBCT-D (Lenz et al., 2016). We hypothesize that these can be attributed to additive and synergistic effects caused by the ethical components of yoga as implemented by MBLM. The ethical component of yoga, on which MBLM is based, is still strongly underrepresented in current research. But the benefit of ethics in mind-body interventions is currently discussed in the mindfulness literature and in theoretical models (Matko et al., 2021). Preliminary clinical studies also suggest additional benefits on well-being and prosocial behaviour (Andy Smith et al., 2011; Chen & Jordan, 2020). With respect to MBLM, the additive effects of the ethics modules on postural yoga and meditation has already been shown in healthy participants (Matko et al., 2021). In a feasibility study with depressive patients and in the qualitative evaluation for a subgroup of patients in the present study, the ethical component of MBLM was identified as a key factor in individual empowerment and appreciation of one's

TABLE 3 Post hoc analyses

Outcome	Contrast	4 weeks (T_1)			8 weeks (T_2)		
		\widehat{DM}	d_c	p	\widehat{DM}	d_c	p
BDI-II	CONTROL versus TAU	-1.29	-0.2098	.886	1.04	0.1686	.886
	CONTROL versus MBLM	6.78	1.0990	<.001	10.70	1.7356	<.001
	TAU versus MBLM	8.07	1.3088	<.001	9.66	1.5670	<.001
BSI-18	CONTROL versus TAU				-0.174	-0.0276	.919
	CONTROL versus MBLM				8.240	1.3036	<.001
	TAU versus MBLM				8.414	1.3312	<.001
PSS-10	CONTROL versus TAU				0.654	0.1835	.502
	CONTROL versus MBLM				7.443	2.0897	<.001
	TAU versus MBLM				6.789	1.9062	<.001

Abbreviations: BDI-II, Beck Depression Inventory-II; BSI-18, Brief Symptom Index-18; d_c , Cohen's d ; \widehat{DM} , estimated difference of means; p , Bonferroni-Holm-adjusted p value; PSS-10, Perceived Stress Scale.

TABLE 4 Follow-up results for exploratory analyses

Outcome	Group	Baseline (T_0)	8 weeks (T_2)	6 months (T_3)	ΔM	p	η_p^2	\widehat{DM}	d_c	p
(A) Phases I and II: MBLM versus non-MBLM; mean (SD), intention-to-treat population ($N = 81$)										
BDI	Without MBLM	24.80 (8.71)		20.80 (10.95)	-4.00	<.001	0.09	8.00	1.18	<.001
	With MBLM	25.90 (8.76)		13.68 (10.36)	-12.22					
BSI-18	without MBLM	23.88 (12.27)		22.10 (14.27)	-1.78	.004	0.05	7.56	0.98	<.001
	With MBLM	22.05 (11.09)		13.10 (10.14)	-8.95					
PSS-10	Without MBLM	28.25 (4.93)		25.85 (6.59)	-2.40	<.001	0.08	4.82	1.22	<.001
	With MBLM	27.63 (4.43)		20.54 (5.64)	-7.09					
(B) Phase II: TAU versus MBLM + TAU; mean (SD), intention-to-treat population ($N = 27$)										
BDI	TAU		21.76 (10.42)	19.88 (11.00)	-1.88	.257	0.03	3.89	0.66	.105
	TAU + MBLM		21.30 (8.77)	15.60 (9.98)	-5.70					
BSI-18	TAU		23.59 (14.86)	24.18 (15.53)	0.59	.084	0.06	5.28	1.01	.015
	TAU + MBLM		22.10 (8.58)	17.50 (8.59)	-4.60					
PSS-10	TAU		26.88 (5.16)	26.47 (4.50)	-0.41	.004	0.16	4.27	1.65	<.001
	TAU + MBLM		27.60 (3.60)	22.80 (4.83)	-4.80					

Abbreviations: BDI-II, Beck Depression Inventory; BSI-18, Brief Symptom Index-18; d_c , Cohen's d ; ΔM , change of mean score between 8 weeks and baseline; \widehat{DM} , estimated difference of means at T_3 ; η_p^2 , partial squared eta for baseline adjusted model; p , p value; PSS-10, Perceived Stress Scale.

own strengths (Bringmann et al., 2021a; Bringmann et al., 2021). Another difference between MBLM and TAU, which could explain the contrast in efficacy, was the dosage of therapy. Although patients in the TAU group received about 1 h more therapy per week, participants in the MBLM group practiced yoga, meditation, and the implementation of ethical principles at home for about 4 h per week. Repetition and steady practice are traditionally important in the yoga tradition (Carpenter, 2003) and it is known from meditation studies that the effect on mental health increases with ongoing practice (Sedlmeier et al., 2018).

Unexpectedly, there was no significant difference between TAU and CONTROL and the improvement of the TAU group after 8 weeks

was relatively small. This may have led to an overestimation of the therapeutic effect of MBLM. We found some evidence for the cause in a qualitative comparison of TAU and MBLM patients, in which TAU patients reported feeling partly uncomfortable in the therapy because the therapy did not seem appropriate to them. MBLM patients, on the other hand, felt inspired and appropriately cared for in the MBLM program (Gross et al., 2021). Another reason might be the patients' prior therapy experience. As shown in Table 1, almost two-thirds of the patients suffered from recurrent depression. This means that these patients had a history of previous experience with therapies from TAU. Thus, a lower expectation of efficacy of TAU may have played a role. Finally, patients in the TAU group reported

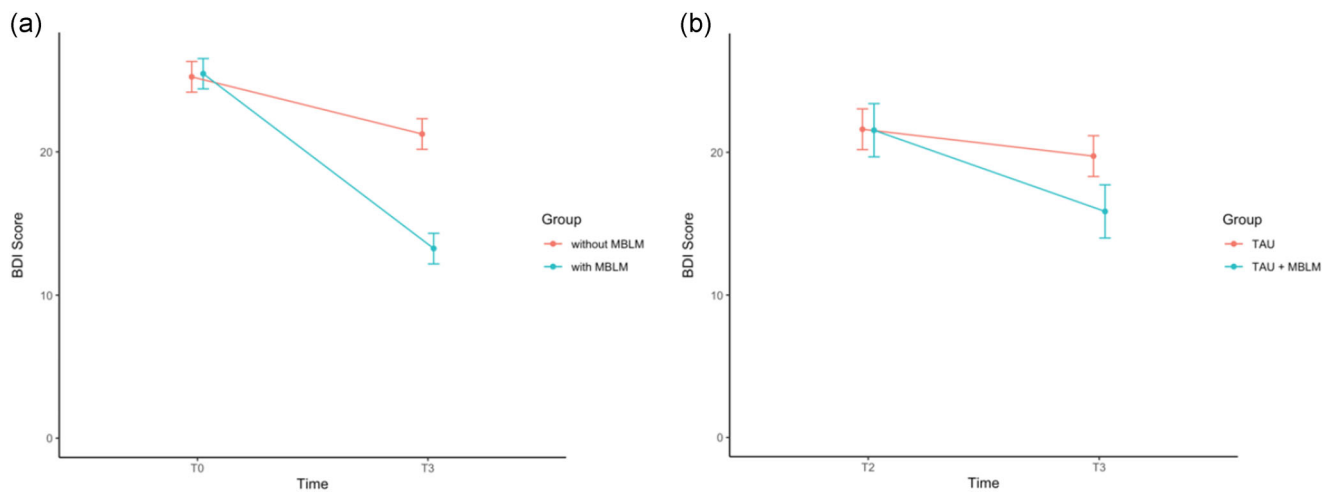


FIGURE 3 Effects of the primary outcome in follow-up analyses. Effects of primary outcome grouped by type of intervention at baseline before the intervention (T_0); during follow-up, 6 months after the intervention had started (T_3). Error bars represent standard errors (SE). BDI-II, Beck Depression Inventory; MBLM, Meditation-Based Lifestyle Modification; TAU, multimodal treatment.

TABLE 5 Top 10 adverse events after 8 weeks (T_2)

Symptom	<i>d</i>	<i>n</i>
MBLM		
Recollection of bad experience	1.3	8
Feeling of exhaustion	1.5	5
Need for continuous meditation	0.2	4
Palpitation	0.2	4
Greater self-criticism	1.4	3
Inner tension	1.3	3
Feeling of illness	0.9	3
Difficulty in feeling comfortable in the world	0.9	3
Tinnitus	0.7	3
Hypersensitivity/rejection of urban life	0.7	3
TAU		
Feeling of exhaustion	2.8	10
Inner tension	3.6	6
More fear/anxiety/depression	2.3	6
Headache	1.9	6
Recollection of bad experience	0.9	5
Palpitation	1.1	5
Dizziness	1.9	5
Diarrhea	0.8	5
Muscular pain	1.5	4
Tinnitus	1.7	3

Abbreviations: *d*, average number of days the symptom was perceived during the 8 weeks of treatment; *n*, number of participants stating the adverse event. Items are sorted by *n* in descending order.

more and longer-lasting side effects, which may also have had a negative impact on treatment outcomes.

Our study was the first trial to evaluate the efficacy of the novel MBLM program in depression. The randomized-controlled design and low drop-out rates allowed a meaningful and reliable evaluation. However, some limitations need to be addressed. The study was designed specifically for depressed patients with an interest in yoga or meditation. Therefore, the results cannot be generally extended to depressed outpatients. Mind-body programs of a different type of cultural adaptations might be important for other populations. From a methodological point of view, the sole use of client-rated questionnaires is problematic due to introspective bias (which, however, can lead to both aggravation and amelioration of symptoms). Also, the trial was conducted in one center by the developers of the MBLM program, possibly inflating effect sizes due to allegiance effects. The aggregation of the three initial groups to two groups after 8 weeks was problematic for the long-term 6-month follow-up assessment. Since more patients from the previous CONTROL group were randomized to the group receiving TAU, the effects of TAU may have been underestimated at 6 months follow-up. Also, expectations of the MBLM program as a novel therapy may have positively biased the effects. Furthermore, it was not monitored whether patients in the TAU group regularly performed exercises at home (e.g., sports or relaxation techniques they had learned in therapy). This would, however, weaken the aforementioned argument of a higher therapeutic dose of MBLM and support greater efficacy of MBLM. Finally, given limited resources, only self-assessment questionnaires were used for the quantitative evaluation. This may have led to an underestimation of treatment effects in the TAU group, based on the lower satisfaction of TAU participants discussed earlier.

The positive study results of MBLM support the need for further research and clinical application of traditional whole system medicine in general, as its potential is not yet being fully realized among most

integrative practices (Mills et al., 2017). MBLM is an example of a more holistic approach based on classical yoga and ayurvedic medicine, which blends into recent developments of second-generation mind-body intervention and fourth-wave psychotherapy that are resource-oriented, strengthen self-efficacy, and are directed toward flourishing (Garcia-Toro & Aguirre, 2007; Hatala, 2013). Whole system approaches may have the potential to address the multifactorial conditions of depression in a more comprehensive way than conventional therapies. Specifically, the ethical and philosophical aspects of underlying traditions like yoga or other meditative practices are underrepresented in research of mind-body interventions and should be further investigated to test their therapeutic use. Follow-up studies should replicate the results of the present study or implement MBLM in other populations and conditions.

Overall, the results support the use of MBLM in depressed patients. Further high-quality controlled clinical studies including qualitative research are needed to investigate the specific and unspecific effects of the MBLM program in depression and other medical conditions. Furthermore, the effects of MBLM support the idea that research in mind-body medicine should also address the traditional background of interventions and examine their contextual factors for their potential therapeutic effects. In addition to efficacy studies, more theory-driven fundamental research is also required to advance the field of research adequately.

ACKNOWLEDGMENTS

We would like to thank Chief Physician Oliver Somburg for his friendly support for our study at the trial site. This project was funded by Karl and Veronica Carstens Foundation under Award Numbers KVC 0/098/2018.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

ETHICS STATEMENT

Ethics approval was granted by the Ethics Review Board of the University of Chemnitz University of Technology (V-276-15-PS-MBLM-D-14062018).

AUTHOR CONTRIBUTIONS

Holger C. Bringmann conceptualized and designed the study under the supervision of Andreas Michalsen and Peter Sedlmeier. Stefan Brunnhuber supervised ethical and regulatory guidelines on the trial site. Holger C. Bringmann, Peter Sedlmeier, Andreas Michalsen, Michael Jeitler, Christian S. Kessler, and Benno Brinkhaus contributed to statistical analysis and reporting. Holger C. Bringmann wrote the first draft of the manuscript. All authors worked on the final version of the manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

How to cite this article: Bringmann, H. C., Michalsen, A., Jeitler, M., Kessler, C. S., Brinkhaus, B., Brunnhuber, S., & Sedlmeier, P. (2022). Meditation-based lifestyle modification in mild to moderate depression—A randomized controlled trial. *Depression and Anxiety*, 1–13. <https://doi.org/10.1002/da.23249>

2.4 "Endlich im Frieden mit mir selbst sein": Eine qualitative Studie über die Erfahrungen mit der Meditationsbasierten Lebensstilmodifikation bei leichten bis mittelschweren Depressionen

Bei dieser Studie handelt es sich um eine qualitative Auswertung für eine Subpopulation der Teilnehmer*innen der im letzten Abschnitt dargestellten Studie. Ziel war es, besser zu verstehen, wie depressive Patient:innen, die MBLM als Behandlung erhielten, die intra- und interpersonellen Ergebnisse ihrer Praxis erleben.

Übernommen aus der Zusammenfassung der Veröffentlichung:⁹⁴ „Im Rahmen einer größeren randomisierten kontrollierten Studie zu MBLM bei ambulanten depressiven Patienten wurde bei einer Teilstichprobe (n = 12) ausführliche Interviews durchgeführt. Um kurz- und langfristige Auswirkungen zu ermitteln, wurden Kohorten zu zwei verschiedenen Zeitpunkten nach Beginn der Intervention befragt (T1 = 8 Wochen; T2 = 6 Monate). Die Transkripte der Interviews im Wortlaut wurden mit Hilfe der thematischen Analyse ausgewertet. Ergebnisse: In den Interviews kristallisierten sich drei Themen heraus: (1) Aufarbeitung vergangener und gegenwärtiger Lebensmuster, die zu einer Reflexion über die eigenen Werte führt; (2) Gelassenheit, die durch Zustände der Ruhe, wachsender Akzeptanz und der Fähigkeit, Grenzen zu setzen, erreicht wird; und (3) achtsames Leben, das sich in erhöhter Selbstwahrnehmung, mehr Präsenz und bewussten Interaktionen ausdrückt. Die ethische Komponente des MBLM wurde als Schlüsselfaktor für die individuelle Befähigung und Wertschätzung der eigenen Stärken identifiziert. Systematische Veränderungen in der Bedeutung der berichteten Themen nach 6 Monaten (T2) spiegeln die nachhaltige Wirkung der Intervention wider. Schlussfolgerungen: Die Ergebnisse sprechen eindeutig für den Nutzen von MBLM bei der Behandlung von Depressionen. Insbesondere die explizite therapeutische Umsetzung der tugendbasierten Ethik bietet eine wertvolle Ergänzung zu bisherigen Yoga- und Meditationsprogrammen.“

“To Be Finally at Peace with Myself”: A Qualitative Study Reflecting Experiences of the Meditation-Based Lifestyle Modification Program in Mild-to-Moderate Depression

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Abstract

Background: Meditation-Based Lifestyle Modification (MBLM) is a new mind–body intervention that is based on classical yoga; it implements virtue-based ethical living, physical yoga, and meditation in a therapeutic context. This qualitative study aimed at understanding better how depressive patients who received MBLM as a treatment experience intra- and interpersonal outcomes of their practice.

Methods: In a larger randomized controlled trial of MBLM in depressive outpatients, a subsample ($n=12$) completed in-depth interviews. To determine short-term and long-term effects, cohorts were interviewed at two different times after intervention onset ($T_1=8$ weeks; $T_2=6$ months). Verbatim interview transcripts were analyzed by using thematic analysis.

Results: Three themes emerged in the interviews: (1) Reappraisal of past and present life patterns, leading to a reflection on one’s own values; (2) Serenity, attained by states of calm, growing acceptance, and the ability to set boundaries; and (3) Mindful living as expressed by increased self-awareness, being more present, and conscious interactions. The ethical component of MBLM was identified as a key factor in individual empowerment and appreciation of one’s own strengths. Systematic changes in the importance of reported themes after 6 months (T_2) reflected the sustained effects of the intervention.

Conclusions: The findings speak clearly for the benefits of MBLM in the treatment of depression. In particular, the explicit therapeutic implementation of virtue-based ethics offers a valuable addition to previous yoga and meditation programs. Clinical Trials.gov ID: Clinical Trial Registration number: NCT03652220

Keywords: qualitative analysis, thematic analysis, yoga, virtue ethics, meditation, lifestyle modification

Introduction

RECENT RESEARCH HAS SHOWN the positive impact of yoga in the treatment of different mental health conditions.^{1,2} In particular, the treatment of depression has been investigated through a larger amount of quantitative and qualitative analyses in different populations.^{3,4} Commonly, yoga practices in mental health care focus on physical exercises,

breathing techniques, and, to some extent, meditation techniques.⁵ These primarily body-oriented techniques contribute to physiological and psychological pathways in alleviating depression: At the physiological level, they likely improve mood based on physiological mechanisms that are related to stress-reducing and anti-inflammatory modulations of the autonomic nervous system and neuroendocrine circuits,⁶ presumably mediated by epigenetic mechanisms.⁷ At the

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psychological level, body-oriented yoga has positive effects on body awareness and mindfulness, and it leads to feelings of connectedness, reappraisal, and improved coping.^{8,9} However, body-oriented aspects represent only part of yoga in the traditional understanding of it as a spiritual practice and path to self-realization.¹⁰ Our work extends research to more traditional—ethical, spiritual, and meditative—aspects of yoga to unveil potentials of yoga practice that have not yet been tapped in mental health care.

