Aus dem Institut für Sozialmedizin, Epidemiologie und Gesundheitsökonomie
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DISSERTATION

Komplementärmedizin bei Senioren

zur Erlangung des akademischen Grades
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Inhaltsverzeichnis

Abkürzungsverzeichnis

ADLs	Activities of Daily Living
AMPS	Assessment of Motor and Process Skills
ANOVA	Analysis of variance
BI	Barthel Index
CAM	Complementary and Alternative Medicine
etc.	et cetera
ggf.	gegebenenfalls
IM	Interventionsgruppe
KORA	Cooperative Health Research in the Region of Augsburg
KT	Kneipp-Therapie
MMSE	Mini Mental State Examination
n	Number
NOSGER	Nurses Observation Scale for Geriatric Patients
OR	Odds Ratio
PW	Profil des Wohlbefindens
QUALIDEM	Quality of Life in Dementia
RV	Routineversorgungsgruppe
SF-12	Short Form 12 Health Survey
TCM	Traditionelle Chinesische Medizin
usw.	und so weiter
vs.	versus
WAI	Work Ability Index
WG	Seniorenwohngemeinschaft

Publikationsübersicht

Der vorliegenden Dissertationsschrift liegen folgende Publikationen zu Grunde.

Publikation 1

Titel:	Effects and feasibility of an Integrative Medicine program for geriatric patients - a cluster-randomized pilot study
Autoren:	Michael Teut, Katharina Schnabel, Ralf Baur, Annette Kerckhoff, Frauke Reese, Nils Pilgram, Franziska Berger, Rainer Lüdtke, Claudia M. Witt
Journal:	Clinical Interventions in Aging
Volume:	8
Seiten:	953-961
Verlag:	Dove Press
Erscheinungsdatum:	20. Juli 2013
Impact Factor:	1,824 (2013)

Publikation 2

Titel:	Use of complementary and alternative medicine by older adults - a cross-sectional survey
Autoren:	Katharina Schnabel, Sylvia Binting, Claudia M. Witt, Michael Teut
Journal:	BMC Geriatrics
Volume:	14
Seiten:	38
Verlag:	BioMed Central
Erscheinungsdatum:	26. März 2014
Impact Factor:	2 (2014)

Publikation 3

Titel:	Complementary medicine in nursing homes - results of a mixed methods pilot study
Autoren:	Miriam Ortiz, Eva Soom Ammann, Corina Salis Gross, Katharina Schnabel, Torsten Walbaum, Sylvia Binting, Herbert Felix Fischer, Michael Teut, Jan Kottner, Ralf Suhr, Benno Brinkhaus
Journal:	BMC Complementary and Alternative Medicine
Volume:	14 (1)
Seiten:	443
Verlag:	BioMed Central
Erscheinungsdatum:	23. September 2014
Impact Factor:	1,877 (2014)

Abstrakt

Hintergrund und Zielstellung: In Deutschland ist die Inanspruchnahme und Wirksamkeit von Komplementärmedizin (CAM) bei Senioren nicht systematisch untersucht. Ziele der Studien waren daher, die Durchführbarkeit eines „integrativmedizinischen"-Programmes und dessen Effekte zu untersuchen (*Publikation 1*), Daten zur Inanspruchnahme von CAM bei Senioren zu erheben (*Publikation 2*) und die Anwendung von Kneipp-Therapie in Pflegeheimen zu erfassen (*Publikation 3*).