What is traditional yoga about? The most authoritative and seminal text answering this question is the *Yoga Sutras* by Patanjali, in which preexisting traditions have been collated and systemized.^{11(p. xxxiii)} Yoga is defined as a primarily meditative practice, by which the mind is stilled to achieve self-realization. The term “self” refers here to “pure consciousness” or innermost self, loosely related to the soul in Western Greco-Abrahamic traditions.^{11(p. xvii)} From a psychological perspective, the humanistic concept of self-actualization is, to some extent, comparable to that of self-realization in the eastern traditions.¹² Yoga can be interpreted as a developmental process that facilitates self-actualization, which, in Maslow’s hierarchy of needs,¹³ describes the attainment of one’s full potential as a human being—a goal that is highly relevant in the psychotherapy of depression.¹⁴ In fact, in yoga psychology, the practitioner ultimately even transcends fulfillment on a personality level, which has been mentioned by Maslow in his later thoughts as a final motivational step beyond self-actualization.¹⁵

In addition to yoga postures and breathing exercises (*asana* and *pranayama*), the yoga sutras name further limbs of yoga’s 8-fold path to self-realization: inter- and intrapersonal virtue-based ethics (*yama* and *niyama*) and four stages of meditative practice (*pratyahara*, *dharana*, *dhyana*, and *samadhi*). From a perspective of positive psychology, moral virtues and character strengths have been widely recognized and their contribution in depression treatment is well founded.¹⁶ Regarding meditation, recent meta-syntheses of randomized controlled trials unanimously concede that meditation has substantial beneficial effects on depressive symptoms in clinical populations.^{17,18}

Meditation-Based Lifestyle Modification (MBLM) is a new therapy developed for mental health care,¹⁹ in which all eight aspects of classical yoga have been integrated and that has been shown to be feasible in the treatment of patients with mild-to-moderate depression.²⁰ The MBLM goes beyond the third wave of behavioral therapy,²¹ seeing itself as representative of more recent developments (second generation mindfulness-based interventions).²² These focus on human virtues, individual strengths, and resilience in the sense of positive psychology; include the body in the individual process of becoming conscious (embodiment); and are overtly spiritual (but conveyed in a strictly non-dogmatic and non-sectarian way).

Mixed methods have proven helpful in understanding complex mind–body interventions such as MBLM. Qualitative approaches aid comprehensive interpretation of intangible experiential information, which is particularly relevant to mind–body practices.²³ A recent synthesis of 11 qualitative studies explored the lived experience of yoga practice for people with depression, posttraumatic stress disorder, and anxiety disorders.⁴ In these studies, the interventions were usually physical yoga exercises with no ex-

plicit focus on ethical and meditative aspects. To evaluate the impact of these ethical and medicative components, we present qualitative data generated through in-depth interviews of psychiatric outpatients with mild-to-moderate depressive disorder who participated in the MBLM program.

The aim of this study was to better understand how MBLM practitioners with depression perceive intra- and interpersonal outcomes of their practice (including subjective assessments of how well it worked), and to discuss these in the light of the existing qualitative findings.

Methods

Design and setting

This qualitative study was part of a larger randomized controlled study, Meditation-Based Lifestyle Modification in Depression (MBLM-D), which was conducted from August 2018 to June 2020. The study was registered at clinicaltrials.gov. All participants completed informed consent forms before the study. All methods used in this study were approved by the Ethics Review Board of University of Chemnitz University of Technology (V-276-15-PS-MBLM-D-14062018). In the MBLM-D study, outpatients at a psychiatric clinic were recruited to investigate the effectiveness of MBLM in depression. The patients were recruited via their attending psychiatrist and via fliers posted in the waiting room of the outpatient department. The study included outpatients who were at least 18 years old, who had been diagnosed with mild-or-moderate depression, and who achieved a total score of at least 10 points in the Beck Depression Inventory (BDI-II,²⁴ questionnaire for assessing subjective depression). Participants were included only if they were physically able to do gentle yoga exercises and to sit still for 20 min. Patients with obsessive-compulsive disorder, cerebral organic diseases, or addictive disorders, psychotic symptoms, or acute suicidality were excluded.

Participants were assessed quantitatively at three points: at baseline, before the intervention (T_0); post-test, immediately after the intervention (T_1); and during follow-up, 4 months after the intervention had ended (T_2). At the first visit (T_0), within 1 week before the MBLM program started, participants provided informed consent and completed a baseline survey, including sociodemographic and psychosocial questionnaires. The participants ($N=81$) were randomized into three treatment groups: (1) MBLM program, (2) tailored psychiatric–psychotherapeutic therapy, and (3) drug continuation therapy (Fig. 1). The intervention lasted 8 weeks.

For this qualitative study, we interviewed participants either post-test (T_1) or at follow-up (T_2), to identify any differences between short-term and long-term effects of the intervention. We interviewed only participants from the MBLM program, as we were interested in their subjective theories on the efficacy and working mechanisms of this specific treatment. Participants were contacted and interviewed consecutively after the first patient in the MBLM arm reached the 6-month follow-up (T_2).

Sample

A total of 12 patients (11 = female; 1 = male) aged 30–69 years (mean = 54; SD = 11.23) were interviewed for the present qualitative analysis. Patients were diagnosed with

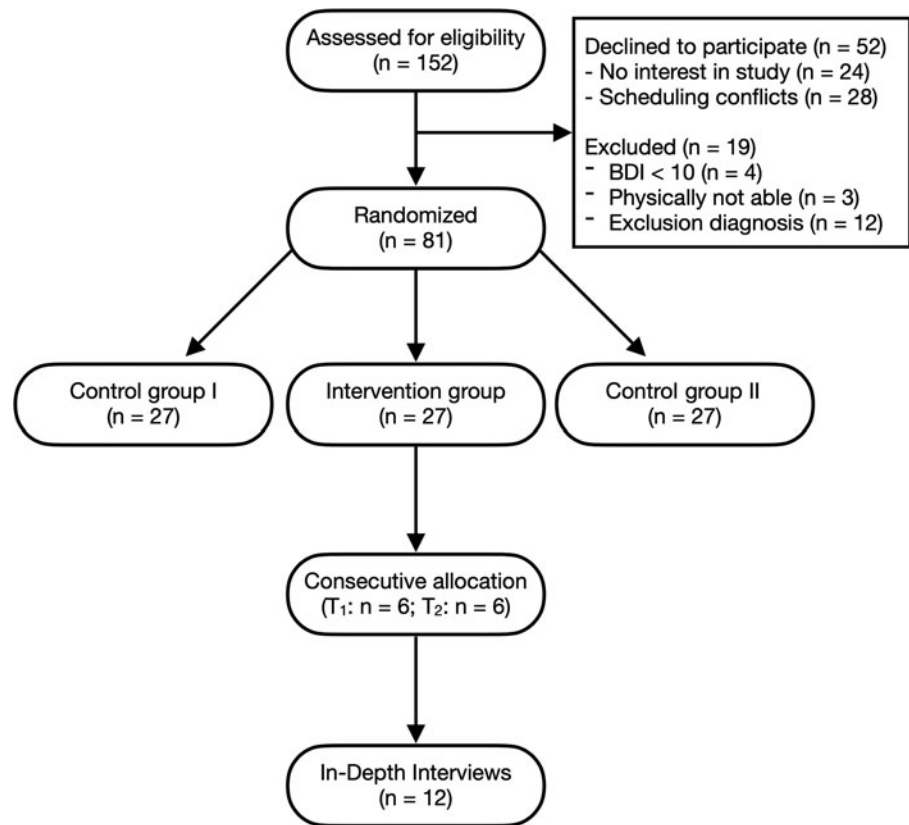


FIG. 1. Participant flow. BDI, Beck Depression Inventory.

depression according to ICD-10 criteria (mild=2; moderate=10). Nine patients (75%) had recurrent episodes of depression (mean number of episodes=2.58; SD=2.47), and three of these patients had psychiatric comorbidities (two patients with somatoform disorders, one patient with posttraumatic stress disorder). All patients had been diagnosed with depression for at least 1 year (mean=9.67, SD=10.65) and had received psychotherapy in the past (mean=33.5 months; SD=30.82). Six patients received regular antidepressant medication, and three of those also received neuroleptic medication. Seven patients reported irregular yoga practice in the past, and none of the patients reported practicing meditation in the past.

Intervention

The MBLM program¹⁹ consists of eight consecutive, weekly group sessions of 180 min each, and 45 min of recommended, daily home practice. Each group session (as well as training at home) includes three domains of practice, based on the 8-fold path of classical yoga: ethical living, healthy lifestyle, and mantra meditation. In the first part, ethical living, the therapists present the major aspects of yoga practice regarding virtue-based ethics, including constraints (nonviolence, truthfulness, non-stealing, non-excess, and non-greed) and spiritual observances (purity, contentment, and transcendence). The topics change each week and the approach is educational and psychotherapeutic, with group discussion, considering participants' indi-

vidual processes, and deepening them through mindful living exercises for home practice. During the second part, healthy lifestyle, the participants learn breathing exercises and gentle yoga postures that are suitable for people with depression and anxiety.^{25,26} The therapist demonstrates all exercises and supports the participants by giving corrections if necessary. Participants also receive individualized healthy lifestyle advice based on basic Ayurvedic recommendations before the course. The third part of each group session is a mantra meditation period where participants silently recite a mantra, which they have chosen themselves from a list and learned to apply in an introductory session before the course.

Data collection

We created a semi-structured interview guideline, including topics that focused on subjectively perceived intra- and interpersonal outcomes of the participant's MBLM practice. The topics were inspired by the results of a previous feasibility study²⁰ and consensually developed by the research team. They referred to general perceptions about program-related changes in everyday life, depressive symptoms, and spirituality (Table 1). The topics were addressed in no specific order, but adapted to the individual course of the conversation, to create the most natural dialogue possible. Finally, the interviewees were offered space for any additional topics. Interviews typically lasted for about 45 min, were audiotaped, and were then transcribed.

TABLE 1. INTERVIEW GUIDELINES

<i>Topics addressed, outlined by example opening questions</i>	
1.	How did you experience and evaluate the intervention in general?
2.	What was your experience with the different parts of the program?
3.	What, if any, changes do you perceive in everyday life?
4.	What, if any, new skills have you gained (intra- and interpersonal)?
5.	How did the intervention affect your depressive symptoms?
6.	What did you suffer most from? Do you perceive a change in this regard?
7.	Would you say your perspective on life has changed since then?
8.	Do you believe in a higher power in life? Do you perceive a change in this regard?

The opening questions were not necessarily asked verbatim or in that particular order. It was more important to address the topic of each question in general, following the natural flow of conversation as directed by the interviewees.

Data analysis plan

Data analysis was subjected to thematic analysis to extract overarching themes, guided by Braun and Clarke's methodology.²⁷ The approach consisted of six steps: (1) transcribing, multiple reading, and writing down of comments to familiarize oneself with the data; (2) generating initial codes through systematic identification of text passages (an inductive approach was used, since the aim was not to test a theoretical framework, but to describe the data comprehensively); (3) condensing by classifying codes into potential higher-level themes and collating all relevant data; (4) aligning the themes with individual coded text passages of an interview and then with the entire data set (in this phase, a thematic map was created to illustrate connections, groupings, and hierarchies); (5) naming and defining the themes; and (6) writing the analysis report, enriched with excerpts from the interviews.

The software f4analyse (version 2.5.4.0) was used to manage and analyze the data. JV and JG conducted the interviews and engaged in a recursive process of consensual coding to increase intercoder reliability. JV analyzed the first $n=6$ (three conducted at T_1 and three at T_2) interviews and created an initial thematic map. Based on the code system of these interviews, HB analyzed the remaining $n=6$ (three conducted at T_1 and three at T_2) interviews and created a final thematic map of the entire data set. In addition, JG checked the coding process with the first $n=6$ interviews by recursive consensual coding to increase the intercoder reliability. Researchers experienced in qualitative data analysis (K.M. and P.S.) supervised and evaluated the process.

Results

Thematic analysis of the interviews with participants in the MBLM program revealed three key themes: (1) reappraisal, (2) serenity (3), and mindful living. All themes

were further differentiated into subthemes (Fig. 2): (1.1) Recognizing past cognitive and behavioral patterns; (1.2) Recognizing new opportunities; (1.3) New values; (2.1) Experiencing calm; (2.2) Recognizing and setting boundaries; (2.3) Acceptance; (3.1) Self-awareness; (3.2) Being present; (3.3) Conscious interactions. Each theme is presented in turn next, and the frequencies with which they were mentioned are shown in Figure 2. At the times when the participants were interviewed, no different themes emerged at T_2 compared with T_1 , but quantitative differences were evident (see Result section). In addition to the quotes in the results section, Table 2 contains statements from the participants to support each summary.

Reappraisal

Reappraisal was identified as the most dominant theme. All participants reported that the course stimulated them to engage with their lives, more precisely with ethical living, although this was more marked at T_2 . In doing so, they considered both their past and present lifestyles in terms of ethical living and reported on new opportunities and values that emerged for them.

“I have become aware of so many things about ethical living; I never paid attention to how important it is before.” (56 years old, T_2)

Recognizing past cognitive and behavioral patterns. During the MBLM course, participants became aware of the basic behaviors and experiences that had caused suffering or difficulties in their previous lives. They mentioned low self-esteem, lack of self-congruence, feeling controlled by others, and aggressiveness toward others.

“My self-esteem and self-confidence had hit rock bottom. And I really had to face up to that here” (63 years old, T_2)

The process of confronting one's own past was repeatedly experienced as painful:

“First of all, THINKING about the fact that you did totally messed things up, that really did hurt a bit.” (53 years old, T_2)

Instead of avoiding these uncomfortable issues, participants were intrinsically motivated to embrace this challenge to reflect beyond the 8 weeks of the course:

“I also want to understand a lot of things and also, because of these questions I want to work on, [...] where I tell myself that I can really calmly and consciously look at it, and think about it.” (59 years old, T_1)

Participants continued to reflect in this way, as is confirmed by their statements at T_2 . Most of them stated that since taking part in the MBLM course they had become more aware not only of their own actions, but also those of the people around them, and would make decisions based on this, as one participant vividly expressed:

“That wouldn't have occurred to me before, I used to go on holiday without thinking about it, but when I'm flying somewhere now, I wouldn't take this all-inclusive [last time we went] we sat there and said: ‘We don't even know what you need it for. We don't want to go on vacation and just eat our fill all day, do we?’ [...] I wouldn't have thought like that last year even IN A DREAM and sometimes I think: ‘You've heard that here somehow.’” (48 years old, T_2)

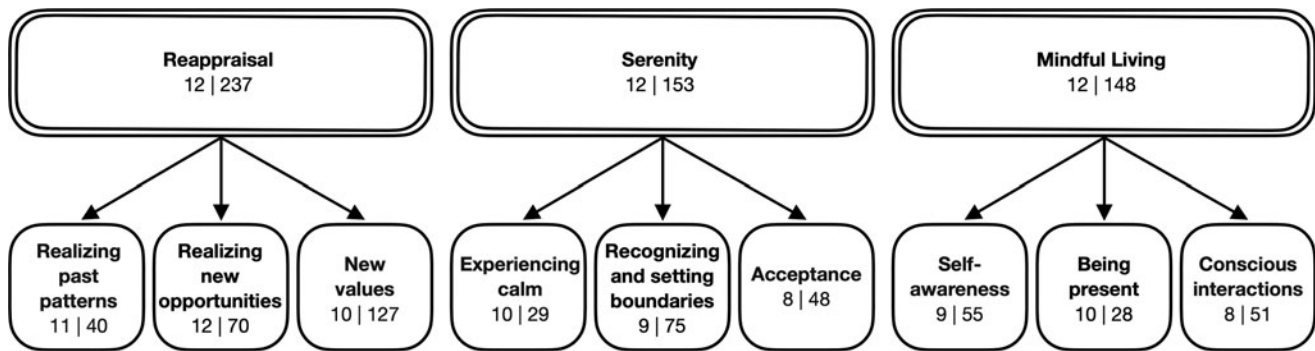


FIG. 2. Themes (*upper row*) and corresponding subthemes (*lower row*). For each entry, two numbers $n | s$ are given: n denotes the number of participants talking about that theme, and s denotes the total number of statements that have been assigned to that particular (sub)theme.

The only man and oldest participant in the sample pointed out that despite his advanced age, certain aspects of ethical living were new to him; these themes had helped him to sort things out and relate values better. At T_1 , although they had taken up the challenge to reflect on their past, some participants doubted whether a fundamental lifestyle change at an advanced age really made sense and whether applying the virtues in Western culture was utopian.

“I question a lot of things that now, that [...] actually I’ve lived through my whole life like this, it’s sometimes not all that good [...] because, yes you question a lot, you’ve already gone a certain way and say [...] Is it worth starting over?” (59 years old, T_1)

In contrast, after 6 months, participants reported entirely positive effects of the reflection process.

Recognizing new opportunities. The course topics not only encouraged people to come to terms with the past, but they also led them to proactively reflect on their own behavior in everyday life.

“Yeah, so this self-study, that’s something, yeah, when I lie in bed at night and think: ‘How could you have done it differently?’” (48 years old, T_2)

This reflection led to more inner clarity and also the courage to take appropriate opportunities for change.

“It has changed that I [...] that everything has become much clearer to me. I have to say.” (55 years old, T_2)

During the course, most participants became aware of intra- and interpersonal mechanisms that can promote a lifestyle with greater eudaimonic well-being.

“the connection between gratitude and contentment, that’s always the ‘aha,’ like a light going on in your head.” (61 years old, T_1)

“And I notice that if I am more responsive to him [life partner], which I can do well at the moment, we quickly find the connection to each other.” (30 years old, T_1)

The overall picture that emerged from the interviews at T_2 was that participants’ experiences had settled, deepened, and occupied a larger space in their own lives:

“my way of life has completely changed.” (55 years old, T_2)

New values. In response to the opening question on perceived changes in daily life, interviewees reported a number of intentional and motivational changes regarding their values at both T_1 and T_2 . Half of the respondents described a desire for more congruence between lived and felt realities in life:

“Yes, this coming to terms with myself, being at peace with myself, that is a very important [...] life lesson for me. Being at peace with myself at last.” (59 years old, T_1)

Some participants expressed gratitude for the opportunities and resources already available in their own lives:

“You can be so grateful and, and, and sit down and smile and say ‘You don’t really have anything to do. Do everything you enjoy, everything.’” (61 years old, T_1)

Several participants mentioned satisfaction as a new value, noting in this context that material wealth no longer played such an important role in their hierarchy of values:

“In the old days, that is, a few months ago, I would have been satisfied with a pile of money that meant I could afford anything. But that doesn’t matter at all. And now, for the first time, this thinking has been stimulated.” (30 years old, T_1)

Another common denominator that emerged was rediscovered value of interpersonal family relationships; coupled with this, domestic duties and media consumption were becoming less important.

“Spending more time with the family, not just cleaning, or cooking all the time.” (53 years old, T_2)

“This togetherness, this listening, even if you just chat with each other for an hour, that’s right, and not the other thing, this radio chatter all day or the TV that just drives you crazy, no, ... and I always used to have something on somehow, even in the car.” (59 years old, T_1)

Broader values, such as nonviolence, forgiveness, or truthfulness, were emphasized by individual participants, especially at T_2 . The overall impression was that the MBLM course turned participants’ attention to new values:

“This letting go and this forgiving. So now this, yes how can I put it, also this being more generous with each other, also the gratitude.” (63 years old, T_2)

TABLE 2. EXAMPLE STATEMENTS

Theme	Subtheme	Examples
Reappraisal	Realizing past way of life	<p>“I separated from my husband 5 years ago now and I think, only now, [...] then I first thought about it in a different way” (48 years old, T₂)</p> <p>“I have become aware of so many things about ethical living, I never paid attention to how important it is before” (56 years old, T₂)</p> <p>“I always functioned until I couldn't go on. First of all, THINKING ABOUT the fact that you did it totally wrong, that did hurt a bit” (53 years old, T₂)</p> <p>“before I was the type to just start yelling if something didn't suit me. I went from zero to 100 instantly freaking out” (30 years old, T₁)</p> <p>“I was so stuffy before. I had to really have everything go according to plan.” (30 years old, T₁)</p> <p>“these thoughts keep coming back: How is it right? How do I do it right? And why don't I do it that way if I did it wrong once?” (56 years old, T₂)</p> <p>“Not stealing is really just thinking about someone taking something from you, but not the whole emotional thing. That, again, made quite a deep impression on me.” (64 years old, T₁)</p> <p>“now it's a new experience again. Well, to get up and look out over my hill, like, I call it a molehill (laughs), to look outside it again.” (55 years old, T₂)</p> <p>“I'm a new person again. Or an old one, like I was. I mean, I'm setting my limits. I am someone, too, and I would like to see my wishes put first, too” (63 years old, T₂)</p>
	Realizing new opportunities	<p>“I'm so very grateful that my children are healthy and that they're there and [...] yes [...] that's certainly been reinforced, that's certainly changed or been reinforced again” (37 years old, T₁)</p> <p>“Well, I would be lying if I said now that I [...] have absolutely no interest in any material things. But [...] I didn't have to [...] ALWAYS [...] wear the latest fashion, or anything” (48 years old, T₂)</p> <p>“The desire to set myself free. And to keep going and not stop. And, um, very simply, yes. To act from my center, autonomously, and not to let myself go, but to decide for myself” (61 years old, T₁)</p> <p>“After all, these mantras all point to this, this nonviolence. And if everybody would do something like that, would live nonviolently, there would be no more wars” (55 years old, T₂)</p> <p>“[I'm] not quite as agitated about everything anymore” (48 years old, T₂)</p> <p>“Yes, I have become more stable again. More balanced, more stable.” (64 years old, T₁)</p> <p>“through meditation also sometimes to take your mind off things and calm down. Well, I must say [...] that is something that has done me good” (55 years old, T₂)</p> <p>“well, this is what I learned here. Not looking [and thinking] 'that has to be done and that has to be done,' nah, that only goes so far today. Well, I definitely learned that especially here.” (37 years old, T₁)</p> <p>“I don't have to please everyone anymore” (48 years old, T₂)</p> <p>“every subject [...] where someone else, a work colleague gets involved, you don't have to participate, that's not you, that's not your opinion” (56 years old, T₂)</p> <p>“my mother has died now, but nevertheless I could forgive then, so that also makes me much calmer, so no more 'At that time there was this and that and why did she do that?'" (53 years old, T₂)</p> <p>“that I have to take a step back on that and let my adult children make their mistakes too.” (61 years old, T₁)</p> <p>“I can see past it. This would never have happened to me before. If the doily hadn't been lying straight I would have been/that would have driven me crazy having to straighten it. It had to be perfect.” (63 years old, T₂)</p> <p>“I was just basically reinforced in what I believe, what is right for me. [...] that I'm living this permanently.” (37 years old, T₁)</p> <p>“if I look inside myself a bit honestly, I find a lot of things that are beautiful now” (48 years old, T₂)</p> <p>“well, you notice the body better. You simply notice yourself more” (55 years old, T₂)</p> <p>“One does a lot of things in passing, even eating, so many things in passing, without being more and more aware, this perception, well, I have become more aware of that in these last weeks.” (59 years old, T₁)</p> <p>“Well, I look up more often, sometimes, and then see these little things that just, I mean, bring a bit of happiness.” (69 years old, male, T₁)</p> <p>“you pay much more attention to yourself and the environment, nature. You perceive everything totally differently.” (30 years old, T₁)</p> <p>“where before a lot was dulled, just on the side. You approach each other more consciously.” (59 years old, T₁)</p> <p>“not to overshoot the mark emotionally, but to react to certain situations or persons in such a way that one tries/that I try to take a step back” (69 years old, male, T₁)</p>
Serenity	Experiencing calm	<p>“You can, when you change your view, also give a lot more because you understand a lot more. And not judging or condemning, but doing it with kindness and with understanding and with a change of perspective” (61 years old, T₁)</p> <p>“this would never have happened to me before: I talk to my father, I tell him about a good thing that happened to me or something, or what I sometimes worry about or what's on my mind” (63 years old, T₂)</p>
	Recognizing and setting boundaries	
Mindful living	Acceptance	
	Self-awareness	
Being present	Being present	
	Conscious interactions	

This interviewee was aware of this through changes in her lifestyle and generating hope for a better life, as she concludes:

“I’ll say this, it’s my only lifeline. I’m relatively sure of that, only if I live that and the sense that I’ve always had inwardly anyway, which I’ve had confirmed here, if I live this serenity and calm, if I live this meditation, if I practice ethical living, I’ll have a beautiful life.” (37 years old, T₁)

Serenity

Engaging with the course content made all participants feel calmer. This was expressed through more balance and inner peace. Often, participants associated this greater composure with a higher level of acceptance on the one hand, and the ability to set boundaries on the other.

Experiencing calm. Feeling calmer was mentioned by almost all interviewees at both interview times and was expressed individually in different experiences. One-third of the participants reported experiencing more calm, especially related to mantra mediation:

“the meditation makes me calmer. Takes me from problems to other issues, to other thoughts, other content.” (55 years old, T₂)

Another third reported feeling more balanced, more stable, and less agitated in everyday situations:

“the last few weeks I’ve had a really intense feeling that I’ve become much calmer, [...] and that I also just don’t get upset anymore.” (30 years old, T₁)

Another comment on this topic concerned communication with other people; one interviewee noted being able to be more present and being less impulsive:

“To just be present, stay calm [...] I also behave differently toward others.” (59 years old, T₁)

Recognizing and setting boundaries. Two-thirds of the participants addressed an awareness of their own limits and the ability to assert this in different contexts; the latter was more important for interviewees at T₁:

“But now I’m trying to set my boundaries a bit. ... because I notice my own limits.” (64 years old, T₁)

Besides recognizing their own (physical) limits, participants mentioned setting boundaries related to circumstances that could not be changed like their own past, the expectations and opinions of other people, and past or harmful relationships:

“I can say now that we also have confrontations at times, I’ve learned that too. To stand by my opinion and not tell anyone what to say anymore.” (63 years old, T₂)

“He’s just like that, but it’s his [ex-partner’s] issue though. I’ll leave that with him.” (61 years old, T₁)

Acceptance. At T₂, more than half the interviewees expressed having achieved a higher level of acceptance. Some mentioned acceptance of the past, of the present, of the course of life, and, in general, of the things they could not change:

“That’s the way things are [...] you just have to be prepared to accept the way things are and make the best of it. And that’s what I think I’ve learned a little bit.” (48 years old, T₂)

Other statements referred to accepting one’s own subjective shortcomings or wrong decisions:

“Oh God, I could be 5 minutes late. Yes, then that’s how it is. My God, we’re all just people.” (30 years old, T₁)

However, reference was also made to allowing for other people’s shortcomings:

“I’ve been really very offended and hurt when sometimes he hasn’t contacted me at all for weeks and months. In the end, now I see it in a different light, he has his job and he is self-employed.” (63 years old, T₂)

Mindful living

All participants reported greater mindfulness in the broader sense, which was expressed in self-awareness, being present in the moment, and conscious interactions.

Self-awareness. The following citations range from a focus on their own person, to increased introspection, to regained perception of their own presence, including their physical presence:

“that I can act from my center, according to my needs, which I first have to feel, the course also helped me with that.” (61 years old, T₁)

“I listen to myself even more now.” (59 years old, T₁)

At T₂, the associated gratitude and self-esteem were also addressed:

“And there’s various gifts that I’ve rediscovered, that I can use them for myself, and that bring me joy and I wouldn’t have got there without the study.” (56 years old, T₂)

Being present. Almost all participants stated that they were able to experience the present moment more consciously and be more present in it, especially at T₁. On this topic, one-third of respondents reported being more focused on the task in hand and multitasking less:

“I do things more thoughtfully now, that is, no longer at the same time, but [...] I concentrate more on things and think about them.” (53 years old, T₂)

For another third of the interviewees, conscious awareness of the present moment had become a source of pleasure:

“well, you see nature quite differently when it awakens [...] spring with the birds and the flowers, well, I never experienced that before.” (63 years old, T₂)

More physicality, associated with the yoga exercises and slowing down, was experienced as positive, although this appeared especially in the T₁ interviews:

“these movements in yoga, that is such a physicality that I feel there. Where I used to just whizz over it.” (61 years old, T₁)

Conscious interactions. All participants expressed more conscious behavior in social interactions at both interview times. In particular, more open and honest interaction with life partners and other family members was cited as leading to deeper relationships:

TABLE 3. DIFFERENCES IN FREQUENCY OF (SUB-)THEMES BETWEEN T₁ AND T₂

Theme	Subtheme	T ₁		T ₂		Δn	Δs
		n	s	n	s		
Reappraisal		6	114	6	123	0	9
	Realizing past patterns	5	15	6	25	1	10
	Realizing new opportunities	6	39	6	41	0	2
	New values	5	60	6	67	1	7
Serenity		6	53	6	100	0	47
	Experiencing calm	5	12	5	17	0	5
	Recognizing and setting boundaries	5	31	5	43	0	12
	Acceptance	3	9	4	39	1	30
Mindful living		6	78	6	71	0	-7
	Self-awareness	4	26	4	29	0	3
	Being present	6	21	5	7	-1	-14
	Conscious interactions	6	22	6	29	0	7

Number of participants mentioning a theme (*n*) and total number of statements that have been assigned to that particular (sub)theme (*s*)—directly after 8 weeks on the MBLM program (T₁) and 4 months later (T₂). The last two columns on the right show the difference between T₂ and T₁ in number of participants (Δ*n*) and statements (Δ*s*).

MBLM, Meditation-Based Lifestyle Modification.

“then we also have deeper conversations, [...] that was not the case before, or very, very rarely, and now we take time out more often.” (53 years old, T₂)

Almost all interviewees experienced taking a calmer, more respectful, and more considered approach. They said that communication was more attentive and receptive, so criticism and needs could also be heard, as the following examples illustrate, both in the context of the relationship and in their social circle:

“And I notice that if I respond to him more, which I can do well at this moment, we can connect really quickly.” (30 years old, T₁)

“There are also situations [...] where I now say ‘I’m listening, I’m listening to this.’ Don’t say so much, just give him a hug and then I’ve already helped.” (61 years old, T₁)

Differences between the interview times. No themes emerged at T₂ that differed from those at T₁. However, the frequencies with which some themes or subthemes were mentioned changed with time. Reappraisal remained the most dominant theme at T₂ and, unlike the other themes, was mentioned by all interviewees in all subthemes. The largest increase in individual mentions was recorded for the theme serenity, whereas two subthemes gained importance: acceptance and “recognizing and setting boundaries.” The theme mindful living lost relevance in the subtheme “being present.” A detailed overview of the changes is presented in Table 3.

Discussion

In this study, we analyzed semi-structured interviews to explore subjectively experienced intra- and interpersonal effects of MBLM practice on 12 outpatients with mild-to-moderate depression.

The most prominent theme that emerged from analysis of these interviews was reappraisal: reflection on past and present life, leading to new health-promoting opportunities and values. Virtue-based ethics (yoga *yamas* and *niyamas*) were explicitly mentioned as a key factor and an inspiring source of reorientation. Individuals sometimes described their insights as shocking, and the ideal of life proposed by yoga was occasionally perceived as utopian. Nevertheless, overall, reappraisal led to individual empowerment and an appreciation

of one’s own strengths. These changes tended to become more manifest after 4 months (T₂) and can be interpreted as an antidepressant factor according to positive psychology.²⁸ The theme of empowerment (found in the subthemes “realizing new opportunities,” “recognizing and setting boundaries,” and “conscious interactions”) has also been reported in qualitative studies of (primarily) body-oriented yoga for people with depression,^{29,30} but it was less prominent and referred to with less explicit cognitive and motivational statements.

As expected, due to its emphasis in MBLM, the participants explicitly highlighted values and virtues, and described them as a source of new vitality, inspiration, and orientation in their lives. This is consistent with Koenig’s well-known model of spirituality and health, in which spiritual practice leads to the development of virtues, which, in turn, promote mental health.³¹

Reappraisal based on insights from virtue-based ethics also played an important role in interpersonal relationships and supported a more relaxed attitude in conflicts, a higher level of acceptance, and better ability to set boundaries and be more compassionate with others.

The centrality of ethical living in this study is in line with neurophysiological models of classical yoga^{32,33} and supplements existing empirical models⁹ with the explicitly cognitive components of MBLM’s virtue-based ethics. Regarding the treatment of depression, developing healthier relationships has been shown to be effective and is one of the key factors in interpersonal psychotherapy.³⁴ Further, the subtheme “experiencing calm” expresses emotional stability and quieting of the mind as a mechanism of self-regulation, which is beneficial to symptoms of depression, such as mood changes, anxiety, intrusive thoughts, and rumination. States of calm, a key element in meditative movement and a recurring theme reported in yoga studies,^{4,35} were mentioned by participants in the present study with regard to body postures, but above all related to the practice of mantra meditation.

In the aforementioned synthesis of qualitative studies on body-oriented yoga practice for people with mental health conditions 6 of 11 studies were conducted with patients with depression.⁴ A comparison of the themes of these studies with the themes and subthemes identified in our study highlighted some differences. First, although the theme “healing as a

process” (with the subthemes “overcoming obstacles” and “barriers to practicing”) was prominent in the synthesis, it was less so for the participants of this study. One reason for this could be our participants’ inspiration from virtue-based ethics, which may have made the daily routine of yoga and meditation practice more varied and attractive. Further, although asked about it directly, our interviewees appeared less focused on their illness than is usually observed in patients with depression.³⁶ Instead of mere symptom relief, they commonly expressed a more global goal with phrases such as “being at peace” or “finding inner peace.” One possible explanation is that participants may have identified less as a “depressed person” after the MBLM program, which would be in line with its salutogenic and eudaimonic mechanisms of action and their effects on well-being.³⁷ Second, the key theme in the synthesis, “alleviation of suffering,” overlaps considerably with a key theme in this study, serenity, centering around emotional and cognitive stability. Although a subtheme in the synthesis, “physical health” was not raised by MBLM participants, they did report on specific psychological mechanisms to reduce suffering (namely, “recognizing and setting boundaries” and “acceptance”). Third, in the synthesis, the key theme of “self as an agent of change” showed a partial overlap with the MBLM study subthemes “realizing new opportunities” and “conscious interactions.” The synthesis subthemes of connectedness and “appreciating a holistic approach” were not explicit themes for the MBLM participants (although mentioned in some individual statements).

Finally, our participants made only sparse explicit statements about any change in spiritual experience or attitude. One possible explanation for this is the brevity of the intervention. Spiritual growth is a long-term and complex process.³⁸ Further, spirituality is a complex psychological construct,^{39,40} to which limited reference was made in the interviewees. Conscious aspects of the human psyche were easier for the interviewees to access and changes could remain unconscious, but these were still visible in behavior. The theme of serenity, and the subthemes of acceptance and new values that we identified could be interpreted as spiritual components, as for example in acceptance and commitment therapy.⁴¹ The MBLM also works well in a secular, humanistic context, however, and participants could have preferred this interpretation.

The study is not without its limitations. Due to the design and the sample size, no statements can be made about the specific effects regarding diagnosis, duration of illness, number of episodes, severity of depression, age or gender, or existing comorbidities. Further, the specific effects of the individual components of MBLM, as well as interactions with existing therapies (e.g., previous psychotherapy, which was highly variable in our sample) can hardly be distinguished. From a sociodemographic point of view, the sample shows a relatively realistic gender ratio, since women are significantly more likely to be affected by depression than men.⁴² Future studies could focus more on male participants, especially at a younger age, to be more representative.

Although the sample size is appropriate for thematic analysis, future studies should replicate the results using a larger sample, ideally in a multi-center approach. Treatment-naïve participants should also be examined to rule out any interactions with previous therapies.

The strengths of the study include the novelty of the program in the field of integrative treatment of depression

and the in-depth insights we gained into participants’ subjective theories on how (well) it worked.

Overall, the results of this qualitative study provide complementary evidence of the effects of MBLM in the treatment of mild-to-moderate depression examined in the MBLM-D study. In particular, the explicit therapeutic implementation of virtue-based ethics may offer a valuable addition to previous mind–body programs. Reflection on virtue ethics in one’s life may lead to transient distress; hence, sensitive therapeutic support is required to respond appropriately to unfavorable psychopathological developments. Nonetheless, new resources could be activated in the therapeutic process, even for patients with a long history of therapy. This shows the power of an integrative approach, in which physical, cognitive–emotional, social, and spiritual aspects are combined in a setting of continuous practice.

Authors’ Contributions

H.C.B. and P.S. conceptualized and designed the study. J.V., J.G. were involved in the acquisition of data. K.M. and P.S. supervised the data analysis. J.V., J.G., H.C.B., and K.M. contributed to qualitative analysis and reporting. H.C.B. wrote the first draft of the article. All authors worked on the final version of the article.

Ethical Approval

Granted by the Ethics Review Board of the University of Chemnitz University of Technology (V-276-15-PS-MBLM-D-14062018).

Author Disclosure Statement

No competing financial interests exist.

Funding Information

This project was funded by Karl and Veronica Carstens Foundation under Award Numbers KVC 0/098/2018.

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2.5 Wie wirkt sich die meditationsbasierte Lebensstilmodifikation auf die Schmerzintensität, die schmerzbezogene Selbstwirksamkeit und die Lebensqualität von chronischen Schmerzpatient:innen aus? Eine experimentelle Einzelfallstudie

Diese Studie untersuchte den Einsatz von MBLM bei einer weiteren hochprävalenten und sich weiter ausbreitenden Indikation, den chronischen Schmerzen. Komplementäre Therapieansätze wie Yoga und Meditation haben bereits Einzug in die multimodale Schmerztherapie erhalten. Bei der vorliegenden Untersuchung handelt es sich um eine explorative Studie, um Erkenntnisse über den Einsatz von MBLM bei Patient:innen mit dieser Erkrankung zu gewinnen.

Übernommen aus der Zusammenfassung der Veröffentlichung:¹⁰³ „In der vorliegenden Studie wurde ein experimentelles Einzelfalldesign mit mehreren Baselines verwendet. [...] Die Zielparameter waren Schmerzintensität (BPI-sf), Lebensqualität (WHO-5) und Schmerzselbstwirksamkeit (PSEQ). Ergebnisse: Zweiundzwanzig Patient:innen mit chronischen Schmerzen (Rückenschmerzen, Fibromyalgie oder Migräne) nahmen an der Studie teil, und 17 Patientinnen schlossen die Behandlung ab. MBLM erwies sich für einen großen Teil der Teilnehmerinnen als wirksame Intervention. Die größten Effekte wurden bei der Schmerzselbstwirksamkeit (TAU-U = 0,35) festgestellt, gefolgt von der durchschnittlichen Schmerzintensität (TAU-U = 0,21), der Lebensqualität (TAU-U = 0,23) und den stärksten Schmerzen (TAU-U = 0,14). Die Teilnehmer reagierten jedoch unterschiedlich auf die Behandlung. Schlussfolgerung: Die vorliegenden Ergebnisse deuten auf relevante klinische Wirkungen der MBLM bei den multifaktoriellen Bedingungen chronischer Schmerzen hin. Zukünftige kontrollierte klinische Studien sollten Effektivität und Sicherheit mit größeren Stichproben untersuchen. Die ethischen und philosophischen Aspekte des Yoga sollten weiter erforscht werden, um ihren therapeutischen Nutzen zu überprüfen.“



Article

How Does Meditation-Based Lifestyle Modification Affect Pain Intensity, Pain Self-Efficacy, and Quality of Life in Chronic Pain Patients? An Experimental Single-Case Study

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Citation: Matko, K.; Burzynski, M.; Pilhatsch, M.; Brinkhaus, B.; Michalsen, A.; Bringmann, H.C. How Does Meditation-Based Lifestyle Modification Affect Pain Intensity, Pain Self-Efficacy, and Quality of Life in Chronic Pain Patients? An Experimental Single-Case Study. *J. Clin. Med.* **2023**, *12*, 3778. <https://doi.org/10.3390/jcm12113778>

Academic Editor: Lukas Radbruch

Received: 10 March 2023

Revised: 8 May 2023

Accepted: 23 May 2023

Published: 31 May 2023



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Abstract: Introduction: Chronic pain is a growing worldwide health problem and complementary and integrative therapy options are becoming increasingly important. Multi-component yoga interventions represent such an integrative therapy approach with a promising body of evidence. Methods: The present study employed an experimental single-case multiple-baseline design. It investigated the effects of an 8-week yoga-based mind-body intervention, Meditation-Based Lifestyle Modification (MBLM), in the treatment of chronic pain. The main outcomes were pain intensity (BPI-sf), quality of life (WHO-5), and pain self-efficacy (PSEQ). Results: Twenty-two patients with chronic pain (back pain, fibromyalgia, or migraines) participated in the study and 17 women completed the intervention. MBLM proved to be an effective intervention for a large proportion of the participants. The largest effects were found for pain self-efficacy (TAU-*U* = 0.35), followed by average pain intensity (TAU-*U* = 0.21), quality of life (TAU-*U* = 0.23), and most severe pain (TAU-*U* = 0.14). However, the participants varied in their responses to the treatment. Conclusion: The present results point to relevant clinical effects of MBLM for the multifactorial conditions of chronic pain. Future controlled clinical studies should investigate its usefulness and safety with larger samples. The ethical and philosophical aspects of yoga should be further explored to verify their therapeutic utility.

Keywords: chronic pain; yoga; meditation; ethics; pain intensity; self-efficacy; quality of life; individual differences; mind-body medicine; single-case research

1. Introduction

Chronic pain affects between 35 and 50% of the global population [1–3] and represents the leading cause of years of life with disability and illness [4,5]. Chronic pain is not only a common, complex, and burdening problem for individuals but also poses significant socioeconomic challenges for society [3,6]. There is a great need for an integrative interdisciplinary management of chronic pain that addresses both patient-centered multimodal and societal levels [4,7].

Interdisciplinary multimodal pain therapy (IMPT) is considered the most important intervention for chronic pain relief. Its effectiveness has been confirmed in several studies [8,9], and it is based on a combination of medical interventions, psychotherapy, and

exercise therapy. Its primary goal is not only to reduce pain but also to educate the affected person to gain a biopsychosocial understanding of the disease and restore their physical, psychological, and social functions despite the pain [10–13]. However, many programs are difficult to access, not integrative or patient-centered, and do not provide effective and, more importantly, long-term strategies for the overall treatment goals of IMPT. As a result, many patients are dissatisfied with conventional methods and, therefore, often turn to alternative treatments [14–16].

Yoga represents a successful mind-body medicine (MBM) practice that is safe, inexpensive, and effective in the complementary treatment of chronic pain [16–18]. Today, approximately 30 million people worldwide practice yoga regularly [19], and one of the most common reasons for practicing yoga is pain [20]. The growing amount of scientific research over the past decade has shown significant improvements in pain intensity, pain-related functional limitations, and wellbeing following yoga interventions [21–24]. In addition, yoga has been effective for people with chronic pain in alleviating concurrent depression, stress, and anxiety disorders and enhancing body awareness, pain acceptance, coping strategies, and self-efficacy [16,25–27]. The growing number of randomized controlled trials (RCTs) and reviews demonstrate the increasing therapeutic importance of yoga [19].

Nevertheless, there is a lack of high-quality studies, interventions are often poorly described, and the practice of yoga is often reduced to physical and breathing exercises without incorporating its ethical roots [19,28,29]. Blinding is often difficult, inducing the possibility of a placebo effect. Furthermore, inconsistent sample sizes and study durations and large methodological heterogeneity make it difficult to summarize study results in meta-analyses and translate them into meaningful outcomes [30,31]. In addition, Sharma et al. [31] criticized the limited informative value of RCTs and suggested that the inclusion of qualitative data may help to better understand the multidimensional effects of yoga on human mental and physical health.

To address some of these limitations, the present study used a single-case multiple-baseline design [32], which is very suitable for capturing individual effects and changes over time in greater detail. Furthermore, we employed the mind-body program Meditation-Based Lifestyle Modification (MBLM), which provides a consistent and comprehensive approach to classical yoga and incorporates its ethical component. It follows a prescribed structure (set duration for the yoga practice, meditation, and ethical teachings, which are taught in a psychotherapy-like setting) and engages participants to practice on their own [33]. The present study examined MBLM's feasibility and effects on pain-related outcomes in patients suffering from various forms of chronic pain. The program has been shown to be feasible and effective in depressed patients as well as healthy individuals [34,35]. Therefore, we hypothesized that it would lead to improvements in pain intensity, pain self-efficacy, and quality of life in chronic pain patients.

2. Materials and Methods

2.1. Study Design

All participants received the same treatment (MBLM), but they were randomly assigned to three baseline groups (10, 17, and 24 days). To keep the group sizes small, participants were split into two groups where treatments took place in the afternoon and evening of the same day. The treatment was delivered over eight weekly group sessions, but due to public holidays during the study, the total intervention length was 10 weeks. Each participant started the intervention according to their assigned baseline length. All measurements were taken online, and the pretest was completed one week before the beginning of the baseline phase. Baseline assessments started on the same day for all participants, and the participants received daily online questionnaires throughout the entire study period. Each participant received a posttest at the completion of the study and a follow-up 8 to 10 weeks later. Figure 1 depicts the study design.

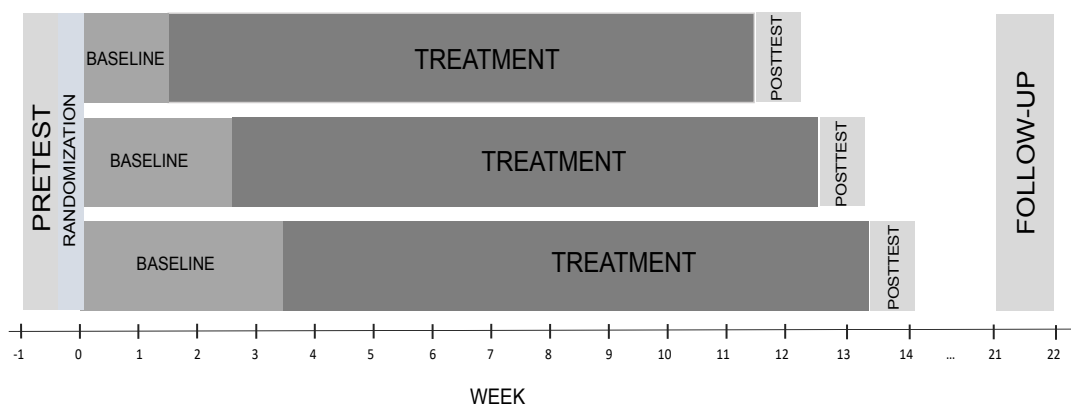


Figure 1. Study design.

2.2. Intervention

The MBLM program is a mind-body intervention based on the eightfold path of classical yoga that consists of 3 domains: ethical living, healthy lifestyle, and mantra meditation. It was delivered in 8 sequential 180 min group sessions that covered all three domains. The ethical living domain introduced participants to the philosophical aspects of classical yoga, presenting 1 of the 10 yamas and niyamas each week (the last 3 niyamas were covered in one session). The yamas and niyamas represent basic attitudes and practices in dealing with oneself and others, such as non-violence, truthfulness, contentment, self-discipline, etc. In the MBLM course, these are communicated to participants in a psychotherapeutic context in a culturally sensitive and application-oriented way. Furthermore, participants are invited to discuss these topics with the group and apply them to their everyday lives with the help of several ethical living activities (e.g., the practice of being truthful instead of “nice”). The healthy lifestyle domain included gentle physical exercises and breathing techniques, as well as general recommendations on diet and daily rhythms according to Ayurvedic medicine. Here, for example, the participants were advised to arise before 6 a.m. and follow a morning routine of personal hygiene, yoga, and meditation and eat their main meal at noon, use the last hours of the day for rest and relaxation, and go to bed no later than 10 p.m. In addition, general dietary recommendations were provided, highlighting the benefits of a plant-based diet with moderate use of natural sweeteners. During mantra meditation, the participants silently repeated a mantra for 20 to 25 min that they had chosen during an introductory session at the beginning of the treatment. The mantra served as an object of concentration to calm the mind and body. In deeper stages of meditation, the mantra could be abandoned and the concentration directed to inner silence. The participants were recommended to engage daily in 45 min of home practice covering the different domains. A detailed description of MBLM can be found in the work by Bringmann et al. [33].

2.3. Inclusion Criteria and Recruitment

The recruitment period was approximately three months between May and August 2019. To be included in the study, participants had to be outpatients who were at least 18 years old and had suffered from recurrent or persistent chronic pain for more than three months. They had to be in good enough physical condition to perform simple yoga exercises and sit still for approximately 20 min according to the self-assessment. Patients were excluded if they had obsessive-compulsive disorder, cerebrovascular disease, addictive disorders, psychotic symptoms, acute suicidality, severe multimorbidity, and yoga and meditation experience (>1 time per week in the past 6 months) or if they were currently participating in another yoga and meditation study. Participants were recruited via flyers and posters distributed in medical practices and chronic pain centers in Dresden and screened by MB through individual telephone calls. After screening 38 prospective participants, 26 of them were invited to attend one of two information events held by the authors.

Twenty-two patients (twenty women and two men) decided to participate in the study and provided written consent. Participation was voluntarily and the participants received no financial compensation for their participation. During the study, five participants (including both men) dropped out for personal reasons (meditation difficulties, lack of interest, work overload, psychological problems, and depression). The final sample consisted of 17 female participants.

2.4. Measures

The instruments for daily and weekly measurements had to be suitable for a single-case experimental design, and thus, they had to be precise and short. All questionnaires were programmed and implemented using SoSci Survey [36] and were made available at www.sosicisurvey.com. The data were collected between 2 September 2019 and 6 February 2020. All dependent variables were collected continuously throughout the study and during the pretest, posttest, and follow-up periods. Furthermore, the pretest assessed sociodemographic and clinical data on chronic pain, and the posttest and follow-up measured course satisfaction.

2.5. Pain

Daily pain was assessed using the German short form of the Brief Pain Inventory (BPI-sf) [37]. The BPI-sf is a 9-item questionnaire for the self-assessment of pain intensity and its impact on daily life. It contains questions about pain intensity over the past 24 h, current treatments, and their perceived effectiveness. In this study, we focus on the daily average and strongest pain participants reported in this questionnaire.

2.6. Pain Self-Efficacy

Pain self-efficacy was measured once each week using the German version of the Pain Self-Efficacy Questionnaire (PSEQ). The questionnaire consists of 10 items reflecting how confident a person feels that they can perform certain activities despite their pain. Items were rated on a 7-point Likert scale from 0 (not at all convinced) to 6 (completely convinced). The German version (FESS) is valid and has high internal consistency ($\alpha = 0.92$) [38].

2.7. Wellbeing

Wellbeing was measured daily using the World Health Organization Wellbeing Index (WHO-5). The WHO-5 is a very short psychometric and generic self-assessment scale for measuring subjective well-being. It has high internal and external validity [39] and consists of five positively worded statements rated on a six-point Likert scale. High scores represent high subjective wellbeing. Due to the daily measurements, the time frame was adjusted from “in the last 2 weeks” to “in the last 24 h”.

2.8. Daily Experiences

The daily questionnaire included questions about the duration and subjective experiences with yoga, meditation, and ethical living. First, participants were asked to enter how many minutes they had practiced yoga and meditation on that day (0 if none) and whether they had engaged with the ethical living topic of the week (yes/no). Then, they were requested to indicate the experienced difficulty of each practice using a 5-point polarity profile ranging from 1 (very difficult) to 5 (very easy). In addition, we provided participants with a free text item in which they could describe any special events that they had experienced during that day.

2.9. Data Analysis

The data were analyzed visually and statistically by calculating the effect size TAU-U. To estimate the overall effect of the intervention, we performed a random-effects meta-analysis on each dependent variable. The results of these meta-analyses are presented visually using forest plots. If the results of all three analyses were consistent, then this

would provide strong evidence for our findings. All statistical analyses were performed using R statistical software [40].

For the visual analysis, we generated individual dependent-variable-by-time plots using the package *lattice* [41]. Then, we assessed trends in the individual phases and level differences between the phases. The visual analysis followed the standards set by Kartochwill et al. [42] and Lane and Gast [43]. We focused on three components: trend, level, and stability. This allowed us to identify the individual effects of the intervention and provided a basis for the subsequent statistical analysis.

The TAU-*U* is a family of non-parametric estimates of effect size in single-case research designs. The effects of the intervention were calculated for each participant and for all three dependent variables using the package *scan* [44]. Then, the appropriate TAU-*U* coefficients were selected according to the recommendations of Parker et al. [45] and Brossart et al. [46]. Trends in the baseline phase (TAU- U_A vs. B–Trend A), treatment phase (TAU- U_A vs. B+Trend B), or both phases (TAU- U_A vs. B+Trend B–Trend A) were corrected if they were visually prominent, larger than 0.40, or statistically significant (at $p < 0.01$). The sizes of the effects were determined following the guidelines set by Solomon et al. [47]. A TAU-*U* smaller 0.28 indicated a small effect, between 0.29 and 0.47 indicated a moderate effect, between 0.48 and 0.57 indicated a large effect, and 0.58 and larger indicated a very large effect.

The R package *meta* [48] was used to conduct a rudimentary meta-analysis for each dependent variable. Individual effect size estimates were plotted in forest plots with corresponding 95% confidence intervals (95% CI), and the overall effect was estimated using a random-effects model. If the 95% confidence intervals did not cross zero, the effect size estimates indicated a statistically significant positive or negative effect; if they crossed zero, they were non-significant [49]. Large differences in the locations and widths of the 95% confidence intervals indicated high heterogeneity and were measured by τ according to DerSimonian/Laird and I^2 according to Higgins/Thompson. High heterogeneity was present when the value of I^2 was greater than 75% [49].

3. Results

3.1. Study Population

The final study population included 17 female Caucasian outpatients of German nationality who were between 19 and 79 years old and mostly suffered from chronic back pain (with or without disc involvement), fibromyalgia, or chronic migraines. Some of the participants suffered from more than one pain-causing condition. In nearly half of the participants, the duration of the pain disorder was more than five years. An overview of the most important participant data can be found in Table 1.

Table 1. Case descriptions.

Case	Baseline	Age	Occupation	Medical Diagnoses	Duration of Pain
1	10	39	Unemployed	Fibromyalgia	>5 years
2	10	65	Employee	Lower back pain and knee arthrosis	1–2 years
3	10	19	Student	Migraines and depression	>5 years
4	10	27	Trainee	Chronic intractable pain, depression, and anxiety disorder	2–5 years
5	17	55	Employee	Lumbar and other intervertebral disc disorders with radiculopathy and depression	6–12 months

Table 1. *Cont.*

Case	Baseline	Age	Occupation	Medical Diagnoses	Duration of Pain
6	17	66	Retired	Chronic pain and headaches	>5 years
7	17	57	Employee	Migraines, vascular headaches, and atypical facial pain	>5 years
8	24	51	Employee	Spinal stenosis	>5 years
9	24	49	Employee	Chronic pain and burnout	>5 years
10	10	47	Employee	Lumbar and other intervertebral disc disorders with radiculopathy and anxiety disorder	2–5 years
11	10	68	Retired	Lumbar and other intervertebral disc disorders with radiculopathy and sleep disorder	>5 years
12	10	47	Employee	Cervical disc disorder and lumbar and other intervertebral disc disorders with radiculopathy	6–12 months
13	17	62	Retired	Chronic back pain, scoliosis, and burnout	>5 years
14	17	54	Self-employed	Interstitial cystitis, other chronic cystitis, lower back pain, and psychological factors associated with chronic pain	2–5 years
15	17	60	Employee	Lumbar and other intervertebral disc disorders with radiculopathy	6–12 months
16	24	34	Homemaker	Migraines	>5 years
17	24	79	Retired	Lower back pain	2–5 years

3.2. Adherence

According to the daily responses, on average, the participants practiced yoga for 20.3 min (SD = 11.6 min) and mantra meditation for 17.7 min (SD = 9.19 min) each day. In addition, they engaged in ethical living exercises, on average, on 51.6 out of 60 days, corresponding to 86% of all days ($M = 0.86$, $SD = 0.35$). Hence, the participants generally showed high adherence to a home practice. Practicing physical yoga was rated as significantly easier ($M = 3.48$, $SD = 1.06$) than practicing mantra meditation ($M = 2.92$, $SD = 1.14$), with $t(964) = 15.34$ and $p < 0.001$, or ethical living ($M = 2.99$, $SD = 0.99$), with $t(841) = 13.17$, $p < 0.001$. Course adherence was high, with most participants attending seven to eight sessions and only one participant attending four sessions. The latter participant also responded irregularly to the daily questionnaire, did not answer the post questionnaire, and did not practice regularly.

3.3. Average Pain

Figure 2 shows the individual changes in average pain levels over time. As pain should decrease over time, a downward trend would represent an effect in the expected direction. Measurements were taken daily so that the baseline phase comprised a maximum of 10, 17, or 24 measurement points. The treatment phase comprised a maximum of 60 measurement points.

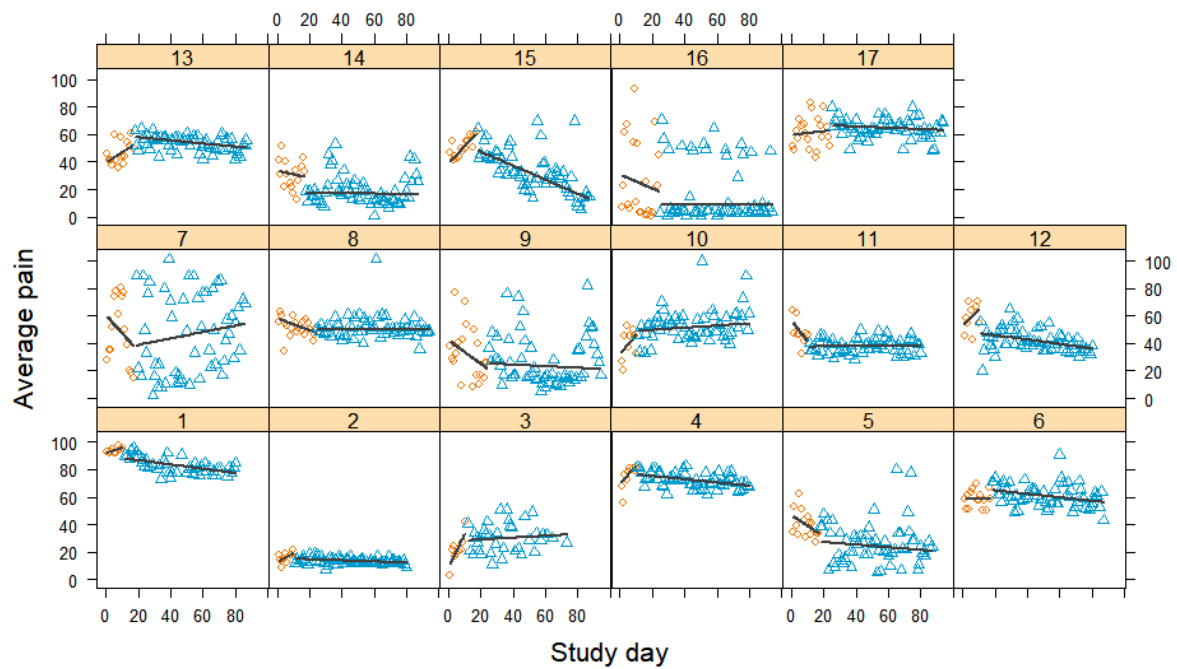


Figure 2. Average pain scores during baseline and treatment for each participant, with regression lines for each phase. Orange circles represent baseline measurements, blue triangles treatment measurements, black lines regression lines, and numerals labels indicate each case.

Participants varied in the daily fluctuations in their average pain levels. While for some participants, their pain levels remained fairly consistent, for others, they fluctuated quite strongly, particularly for the patients suffering from chronic migraines (cases 3, 7, and 16). Three quarters of the participants exhibited either decreases or increases in average pain levels during the baseline phase. In the treatment phase, the average pain levels improved for more than half of the participants. The pain reductions mostly followed a linear trend, with recurring pain spikes for some participants (cases 5, 6, 9, 14, 15, and 16). For some participants, perceived pain first increased at the beginning of treatment and then decreased, followed by mostly returning to baseline levels (cases 6, 13, and 17). We observed consistent increases in pain levels for participants 3 and 10; however, for the former, the variations in pain levels appeared to decrease over time.

Figure 3 shows the results of the meta-analysis for this variable in a forest plot. The orange diamond shows the weighted total effect size with corresponding 95% confidence intervals and indicates the average treatment effect, which was $\text{Tau-U} = 0.21 [0.35; 0.08]$. Hence, average pain showed a small significant improvement over time. Eleven effects yielded significant decreases in pain, three effects indicated significant increases, and three effects were non-significant. This variability was also reflected in the high heterogeneity measures ($I^2 = 99\%$ and $\tau = 0.29$, where τ was the standard deviation of the average effect size). As the study conditions and measurements remained constant across the participants, this heterogeneity could be attributed exclusively to the interindividual differences between the participants. Hence, although the average treatment effect was significant, we had to assume that not all participants benefitted equally well from the treatment.

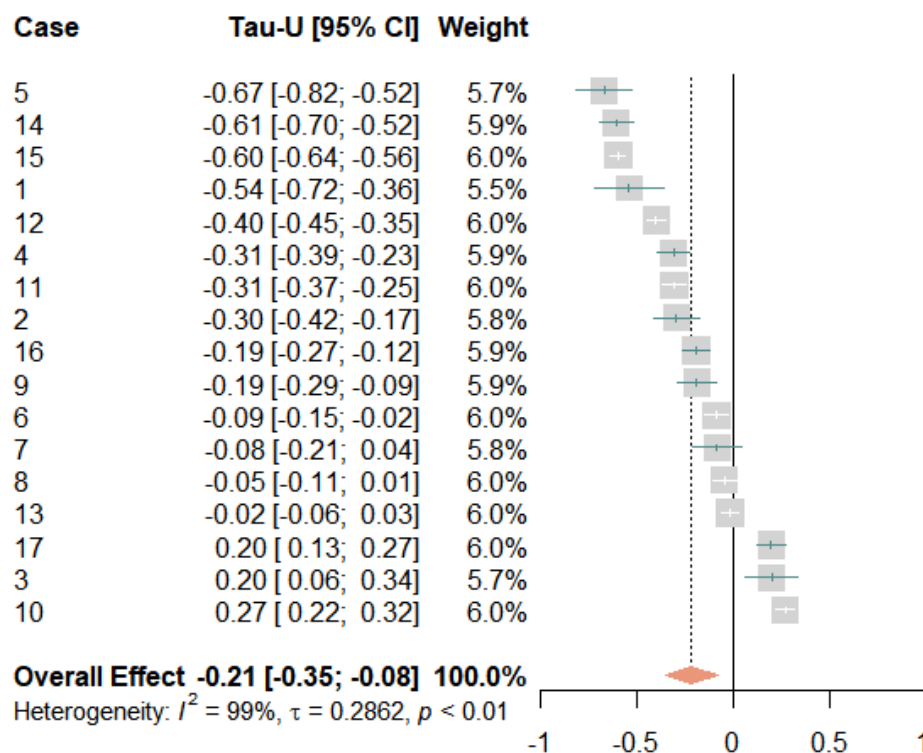


Figure 3. Forest plot of the average pain levels. The grey squares indicate the weight of each case with the mark in the middle representing the observed effect size and the corresponding line the confidence interval. The orange diamond shows the pooled effect size and its length symbolizes the confidence interval.

3.4. Strongest Pain

Figure 4 shows the individual changes in the strongest perceived pain levels over time. These corresponded to the patterns observed for average pain, albeit on a generally higher level. We saw similar increases and decreases in the baseline phase but with slightly smaller treatment effects. Figure 5 shows the corresponding forest plot. Overall, the treatment had a small effect, with $\text{Tau-U} = -0.14 [-0.28; -0.00]$. Eight participants exhibited significantly small to very large reductions in their strongest pain levels. Four participants reported no changes in their strongest pain levels and five participants reported small to moderate increases. The latter included the three participants whose average pain levels increased, plus one participant who experienced no change in average pain (case 8) and one participant whose average pain decreased (case 4). Again, heterogeneity was very high ($I^2 = 99\%$ and $\tau = 0.28$), suggesting an inconsistent effect of the treatment.

3.5. Pain Self-Efficacy

Figure 6 depicts the development of participants’ pain self-efficacy ratings over the course of the study. Due to the weekly measurements, there were a maximum of three measurement points in the baseline phase and a maximum of ten in the treatment phase. Pain self-efficacy fluctuated, to some extent, in the baseline phase, but it was difficult to draw firm conclusions about trends as there were too few measurements. In the beginning of the intervention, most participants showed a gradual increase in pain self-efficacy ratings. For some, these increases were linear, while others fluctuated (to a larger extent). Overall, there were marked interindividual differences in the general levels and slopes of the curves.

Figure 7 presents the results of the meta-analysis. With a mean Tau-U of $0.35 [0.13, 0.57]$, the overall effect showed a significant medium-sized improvement in the pain self-efficacy rating. Twelve effects yielded significant results, with moderate to very large effect sizes in the expected direction. Four effects were significantly negative, and one effect was non-significant. The negative effects were found for two participants who also experienced

increased pain (cases 10 and 17), plus two participants whose pain levels did not change much (cases 6 and 7). A very large amount of variation was not accounted for ($I^2 = 97\%$ and $\tau = 0.45$), suggesting strong variations in the responses to the treatment.

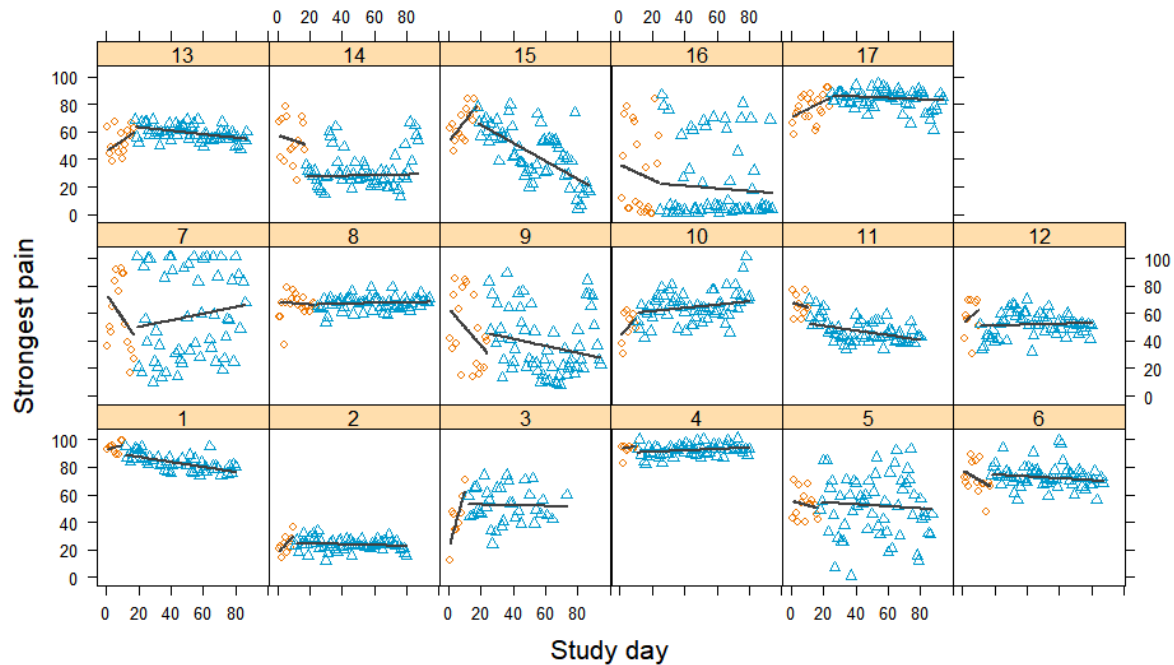


Figure 4. Strongest pain scores during baseline and treatment for each participant, with regression lines for each phase. Orange circles represent baseline measurements, blue triangles treatment measurements, black lines regression lines, and numerals labels indicate each case.

Case	Tau-U [95% CI]	Weight
14	-0.72 [-0.80; -0.63]	5.9%
1	-0.58 [-0.77; -0.40]	5.5%
15	-0.54 [-0.58; -0.50]	6.0%
11	-0.44 [-0.49; -0.39]	6.0%
12	-0.33 [-0.45; -0.21]	5.8%
9	-0.19 [-0.29; -0.09]	5.9%
16	-0.12 [-0.20; -0.05]	6.0%
13	-0.08 [-0.13; -0.04]	6.0%
6	-0.06 [-0.12; 0.01]	6.0%
2	-0.01 [-0.15; 0.13]	5.7%
7	-0.01 [-0.14; 0.12]	5.8%
5	-0.00 [-0.15; 0.15]	5.7%
17	0.05 [0.01; 0.09]	6.1%
4	0.09 [0.00; 0.17]	5.9%
8	0.12 [0.02; 0.23]	5.9%
3	0.14 [0.01; 0.28]	5.7%
10	0.30 [0.25; 0.35]	6.0%

Overall Effect -0.14 [-0.28; -0.00] 100.0%
 Heterogeneity: $I^2 = 99\%$, $\tau = 0.2815$, $p < 0.01$

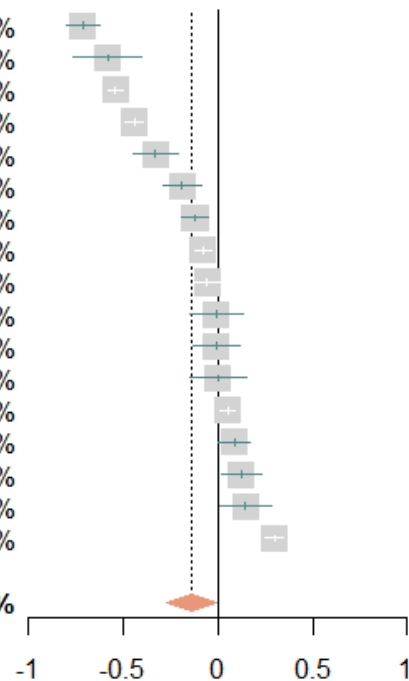


Figure 5. Forest plot of the strongest pain levels. The grey squares indicate the weight of each case with the mark in the middle representing the observed effect size and the corresponding line the confidence interval. The orange diamond shows the pooled effect size and its length symbolizes the confidence interval.

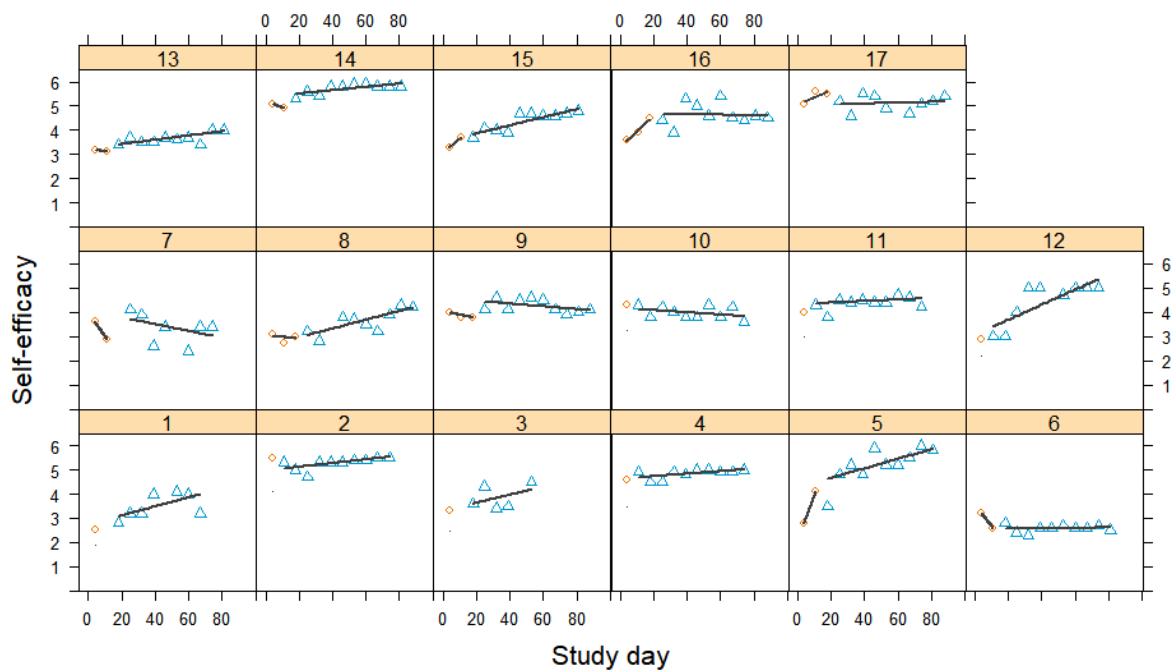


Figure 6. Self-efficacy scores during baseline and treatment for each participant, with regression lines for each phase. Orange circles represent baseline measurements, blue triangles treatment measurements, black lines regression lines, and numerals labels indicate each case.

Case	Tau-U [95% CI]	Weight
17	-0.53 [-0.65; -0.41]	6.2%
6	-0.43 [-0.64; -0.22]	5.9%
10	-0.38 [-0.54; -0.23]	6.1%
7	-0.23 [-0.43; -0.03]	6.0%
11	0.34 [0.20; 0.49]	6.1%
2	0.42 [0.07; 0.76]	5.4%
4	0.46 [0.21; 0.70]	5.8%
3	0.47 [0.07; 0.87]	5.2%
16	0.54 [0.43; 0.66]	6.2%
1	0.57 [-0.02; 1.16]	4.3%
13	0.60 [0.48; 0.72]	6.2%
14	0.61 [0.49; 0.74]	6.2%
8	0.67 [0.51; 0.82]	6.1%
12	0.67 [0.52; 0.82]	6.1%
15	0.68 [0.57; 0.80]	6.2%
5	0.70 [0.50; 0.89]	6.0%
9	0.88 [0.72; 1.04]	6.1%
Overall Effect	0.35 [0.13; 0.57]	100.0%
Heterogeneity: $I^2 = 97%$, $\tau = 0.4457$, $p < 0.01$		

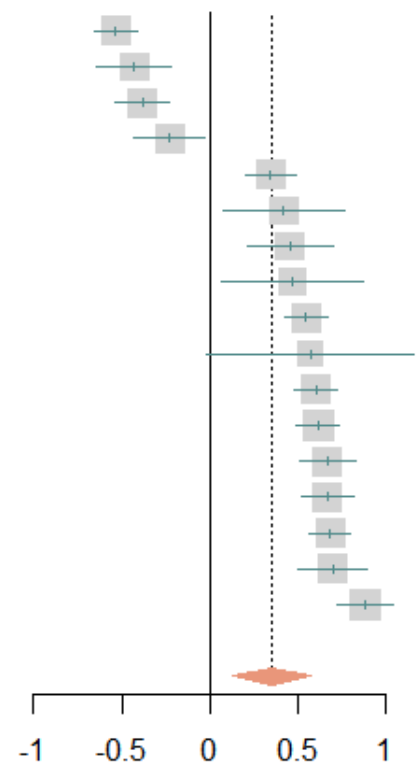


Figure 7. Forest plot of the self-efficacy ratings. The grey squares indicate the weight of each case with the mark in the middle representing the observed effect size and the corresponding line the confidence interval. The orange diamond shows the pooled effect size and its length symbolizes the confidence interval.

3.6. Wellbeing

Figure 8 displays how daily wellbeing developed over time for each participant. In both phases, wellbeing fluctuated day to day, with some participants reporting stronger daily variations than others. Most participants showed either a negative trend or no trend in the baseline phase. In contrast, more than two-thirds of the participants experienced a gradual and linear improvement in wellbeing during the treatment compared to the baseline. Only a few of the participants showed no or small negative effects. The meta-analysis yielded a significant mean effect, with $\text{Tau-U} = 0.23 [0.07, 0.38]$, suggesting that wellbeing improved to a moderate extent (see Figure 9). Nine effects yielded significant results, with moderate to very large effect sizes in the expected direction. Three effects were non-significant and five effects indicated significant small decreases in wellbeing. Only two of these participants (cases 8 and 10) had also reported increased pain—one had experienced reduced self-efficacy (case 6) and the other two had reported positive effects (cases 11 and 14). Again, a large amount of variation was not accounted for ($I^2 = 99\%$ and $\tau = 0.33$).

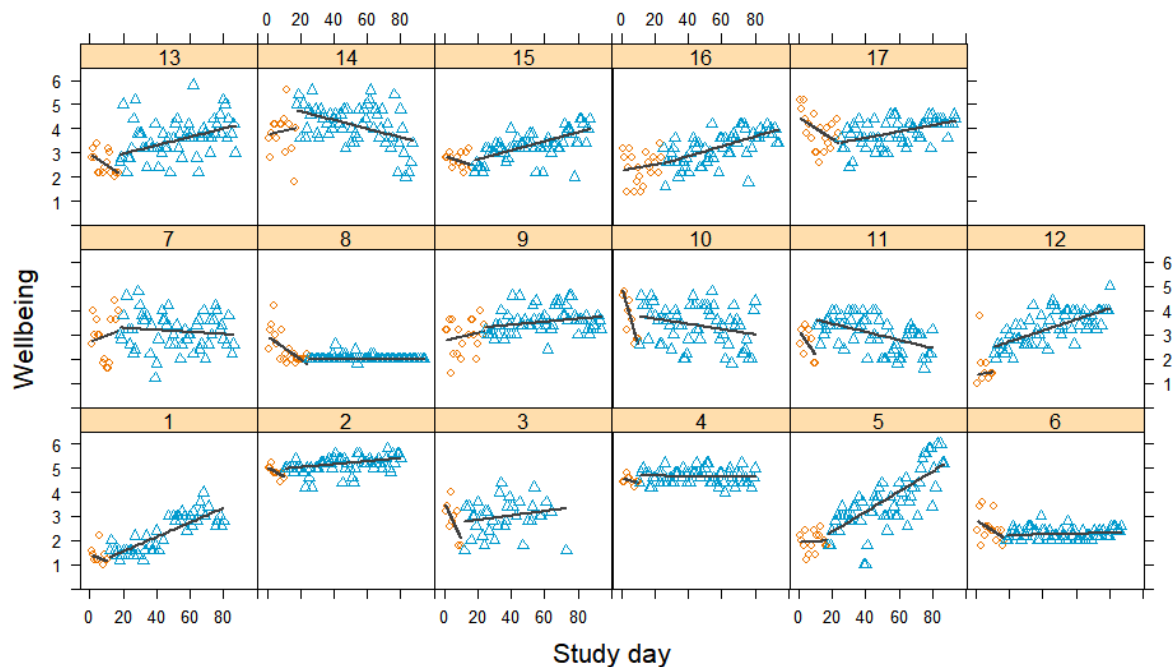


Figure 8. Wellbeing scores during baseline and treatment for each participant, with regression lines for each phase. Orange circles represent baseline measurements, blue triangles treatment measurements, black lines regression lines, and numerals labels indicate each case.

3.7. Possible Explanations for the Findings

Chronic pain is often affected by life circumstances, and our participants readily reported daily events and reflections in the questionnaires. We have analyzed these qualitative statements to elaborate on and find possible explanations for our reported results. On average, the participants were very satisfied with and deeply grateful for their course and had continued to practice until follow-up. Although not all participants experienced reductions in pain, during follow-up, most stated how they had learned important lessons for their lives. These included perceiving and respecting their needs, behaving more kindly and mindfully to themselves and others, and finding ways to deal with or alleviate their pain.

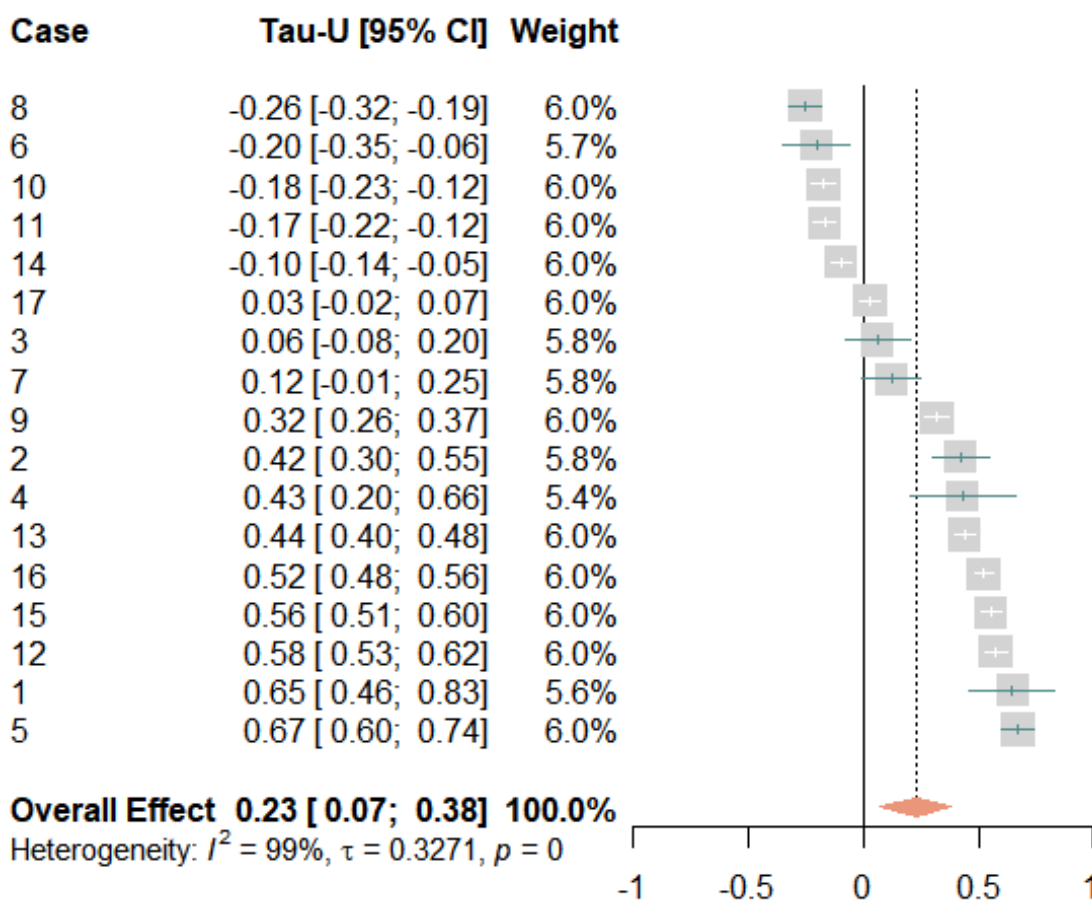


Figure 9. Forest plot of the wellbeing measurements. The grey squares indicate the weight of each case with the mark in the middle representing the observed effect size and the corresponding line the confidence interval. The orange diamond shows the pooled effect size and its length symbolizes the confidence interval.

Two of the three participants who suffered from migraines (cases 3 and 7) did not benefit from the treatment regarding pain or wellbeing, but they experienced increased levels of self-efficacy. They reinforced this finding in their qualitative statements at the end of the study. Participant 7 experienced a range of very stressful life events throughout the course of the study, including multiple deaths of family members and friends. Her pain scores fluctuated the most and she was the only participant who repeatedly marked the highest pain score (100). She stated that the course was very helpful for her during this difficult time.

Participants 10 and 17 exhibited deteriorations in almost all variables over time. Nevertheless, both of them qualitatively stated that they had benefitted from the course and the practices as these helped them to find calmness and change their perspective. Interestingly, while participant 10 reportedly noted work stress or family problems throughout the study, participant 17 reported a lot of positive events such as family visits or participating in musical events. Participants 6 and 8 experienced worsening in some but not all variables. While participant 8 reported some family- and work-related difficulties during the study, participant 6 experienced a throwback during follow-up due to the sudden death of a loved one. Both expressed gratitude for the course and experienced the practices as very helpful.

Moreover, other participants in our sample were exposed to a wide range of stressful life events that had negative impacts on their quality of life. These events included a depressive episode (case 11), the death of a loved one (cases 13 and 14), and the deterioration of an illness (case 14). Nonetheless, many participants perceived the treatment as beneficial and stress-relieving. During the last two weeks of the treatment, participant 9 entered a day

clinic to treat her pain. Therefore, an amelioration of her symptoms could not be attributed solely to MBLM.

In contrast, the strongest pain decreases were reported by patients with chronic back pain. Particularly participants 1, 5, 14, and 15 benefitted from the treatment across variables. In the qualitative statements, they expressed great enthusiasm for the course and how its' different elements helped and inspired them in numerous ways. They reported being calmer and more mindful and present, and some described profound changes in their perspectives after engaging with the ethical component of MBLM.

In addition, we explored the relation between the amount of home practice and the outcomes. The duration of home yoga practice was moderately related to reductions in the strongest pain levels ($r = -0.42$), and it showed small correlations with reduced average pain levels ($r = -0.23$) and improved self-efficacy levels ($r = 0.24$) but no correlation with quality of life ($r = -0.08$). Likewise, the duration of meditation practice was correlated with reduced strongest pain levels ($r = -0.25$) but not with average pain levels ($r = -0.08$). Surprisingly, meditation practice exhibited small negative correlations with self-efficacy levels ($r = -0.21$) and quality of life ($r = -0.12$). In contrast, the engagement in ethical living activities was related to small improvements in all variables (strongest pain ($r = -0.13$), average pain ($r = -0.14$), self-efficacy ($r = 0.17$), and quality of life ($r = 0.24$)). Hence, the more participants engaged in home yoga or ethical practice, but not necessarily meditation practice, the better they responded to the treatment.

4. Discussion

The current study provided further insight into the effects of MBLM as a second-generation mind-body intervention [50], complementing the results published by Matko et al. [35,51] and Bringmann et al. [34,52]. It evaluated MBLM's effects on pain-related outcomes in outpatients suffering from chronic pain using a single-case multiple-baseline design. The intervention moderately enhanced the participants' pain self-efficacy ratings and their average pain and wellbeing levels, and it slightly reduced their strongest pain levels. However, the participants' responses were heterogeneous, indicating large interindividual differences. Interestingly, the treatment was perceived as very helpful by most participants, even if the experienced pain or wellbeing did not improve. In addition, the home yoga and ethical practices were related to improved outcomes, whereas the home meditation practice was only related to reduced strongest pain levels. The current results consolidated previous knowledge on the effectiveness of yoga interventions in improving pain self-efficacy, wellbeing, and pain perceptions [21,23,24]. Yet, as reactions to the intervention varied and we observed a relatively high dropout rate, we concluded that it did not help all participants equally well, and thus, it does not necessarily represent a good addition to interdisciplinary multimodal pain therapy.

MBLM teaches classical yoga, incorporating its ethical and philosophical roots and providing participants with a range of beneficial practices. As such, it differs from most previous studies, which mostly neglected the aspect of yogic philosophy [29,53]. Furthermore, because of the heterogeneity of yoga interventions and differences in study designs, it is difficult to compare our results with those of previous studies. Nevertheless, this study complements and extends previous research.

4.1. Beneficial Effects of MBLM

Previous studies substantiated how yoga interventions improved pain self-efficacy, to a significant extent [27,54,55]. Likewise, high pain self-efficacy positively influenced perceived pain intensity [54,56,57]. As yoga interventions do not always result in pain reductions for all chronic pain patients [16,26,27], improving patients' pain self-efficacy can change their internal engagement and, as a result, their relationship to pain itself. The accompanying change in body awareness can help to manage the common fear of physical activity and the day-to-day management of chronic pain [27,54,56]. This corresponded with the qualitative statements of the participants in this study. Pearson et al. [16] hypothesized

that incorporating the philosophical and spiritual components of yoga may induce better and more lasting effects on self-efficacy and physical and mental health. The current study provides evidence for this notion as the treatment included the ethical component of yoga and elicited large increases in self-efficacy for a majority of the participants.

The results of this study were consistent with previous research that found small to moderate effects of yoga treatments on wellbeing and quality of life in pain patients [23,26,55], particularly for complex yoga interventions [16,58,59]. Tekur et al. [26] proposed that practicing meditation could lead participants to practice mindfulness and avoid emotional overreactions to stress in the future. Although the dismantling trial on MBLM underpinned that mantra meditation may be the driving force in improving participants' emotional regulation and body awareness skills [51], it substantiated that the ethical component was crucial for increasing wellbeing [35]. This is in line with the present study, which suggests that engaging in yoga or ethical exercises might be more beneficial and/or feasible in this respect than meditating.

4.2. Participants Differed in Their Response to the Treatment

The effects on perceived pain were small and inconsistent. This contrasted with previous studies that reported moderate to large effects on pain reduction from yoga interventions. However, many of these interventions focused on specific conditions, such as migraines, rheumatoid arthritis, or chronic low back or neck pain [24,60–62]. Reasons for the varying strength of the effects could depend on the type, location, or cause of the chronic pain, comorbidities, or yoga style [27,63,64]. In the present study, we found stronger effects for patients with back pain compared to patients with migraines. This corresponded with earlier studies that did not find a positive effect of yoga on migraine pain intensity [65,66]. However, in our study, there was one participant with migraines who did benefit from the treatment. This underpins the need to take into account the great variability between participants that we observed. People differ in their pathology, their individual preferences and needs, and their resilience to challenging life events [67–69]. Accordingly, the participants in our sample who faced similar stressful life events responded quite differently with respect to their perceived pain and wellbeing over time. Hence, clinical practice and research should consider these interindividual differences in the multimodal treatment of pain and aim to develop and evaluate personalized treatments [41]. This personalization should go beyond personalized medication and include complementary mind-body interventions.

4.3. Limitations

The study had several limitations. For self-efficacy, there were only few measurements in the baseline phase, which could lead to an overestimation of effect sizes. Despite this limitation, the TAU-U remains one of the most common and valid methods for effect size estimation [46]. Another limitation concerns the female-only participants, which limited the generalizability of the results. Our initial sample included two men who, unfortunately, dropped out of the study. In general, women are at higher risk for many common pain conditions and are more sensitive to pain, but they also appear to benefit more from multimodal pain treatment [44]. Nevertheless, future studies should try to recruit both men and women to evaluate this type of intervention. Furthermore, we had to assume that the participants were intrinsically motivated and interested in yoga and meditation. The drop-outs included two participants who, according to the therapists, were not responding well to the intervention or were not experiencing the quick relief they had hoped for. Hence, clinicians should consider individual patient characteristics, such as openness and patience, when prescribing MBM practices and should not make exaggerated claims regarding their efficacy.

Nevertheless, this study was the first study to evaluate the feasibility of the MBLM program in chronic pain, and further studies with larger sample sizes are warranted. In addition, the diagnosis and duration of pain varied among the participants from a few

months to longer than five years. Many participants had long histories of pain treatments and stated their eagerness to try out a new intervention in the hope that it could help. Chronic pain is a complex syndrome that requires multimodal treatment, and sometimes pain management represents a more realistic goal than achieving freedom from pain. In this context, larger gains in pain self-efficacy than in pain reduction might be a promising pathway. Future studies could be limited to a specific type of chronic pain in order to make clearer statements about when and where MBLM could be a helpful adjunct treatment.

5. Conclusions

The present findings support the efficacy of yoga interventions in chronic pain and demonstrate the potential of the comprehensive approach of Meditation-Based Lifestyle Modification in the treatment of chronic pain. The ethical and philosophical aspects of classical yoga proved to be valuable treatment components and should be further explored in controlled studies to verify their therapeutic utility in multimodal pain management [70,71].

Author Contributions: H.C.B. conceptualized and designed the study under the supervision of A.M., H.C.B., K.M. and M.B. prepared and implemented the study. K.M., M.B., H.C.B., M.P. and B.B. contributed to the statistical analysis and its interpretation. K.M. and M.B. wrote the first draft of the manuscript. All authors have read and agreed to the published version of the manuscript.

Funding: This project was funded by the Karl and Veronica Carstens Foundation (grant number KVC 0/098/2018). The funding source had no influence on the trial methodology, implementation, analysis, and interpretation of the data.

Institutional Review Board Statement: Ethical approval was granted by the Ethics Review Board of the University of Chemnitz University of Technology (V-276-15-PS-MBLM-D-14062018).

Informed Consent Statement: Not applicable.

Data Availability Statement: The data that support the findings of this study are available on request from the corresponding author (H.C.B.). The data are not publicly available due to the sensitivity of human data, which could compromise the research participant privacy/consent.

Acknowledgments: The authors would like to thank T. Kupke and his team at the Zentrum für ganzheitliche Schmerzmedizin in Dresden, Germany, for their friendly support for our study at the trial site.

Conflicts of Interest: The authors declare that there are no conflict of interest.

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3. Diskussion

Die ersten Ergebnisse aus der Entwicklung und Evaluation der Meditation-Based Lifestyle Modification haben gezeigt, dass die Intervention sowohl in einem klinisch-therapeutischen, als auch einem präventiven oder gesundheitserhaltendem Kontext einsetzbar ist. Bei gesunden Teilnehmer:innen zeigte sich der additive Effekt von körperorientiertem Yoga und der ethischen Komponente zur reinen Meditationspraxis und weist damit auf die *a priori* vermuteten synergistischen Effekte innerhalb der komplexen Intervention hin. Bei Patient:innen mit leichter oder mittelgradiger Depression schnitt MBLM besser ab als die psychiatrisch-psychotherapeutische Standardtherapie – bemerkenswerterweise auch im 6-Monats-Follow-Up, was die Nachhaltigkeit des Programms und die intendierte Fähigkeit zur selbständig fortgeführten Praxis der Patient:innen unterstreicht. Herauszustellen sind auch die qualitativen Ergebnisse, die insbesondere der Ethik-Komponente im Gegensatz zu bestehenden MBI eine neue Wirkdimension zukommen lässt, die auch bei in der Psychotherapie erfahrenen Patient:innen besonders herausgestellt wurde. Bei Patient:innen mit chronischen Schmerzen führte die Teilnahme an MBLM zu einer leichten Schmerzreduktion, vor allem aber zu einer verbesserten schmerzspezifischen Selbstregulation.

Inhaltlich ist eine Stärke von MBLM, dass erstmals der 8-fache Pfad des klassischen Yoga mit einer psychotherapeutischen Aufbereitung der lebensethischen Aspekte des Yoga (*yamas* und *niyamas*) in eine umsetzbare und adaptierbare klinische Intervention übersetzt wurde. Nach dem besten Wissen des Autors stellt es demnach das erste *second-generation* MBI aus dem Kontext der Traditionellen Indischen Medizin dar und ist ein erster Hinweis auf die Sinnhaftigkeit der Integration traditioneller, spiritueller Aspekte von Yoga und Meditation. Durch die hohe Strukturiertheit, Modularität und aus Sicht der Therapiedosis nahen Verwandtschaft zum MBSR ist der Weg geebnet für vergleichende Untersuchungen bei weiteren Populationen oder zur fokussierten Weiterentwicklung des Programmes. Methodisch profitierten die durchgeführten Untersuchungen von verschiedenen Forschungsdesigns und Methoden innerhalb des *Mixed Methods* Ansatzes. Auf diese Weise konnten komplexere Informationen über individuelle Therapieverläufe gewonnen werden und ebenfalls berichtete mittlere Effektgrößen und Gruppenvergleiche in einen erklärenden Kontext gestellt werden.

Limitierende Faktoren bei allen Untersuchungen war eine fehlende Verblindung der Proband:innen. Eine einfache Verblindung der Teilnehmer:innen wäre zwar theoretisch denkbar über den Einsatz einer Scheinintervention. Angesichts der Komplexität von MBLM kam dies jedoch aus praktischen Gründen nicht in Frage. Alle Studien haben zudem Selektionsverzerrungen, da die Teilnehmer:innen vermutlich eine Offenheit oder ein Interesse an den Bereichen Yoga und Meditation mitbrachten. In diesem Zusammenhang ist auch anzumerken, dass deutlich mehr Frauen als Männer an den Studien teilnahmen. Bei den depressiven Patient:innen entsprach der Anteil jedoch ungefähr dem indikationsspezifischen Geschlechterverhältnis. Bei den Analysen, in denen Gruppenvergleiche durchgeführt wurden,

waren die Teilnehmerzahlen teilweise zu gering, um zu konfirmatorischen Aussagen zu gelangen. Teile der Ergebnisse sind damit als explorativ zu betrachten und auch die konfirmatorisch angelegten, randomisiert-kontrollierten Studien sollten natürlich zur weiteren Evidenz repliziert und multizentrisch durchgeführt werden. Bei den experimentellen Einzelfallanalysen waren die *Baselines* (Phasen vor Interventionsbeginn) teilweise so kurz gewählt, dass nur eine unzureichende Anzahl von Messpunkten aufgezeichnet werden konnte, um z.B. Trends zu bestimmen. Hierbei handelt es sich um eine generelle Schwierigkeit in den experimentellen Einzelfallanalysen mit Multiple-Baseline-Designs, denn einerseits benötigt man genügend Messpunkte aus der Zeit vor der Intervention für eine robuste statistische Analyse, auf der anderen Seite kann man den Proband:innen nur einen gewissen Aufwand von Messungen zumuten – zumal in der Phase vor der Intervention.

Aus inhaltlicher Perspektive ist davon auszugehen, dass die Sichtweise der Integrativen Medizin auch im Bereich der psychischen Gesundheit in Europa einen zunehmenden Einfluss gewinnen wird. In der Veranstaltung *'Integrative Mental Health – the way forward'* der MEP Interest Group on Integrative Medicine and Health, welche am 28.03.2023 im Europäischen Parlament stattfand, wurde von führenden Experten an der Schnittstelle zwischen psychischer Gesundheit und traditioneller, komplementärer und Integrativer Medizin (TCIM) eindrücklich die Notwendigkeit neuer Lösungen im Bereich der globalen psychischen Gesundheit und die Vorteile des Einsatzes von TCIM in diesem immer wichtiger werdenden Bereich evidenzbasiert dargestellt.¹⁰⁴

Der Mind-Body-Medizin kommt dabei eine tragende Rolle als Antwort auf stressassoziierte Erkrankungen zu. Während vor 50 Jahren noch kaum Bewusstsein dafür bestand, dass achtsamkeitsbasierte, resilienzfördernde, meditative Verfahren und Lebensstiländerungen einen Einfluss auf die Gesundheit haben könnten, sprechen sich Pioniere wie der US-Arzt und Wissenschaftler Herbert Benson nach jahrzehntelanger Forschung klar dafür aus, dass die Mind-Body-Medizin sowohl im Bereich der Primär- und Sekundärprävention, in der Routineversorgung als auch im primären und sekundären edukativen Bereich wachsende Bedeutung erhalten sollte.¹⁰⁵ Stressregulation ist elementarer Baustein für die Entstehung, Aufrechterhaltung bzw. Verschlechterung, Behandlung und Rückfallprophylaxe psychischer Erkrankungen – und damit auch körperlicher Erkrankungen, denn Gesundheit gibt es nicht ohne psychische Gesundheit.¹⁰⁶

Dafür muss sich die Mind-Body-Medizin „horizontal“ weiterentwickeln, indem sie mehr Menschen in der Gesellschaft erreicht – insbesondere auch präventiv und gesundheitserhaltend bzw. gesundheitsfördernd. Zum anderen ist eine „vertikale“ Entwicklung wünschenswert, in der sogenannte „second generation“ Mind-Body-Interventionen mehr inhaltliche Tiefe, realem Lebensbezug und Nachhaltigkeit im Alltag der Teilnehmerinnen z.B. durch den Einbezug von Ethik und Spiritualität erzeugen. Auf diese beiden Dimensionen soll im Folgenden eingegangen werden.

3.1 Breiter Einsatz von Mind-Body-Interventionen

Wie bereits in der Einleitung erwähnt, haben Studien zu Mind-Body-Interventionen mit dem Schwerpunkt auf achtsamkeitsbasierte Verfahren in den letzten Jahren exponentiell zugenommen und werden sowohl komplementär als auch in der Standardversorgung vor allem in der Behandlung von chronischen Erkrankungen eingesetzt.¹⁰⁷ In den USA nutzen bereits seit den 1990er Jahren knapp 20% der Bevölkerung MBM – vor allem Frauen, Menschen mit höherem Bildungsniveau, Singles und Menschen, die an mehreren chronischen Krankheiten leiden.¹⁰⁸ Übersichtsarbeiten berichten vor allem über einen Einsatz von MBM bei hochprävalenten somatischen Erkrankungen wie dem Metabolischem Syndrom,¹⁰⁹ arterieller Hypertonie,¹¹⁰ Typ-II-Diabetes,¹¹¹ Adipositas,^{112,113} Krebserkrankungen,^{114–116} chronischem Rückenschmerz,¹¹⁷ Asthma bronchiale,¹¹⁶ rheumatoider Arthritis,¹¹⁸ kognitiven Einschränkungen,¹¹⁹ multipler Sklerose¹²⁰, dem Reizdarmsyndrom¹²¹ und Hauterkrankungen.¹²² In aller Regel zeigen sich in diesen Studien positive Effekte auf den Erkrankungsverlauf bei kleinen bis mittleren Effektstärken. Potentiale der MBM werden darin gesehen, dass diese aufgrund ihrer geringen oder nicht vorhandenen Nebenwirkungen komplementär einsetzbar sind und so gegebenenfalls nebenwirkungsreichere Medikamente reduziert werden können. Zu den häufig genannten Einschränkungen gehören eine niedrige Qualität der Evidenz aufgrund von kleinen Stichprobengrößen, fehlenden Langzeituntersuchungen und fehlenden Kontrollgruppen. Auch eine unzureichende Standardisierung der Behandlungskomponenten, der Dosis, der Intensität, der Interventionsdauer und der Ausbildung der Behandler erschweren die Verallgemeinerung über Studien hinweg. Aufgrund der Vielfalt von Mind-Body-Interventionen ist darüber hinaus von verschiedenen und wechselseitigen Wirkmechanismen auszugehen, was eine theoriegeleitete Forschung vor große Herausforderungen stellt.

Bei psychischen Erkrankungen liegen ebenfalls mehrere aktuelle Übersichtsarbeiten vor, wobei vorrangig die Wirkungen von Mind-Body-Interventionen bei Krankheitsbildern der Depression,^{50,74,76,79,80,123–125} Schizophrenie,^{51,79,80,125–128} PTBS,^{125,129} kognitiver Störungen im Alter,^{119,130} ferner auch der Angststörungen¹³¹ und Schlafstörungen¹³² abgebildet werden. Einzelne Studien weisen sogar hohe Effektgrößen der Mind-Body-Interventionen auf, zum Beispiel das körperorientierte Yoga in der Behandlung von Schizophrenie oder Depression.⁸⁰ Eine aktuelle Metasynthese¹²⁵ unterstützt die Aussage, dass vor allem achtsamkeitsbasierte Interventionen in einem breiten Anwendungsgebiet hilfreich in der komplementären Behandlung von psychischen Erkrankungen sind. Aufgrund ähnlich gelagerter Einschränkungen wie bereits im vorhergehenden Absatz bei den somatischen Erkrankungen erläutert, fehlen jedoch noch ausreichende Daten, um genauere Empfehlungen auszusprechen.

Eine weitere Entwicklung ist das Angebot von MBM/MBI für Kinder, Schüler:innen und Student:innen sowohl im therapeutischen Bereich (z.B. verhaltensauffällige Kinder oder gestresste Student:innen) als auch im primärpräventiven Bereich, um eine gesunde Entwicklung

von sozial-emotionalen Kompetenzen zu fördern. Bei Kindern im Vorschulalter zeigte eine aktuelle Übersichtsarbeit¹³³ dass MBI insbesondere bei Kindern, die eine schwächere sozial-emotionale Ausgangslage haben, positive Auswirkungen auf Selbstregulation, Aufmerksamkeitsfähigkeit, prosoziales Verhalten sowie das allgemeine Wohlbefinden haben. Fundierte theoretische Überlegungen legen nahe, dass beispielsweise das Angebot von Yoga im Rahmen eines schulischen Lehrplans ein wirksames Mittel sein kann, um Schüler:innen bei der Entwicklung von Selbstregulierung, Körperbewusstsein und körperlicher Fitness zu helfen. Diese Fähigkeiten fördern wiederum Kompetenzen der sozial-emotionalen Entwicklung und damit prosoziales Verhalten, eine Verbesserung der psychischen Verfassung, der körperlichen Gesundheit und der schulischen Leistung.^{134,135} Empirische Studien zu schulbasierten Yogaprogrammen zeigen eine Verbesserung von affektiver Regulation, Selbstkonzept, Resilienz, Selbstwertgefühl, subjektivem und psychologischem Wohlbefinden, sowie kognitiv-exekutiven Funktionen mit positiver Auswirkung auf die Schulleistung bei gesunden („neurotypischen“) Bevölkerungsgruppen.¹³⁶ Auch bei „neurodiversen“ Teilnehmer:innen gibt es Hinweise zu Verbesserungen des Selbstkonzepts, des subjektiven Wohlbefindens, der exekutiven Funktion, der schulischen Leistung und der Aufmerksamkeit.¹³⁶ Eine Übersichtsarbeit über schulbasierte Meditation bei Jugendlichen zeigte eine Verbesserung der affektiven Regulation und Stimmungslage, der sozialen Interaktion, eine Abnahme von Stress und negativen Emotionen sowie eine signifikante Verbesserung der Selbstreflexion und der schulischen Aufmerksamkeit.¹³⁷ Eine Übersichtsarbeit mit Meta-Analyse zeigte, dass sich Mind-Body-Interventionen mit körperlicher Aktivität positiv auf bestimmte physiologische Parameter bei Schüler:innen und Studierenden auswirken können, insbesondere im Hochschulbereich: es zeigten sich statistisch signifikante und zugleich große Effekte für die Wirksamkeit solcher Interventionen auf die Senkung der Herzfrequenz, des Cortisols sowie des systolischen und diastolischen Blutdrucks.¹³⁸ Randomisiert-kontrollierte Studien zeigten, dass Yogaübungen bei psychisch belasteten Student:innen die autonome Regulation von Atmung, Blutzirkulation, und Schlaf verbesserten und insbesondere das Zusammenspiel von unterschiedlichen Yoga-Komponenten (körperliche Positionen, Atmung und Meditation) die psychische Gesundheit verbesserte.¹³⁹ Aus der Perspektive der Selbstregulation könnte ein weiterer Einsatzbereich von MBM der unter jungen Erwachsenen weit verbreitete Missbrauch von Alkohol und anderen Drogen sein, welcher regelhaft zu diversen sozialen, wirtschaftlichen und gesundheitlichen Langzeitfolgen führt. Dabei sind bestehende Therapieprogramme zugleich uneinheitlich und unzureichend in ihrer Wirksamkeit. Mind-Body-Ansätze wie Meditation und Yoga könnten ein wichtiger Baustein sein, Resilienz und Regulationsfähigkeit aufzubauen und so maladaptive Strategien im Umgang mit Stress und belastenden Lebensereignissen zu vermeiden.¹⁴⁰ Die meisten Übersichtsarbeiten mit Populationen von Schüler:innen und Studierenden bemängeln eine unzureichende Studienqualität, so dass zusammen mit der großen Heterogenität von Interventionen, Interventionsdauer, Studiendesigns und Populationen zum jetzigen Zeitpunkt nur eingeschränkte Schlussfolgerungen gezogen werden können.^{133–140}

Ein nächster wichtiger Bereich in der breiten Anwendung von MBM ist der Einsatz am Arbeitsplatz bzw. beruflichem Umfeld. In einer Übersichtsarbeit für achtsamkeitsbasierte Meditation zeigten sich bei chronischer Krankheit, Schmerz, Substanzkonsum, Depression, Angst, Stressempfinden, Somatisierung, Coping bei Krebserkrankung und Reizdarmsyndrom mögliche positive Effekte.¹⁴¹ Weitere Übersichtsarbeiten deuten darauf hin, dass sich Yoga positiv auf die Gesundheit am Arbeitsplatz auswirkt, insbesondere auf den Abbau von Stress und Burnout. Auch hier zeigen sich in den eingeschlossenen randomisierten kontrollierten Studien keine oder nur zu vernachlässigende negative oder unerwünschte Auswirkungen der Interventionen.¹⁴²⁻¹⁴⁴ Auch aus Arbeitgebersicht gibt es Hinweise, dass achtsamkeitsbasierte Anwendungen zur Verbesserung der psychischen Gesundheit, des Wohlbefindens und der Leistungsfähigkeit von Mitarbeitern beitragen: in einer aktuellen Übersichtsarbeit zeigten sich neben positiven Ergebnissen auf der individuellen Eben auch positive Effekte auf Ebene des Arbeitsplatzes, auf Ebene der Teams und auf höheren Organisationsebenen. Die Autor:innen weisen jedoch darauf hin, dass trotz der Vorteile bislang nur wenige Unternehmen die Achtsamkeitstrainings für ihre Mitarbeiter nachhaltig eingeführt haben.¹⁴⁵

Zusammenfassend zeigt sich ein Bild im Gesundheitswesen westlicher Industrienationen, in dem die MBM viele Bereiche der Prävention und Therapie zwar experimentell erreicht hat, jedoch vor allem Bereich der Prävention und Gesundheitserhaltung noch nicht ausreichend Fuß für eine flächendeckende Anwendung gefasst hat. Es fehlen einerseits hochwertige, aussagekräftige Studien (s.o.), aber andererseits auch eine zielgerichtete Agenda des Gesundheitswesens für eine stärkere Integration von Achtsamkeitsansätzen in globale, nationale und lokale Bemühungen um die öffentliche Gesundheit,¹⁴⁶ obwohl MBM/MBI das Potential haben, zu Kosteneinsparungen im Gesundheitswesen bei gleichzeitiger Steigerung der Lebenszufriedenheit zu führen.^{147,148}

3.2 Vertiefung von Mind-Body-Interventionen

Wie im vorangegangenen Abschnitt dargestellt, gehören Yoga und Achtsamkeit („Mindfulness“) in der wissenschaftlichen Untersuchung klinischer Interventionen zu den prominentesten Vertretern der Mind-Body-Medizin und bilden häufig entweder die Grundlage oder Bestandteil von klinischen Mind-Body-Therapien. Bei der Translation dieser aus dem Hinduismus und Buddhismus stammenden Konzepte und Praktiken in den westlichen Kulturkreis ist es zu Anpassungsvorgängen gekommen, die wesentlich zu einer Säkularisierung, Dekontextualisierung und Kommerzialisierung traditioneller Inhalte der Ursprungskultur geführt haben. Am differenziertesten ist die Diskussion dieser Phänomene wohl bei achtsamkeitsbasierten Interventionen fortgeschritten, die auf dem MBSR-Programm nach Kabat-Zinn basieren. Im Zuge des großen Erfolges des Programms für verschiedene Anwendungsgebiete und seiner Weiterentwicklung in explizit psychotherapeutische Bereiche hinein¹⁴⁹⁻¹⁵¹ ist auch Kritik zum Vorschein getreten. Beginnend mit dem 2013 in der *Huffington*

Post erschienenen Artikels „*Beyond McMindfulness*“ wurden tatsächliche Effektivität, zugrundeliegende Ethik und zielgerichtete Interessen von unternehmensgeförderten Achtsamkeitsprogrammen in Frage gestellt.¹⁵² Zudem wurde von buddhistischen Gelehrten und/oder auch im wissenschaftlichen Kontext kontrovers diskutiert, ob MBSR tatsächlich den Kern buddhistischer Lehren darstelle – und damit ebenfalls die Leitfrage der vorliegenden Arbeit in den Raum stellt, ob die ursprüngliche Tradition nicht mehr Tiefe und ggf. „Wirkfaktoren“ bereithält als eine säkularisierte und dekontextualisierte Intervention.^{153,154} Auch Teilnehmer vertraten die Ansicht, dass MBI nicht immer eine authentische Darstellung von Achtsamkeit widerspiegeln und waren sich beispielsweise der Problematik bewusst, dass eine Kommerzialisierung zu einer eher oberflächlichen Konzeptualisierung von Achtsamkeit in modernen MBI führen könnte. Damit verbunden war die Präferenz für eine authentischere Präsentation mit spirituelleren oder traditionsverbundeneren Inhalten innerhalb der angebotenen Programmen.¹⁵⁵

Auch in der Translation von Yoga in den okzidentalen Kulturkreis kam es zu Veränderungen traditioneller Inhalte. Neben der geschichtlichen Entwicklung eines im Wesentlichen meditativen, spirituell ausgerichteten Yogas hin zu einem körperorientierten Yoga in Indien selbst standen auch im westlichen Kontext zunehmend Körperpositionen, Atemübungen und unterschiedliche meditative Komponenten im Fokus der wissenschaftlichen Erforschung, klinischen Anwendung und gesellschaftlichen Rezeption.⁴⁶ Die ethischen Komponenten des klassischen Yogas sowie ihre bewusstseinsphilosophischen Aspekte blieben zwar in der internationalen wissenschaftlichen Literatur erwähnt, finden in den klinischen Interventionen jedoch nur eine rudimentäre Umsetzung.^{59,61} Auch in der medialen Darstellung entwickelte sich Yoga von einer geistigen und philosophisch-spirituellen Disziplin zu einer kommerzialisierten Form körperlicher Praxis, in der zugleich gerichtete Vorstellungen von Weiblichkeit in der Präsentation schlanker, junger, weißer Frauenkörper als Sinnbild für die Yogapraxis kolportiert wurden.¹⁵⁶

Im Kern stellen sich zwei komplexe und wohl nur im zeitlichen Prozess der weiterführenden Forschung und Reflektion zu beantwortenden Fragen. Auf der einen Seite, wie weit fernöstliche traditionelle Lehren, wenn sie aus ihrem soziokulturellen Kontext entnommen werden, angepasst werden *müssen*, um überhaupt in der westlichen Kultur Fuß fassen zu können - hier geht es um eine notwendigerweise kultur- und religions/spiritualitätssensible Integration von Inhalten und Praktiken.¹⁵⁷ Auf der anderen Seite, wie weit *dürfen* sie verändert werden, um nicht in einer zielkulturkompatiblen, aber dafür „verdünnten“ und möglicherweise sogar verfehlten Form zu etwas ganz anderem zu werden, als ursprünglich intendiert. Mediale Narrative von Well-Being und Fitness sowie in der bisherigen Forschung hauptsächlich untersuchte Zielparameter wie Stress- und Symptomreduktion bei chronischen Erkrankungen stehen hier ursprünglichen Zielen wie eudaimonischem Wohlbefinden und spiritueller Befreiung gegenüber (s.o.).

Seit etwa 2014 wird von einer zunehmenden Untersuchung sogenannter MBIs der zweiten Generation berichtet, die im Vergleich zu den MBIs der ersten Generation eine größere Übereinstimmung mit den traditionellen Konzeptualisierungen von Achtsamkeit aufweisen sollen.¹⁵⁸ Wie bereits in der Einleitung dargestellt, ist für diese charakteristisch, dass sie offen psycho-spirituell sind, Meditation zentral und in einem breiterem Kontext thematisieren, Ethik eine Schlüsselkomponente der Interventionen darstellt und strukturierte Ausbildungsprogramme für die Therapeuten beinhalten.⁸⁵ Zu den ersten MBI der zweiten Generation gehören z.B. das *Meditation Awareness Training* (MAT), mit Wirksamkeitsnachweisen u.a. bei der Verbesserung arbeitsplatzbezogenen Wohlbefindens und verschiedenen Symptomen bei Fibromyalgie.^{159,160} Weitere MBI der zweiten Generation sind z.B. das *Awareness Training Program* (ATP), das sich textlich an der buddhistischen Mahayana-Sūtra orientiert¹⁶¹ oder das *Mindfulness-Based Positive Behavior Support* (MBPBS), welches u.a. Unterweisungen zu buddhistischen Kernqualitäten wie liebende Güte, Mitgefühl, Freude und Gleichmut beinhaltet, die Abkehr von Anhaftung, Ärger und Unwissenheit thematisiert und meditative Techniken beinhaltet.¹⁶²

Interessant sind in diesem Zusammenhang auch neuere Entwicklungen der Psychotherapie. In der dritten Welle der Verhaltenstherapie¹⁶³ wurde Achtsamkeit zusätzlich zu kognitiven Verfahren erfolgreich eingesetzt, um bestehende Therapietechniken zu ergänzen – beispielsweise in der achtsamkeitsbasierten kognitive Therapie (MBCT)¹⁵⁰ oder der Akzeptanz- und Commitment-Therapie (ACT).¹⁵¹ Neuere Entwicklungen in der Psychotherapie setzen darüber hinaus *Human Flourishing*¹⁶⁴ und eudaimonisches Wohlbefinden¹⁶⁵ in den Mittelpunkt der Therapie und lenken damit den Fokus weiter weg von einer pathogenetischen und symptomkorrektiven Sichtweise hin zur individuellen Potentialentfaltung und tiefergehenden Ressourcenarbeit. Zu den Ansätzen dieser möglicherweise "vierten Welle" der Psychotherapie gehören z.B. Interventionen der Positiven Psychologie und spirituell orientierte Therapien, die sich aus existenziellen und humanistischen Hintergründen entwickelt haben.¹⁶⁶

Achtsamkeitsbasierte Interventionen der zweiten Generation harmonieren gut mit der Philosophie und Praxis der positiven Psychologie.¹⁶⁷ In dieser Überschneidung kann auch das in dieser Arbeit dargestellte MBLM-Programm verortet werden. Wie in den präsentierten Publikationen dargestellt, zeichnen sich beispielsweise sowohl die additiven Effekte der ethischen Komponente von MBLM ab⁸⁹ als auch die Schlüsselfunktion der psychotherapeutische Herangehensweise, mit der diese den Teilnehmern vermittelt wird.⁹⁴

3.3 Forschungsperspektiven

Im Sinne der Argumentation einer weiteren horizontalen Anwendungsverbretung von Mind-Body-Therapien und einer vertikalen Vertiefung der Interventionen erscheinen verschiedene Forschungsperspektiven relevant für das zukünftige Vorgehen.

Wie in den vorangegangenen Abschnitten dargestellt, mangelt es zumindest im Bereich von MBIs und Yoga nicht an wissenschaftlicher Literatur zur Effektivität von Interventionen in bestimmten Zielpopulationen – wenn auch mit Einschränkungen in der Studienqualität. Neben hochqualitativeren randomisiert-kontrollierten Studien zur Untersuchung der Wirksamkeit unter speziellen Bedingungen erscheint es zunehmend wichtig, mit den Methoden der Versorgungsforschung etabliertere Interventionen in der Regelversorgung zu untersuchen. Dazu gehören Fragestellungen der Kosten und Finanzierung dieser Therapien, die Erforschung sozialer und individueller Faktoren in der Zugänglichkeit von Interventionen, der Qualitätskontrolle und der Wirkung auf die gesellschaftliche Gesundheit.¹⁶⁸ Hierzu gehören auch im weiteren Sinne generalisierte Kosten-Nutzen-Analysen, die nicht nur neue Interventionen mit bestehenden vergleichen, sondern tiefergehende Analysen beispielsweise unter Gesichtspunkten der Gesundheitserhaltung und Prävention ermöglichen.¹⁶⁹ Für MBLM würden diese Schritte freilich erst nach weiterer Evaluation zum Beispiel im Rahmen von multizentrischen Studien, Implementation in anderen Zielpopulationen und der Entwicklung von standardisierten Ausbildungsprogrammen sinnvoll.

Mehrdimensionale („ganzheitliche“) komplementärmedizinische Ansätze basieren auf der grundlegenden Perspektive von einer Verbundenheit der Komponenten und deren Wechselwirkung untereinander innerhalb eines komplexen Behandlungsansatzes. Dabei bestimmen emergente, synergistische und nicht-lineare Effekte den therapieinduzierten und -geleiteten Veränderungsprozess des Menschen, welcher wiederum in seiner Wechselwirkung und seinem Erleben untrennbar verbunden ist mit seiner Umwelt. Diese grundlegenden Überzeugungen und Prinzipien stehen im Gegensatz zu den Annahmen des Reduktionismus und konventioneller biomedizinischer Forschungsmethoden, die von eher eindimensionalen Ursachen ausgehen und in der Regel Interventionen überprüfen, die nur einzelne Aspekte eines mehrdimensionalen Therapiesystems („Whole Medical System“) für teils hochspezifische Patient:innenpopulationen betrachten.¹⁷⁰ Benötigt wird daher ein *Whole Medical System Research*, zu dessen synergistischen Konstruktionsmerkmalen die Rekrutierung multimorbider Teilnehmer:innen, die Durchführung von Interventionen mit multiplen Zielparametern, die Einbeziehung subjektiver Patient:innenerfahrungen, diversifizierte und mehrfache Messungen der Behandlungseffekte und die gleichzeitige Anwendung quantitativer und qualitativer Methoden gehören. Auf diese Weise können komplexe Verläufe intraindividuell abgebildet werden und mit entsprechenden statistischen Methoden so ausgewertet werden, dass einerseits die Effektivität eines therapeutischen Systems in realer Anwendungssituation dargestellt werden kann, als auch seine paradigmatische Kompatibilität, Konsistenz und Spezifität.¹⁷¹ Wie einleitend diskutiert, wurden diese Herangehensweisen teilweise auch in den vorliegenden Studien zu MBLM umgesetzt.

Im Bereich der Grundlagenforschung wird für ein tiefergehendes Verständnis und eine weiterführende Integration traditioneller Systeme mit spiritueller-religiöser oder ethischer

Inhalten notwendig sein, deren psychologischen Anteile methodisch zu testen und in den Kontext der westlichen Psychologie zu stellen und diesen gegebenenfalls zu erweitern. Methodische Überlegungen dazu finden sich z.B. bei den Arbeiten von P. Sedlmeier⁵⁶⁻⁵⁸ Neben einer Naturalisierung von spirituell-religiösen Inhalten wird aber auch das materialistische, naturwissenschaftliche Paradigma sich neuen Ergebnissen aus der Bewusstseinsforschung wie z.B. empirischen Hinweisen auf Non-Lokalität des Bewusstseins stellen müssen.¹⁷² Dies könnte aus neuen Forschungsparadigmata der sich formierenden *Contemplative Sciences* geschehen, bei denen z.B. Erkenntnisse aus Strukturanalogien traditioneller spiritueller Philosophien als Grundlage für empirisch testbare Modelle entwickelt werden oder zentrale Fähigkeiten, Prozesse und Zustände des Geistes untersucht werden, die durch kontemplative Praktiken verändert werden.^{173,174}

Es gibt also weitreichende Aufgaben in der „neuen Ära für die Mind-Body-Medizin.“¹⁰⁵ Wenn die hier diskutierte „horizontale“ und „vertikale“ Entwicklung weiterhin gelingt, birgt sie das Potential, einen wesentlichen Beitrag zur globalen psychischen Gesundheit und Lebensqualität zu leisten. Dafür braucht es neben einer wissenschaftlichen Generierung und Evidenzsicherung von MBM Verfahren nachhaltige Entscheidungen der Bildungs- und Gesundheitspolitik, um die notwendigen Ressourcen für Forschung, Lehre und Praxis in diesem Bereich zu fördern.

4. Zusammenfassung

Psychische Gesundheit stellt eine der zentralen Herausforderungen für das Gesundheitssystem des 21. Jahrhunderts dar. Vor dem Hintergrund global hoher Prävalenzraten psychischer Erkrankungen und zugleich ungedecktem Behandlungsbedarf, gepaart mit Limitationen hinsichtlich der Wirksamkeit und Sicherheit von psychopharmakologischen Interventionen, wird deutlich, dass weiterer Bedarf an wirksameren, sichereren, erschwinglicheren und leichter zugänglichen Therapieansätzen besteht. In diesem Zusammenhang hat auch die Integrative Medizin ihren Einzug in Psychiatrie, Psychosomatik und Psychotherapie gehalten und wird von Patient:innen entsprechend stark nachgefragt. Der Mind-Body-Medizin kommt hierbei eine besondere Rolle zu, bei der durch multimodale Interventionen körperliche, mentale, emotionale, soziale und spirituelle Einflussfaktoren zur mehrdimensionalen Förderung einer individuellen gesundheitlichen Lebensstilgestaltung zum Tragen kommen. Insbesondere achtsamkeitsbasierte Therapieansätze und körperorientiertes Yoga sind inzwischen wissenschaftlich gut untersucht und die Wirkung insgesamt zunehmend gut belegt. Seit einigen Jahren zeichnet sich die Entwicklung einer zweiten Generation von achtsamkeitsbasierten Interventionen ab, die über die bisherige Dekontextualisierung und Säkularisierung traditioneller fernöstlicher Praktiken hinaus gehen und gezielt ethische und spirituelle Inhalte der entsprechenden Interventionen thematisieren. In diesem Kontext ist auch die in dieser Arbeit präsentierte, auf traditionellem Yoga basierende *Meditation Based Lifestyle Modification* (MBLM) einzuordnen. Erste Ergebnisse zeigen ihre positiven Effekte bei gesunden Menschen sowie in den Indikationen leichte bis mittelgradige Depression und chronische Schmerzerkrankungen unterschiedlicher Genese. Der ethischen Komponente des Programms kommt dabei angesichts der quantitativen und qualitativen Ergebnisse eine besondere Rolle zu. Für die flächendeckendere Anwendung bzw. Verbreitung bereits gut untersuchter Mind-Body-Interventionen der ersten Generation sind Methoden der Versorgungsforschung auch in den Bereichen Präventionen und Gesundheitserhaltung zunehmend relevant. Für eine weitere Erforschung der vielversprechenden Interventionen der zweiten Generation sind sowohl Grundlagenforschung zur Untersuchung von spezifischen bzw. unspezifischen Effekten der jeweiligen Intervention als auch die weitere klinische Forschung und Versorgungsforschung unter der Einbeziehung von modernen Studiendesigns mit einem Mixed-Methods-Ansätzen und unter der Beachtung eines Whole-Medical Research Ansatzes relevant, um zu weiterführenden Erkenntnissen zu gelangen.

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6. Danksagung

Mein erster Dank gilt meinen Eltern, mit deren Unterstützung die Möglichkeiten überhaupt entstanden, mich einer Arbeit wie dieser zu widmen.

Ich danke meinen spirituellen Lehrern für das Bewusstsein und den Atem, die es mir ermöglicht haben, die vielfältigen Lehren dieser Arbeit erfolgreich genutzt haben zu können.

Ich danke der umfangreichen Unterstützung wichtiger Menschen in diesem Projekt, mit deren individueller Kompetenz, aber auch deren Offenheit, Zuversicht und Vertrauen Dinge im Großen und im Kleinen möglich wurden: Prof. Dr. Andreas Michalsen, Prof. Dr. Dr.

Brunnhuber, Prof. Dr. Peter Sedlmeier, Prof. Dr. Benno Brinkhaus, Prof. Dr. Stefan Willich, den Mitarbeiter:innen der Karl und Veronica Carstens-Stiftung, Chefarzt Dr. Somburg und den Mitarbeitern der Klinik für Psychiatrie, Psychosomatik und Psychotherapie in Zschadras sowie Dr. T. Kupke und seinem Team des Zentrums für ganzheitliche Schmerzmedizin in Dresden.

Insbesondere danke ich allen Koautor:innen für ihre Mitarbeit an den Publikationen, allen voran Dr. Karin Matko, die das Projekt über die gesamte Laufzeit und darüber hinaus mit großem Engagement und wissenschaftlicher Kompetenz ganz wesentlich unterstützt hat. Ich danke Dr. Michael Jeitler und PD Dr. Christian Kessler für die freundschaftliche und wertschätzende Zusammenarbeit.

Ich danke meiner Frau für die Mitentwicklung und Umsetzung der *Meditation-Based Lifestyle Modification*, für ihre Geduld und ihre liebevolle Unterstützung in allen Phasen des Projektes.

Ich danke allen Patienten:innen, die innerhalb und außerhalb der Studien an den von uns entwickelten meditativen Therapien teilgenommen haben. Es waren die Freude am gemeinsamen Weg und die gegenseitige Dankbarkeit, die letztlich allen Bemühungen dieses Projektes Wert schenkten.

Erklärung

§ 4 Abs. 3 (k) der HabOMed der Charité

Hiermit erkläre ich, dass

- weder früher noch gleichzeitig ein Habilitationsverfahren durchgeführt oder angemeldet wurde,
- die vorgelegte Habilitationsschrift ohne fremde Hilfe verfasst, die beschriebenen Ergebnisse selbst gewonnen sowie die verwendeten Hilfsmittel, die Zusammenarbeit mit anderen Wissenschaftlern/Wissenschaftlerinnen und mit technischen Hilfskräften sowie die verwendete Literatur vollständig in der Habilitationsschrift angegeben wurden,
- mir die geltende Habilitationsordnung bekannt ist.

Ich erkläre ferner, dass mir die Satzung der Charité – Universitätsmedizin Berlin zur Sicherung Guter Wissenschaftlicher Praxis bekannt ist und ich mich zur Einhaltung dieser Satzung verpflichte.

...10.06.2023.....

Datum



Unterschrift