Methodik: Es wurden eine cluster-randomisierte Pilotstudie (*Publikation 1*), eine Umfragestudie (*Publikation 2*) und eine Querschnittstudie mit Mixed Methods (*Publikation 3*) durchgeführt. *Publikation 1:* Die Hälfte der Seniorenwohngemeinschaften erhielt nur die konventionelle Versorgung und die andere Hälfte zusätzlich ein 12 monatiges „integrativmedizinisches"-Programm, bestehend aus Sport, Homöopathie und naturheilkundlicher Pflege. Outcomeparameter waren die Nurses Observation Scale for Geriatric Patients (NOSGER), der Barthel-Index (BI), der Quality of Life in Dementia (QUALIDEM), das Profil des Wohlbefindens (PW), der Mini Mental State Examination (MMSE) und das Assessment of Motor and Process Skills. Es wurden explorativ Effektstärken berechnet. *Publikation 2:* Mit Hilfe von Fragebögen erfasste die Umfragestudie Daten zu Demographie, aktuelle Nutzung von CAM, medizinische Diagnosen, Meinungen und Vorlieben der Nutzer/-innen. *Publikation 3:* Im quantitativen Studienteil wurden die Assessments NOSGER, BI, QUALIDEM, PW, MMSE, Short Form 12 Health Survey, Work Ability Index und Aussagen zur Kneipp-Therapie erhoben und im qualitativen Teil subjektiv erlebte Veränderungen.

Ergebnisse: *Publikation 1:* Ein „integrativmedizinisches"-Programm ist durchführbar jedoch zeitaufwändig. Nach 12 Monaten wurden mittlere Effektstärken für die Aktivitäten des täglichen Lebens (ADLs) und Lebensqualität im Vergleich zur Routineversorgung beobachtet. *Publikation 2:* In Berlin und Brandenburg zeigte sich eine hohe Anwendung von CAM: von 400 befragten Senioren wendeten 61% CAM an. Jedoch nur 59% informierten ihren Hausarzt über diese CAM-Nutzung. Ferner konnten mehr als 58% die Neben- und Wechselwirkungen ihrer CAM-Präparate nicht beurteilen. Dennoch würden 65% der Senioren eine Kombination von CAM und Schulmedizin für ihre Behandlung bevorzugen. *Publikation 3:* Es zeigten sich positive Effekte auf das Wohlbefinden. Für die multimorbiden und in ihren ADLs eingeschränkten Bewohner/-innen wurde das Wohlbefinden durch Aufmerksamkeit, Fürsorge und die Anerkennung ihres Laienwissens über Kneipp und alte Hausmittel gefördert. Die Mitarbeiter/-innen hatten durch zufriedenere und ruhigere Bewohner/-innen, eine größere Abwechslung in der Grundpflege und einen selbstbestimmten Handlungsspielraum positive Auswirkungen auf ihr

Wohlbefinden. Die Arbeitsfähigkeit und gesundheitsbezogene Lebensqualität waren höher als in der deutschen Vergleichsstichprobe.

Schlussfolgerung: Die Parameter ADL und Lebensqualität scheinen für größere Studien am ehesten sinnvoll zu sein (*Publikation 1*). Aufgrund der hohen Nutzung von CAM durch Senioren bedarf es einer umfassenderen Information über die Risiken (*Publikation 2*). Die Bewohner/ -innen und Mitarbeiter/-innen von Pflegeheimen nahmen die Kneipp-Therapie positiv wahr (*Publikation 3*).

Abstract

Background and Objectives: In Germany, the use and efficacy of complementary and alternative medicine (CAM) among older adults has not been studied systematically yet. Objectives of the study were therefore the feasibility of an "integrative medical" program and to examine its effects (*publication 1*), to collect data on the use of CAM among older adults (*publication 2*) and to collect data about the application of Kneipp therapy in nursing homes (*publication 3*).

Methods: A cluster-randomized pilot study (*publication 1*), a survey (*publication 2*) and a cross-sectional study with mixed methods (*publication 3*) have been carried out. *Publication 1*: Half of the shared apartments communities received only conventional care and the other half in addition a 12-month "integrative medical" program, consisting of physical activity, homeopathic treatment and naturopathic nursing care. As explorative outcomes were used Nurses Observation Scale for Geriatric Patients (NOSGER), Barthel Index (BI), Quality of Life in Dementia (QUALIDEM), Profile of Well-being (PW), the Mini Mental State Examination (MMSE) and the Assessment of Motor and Process Skills. Effect sizes were calculated exploratory. *Publication 2*: With the help of questionnaires, the survey covered the parameters demographics, the current use of CAM, medical diagnosis, opinions and preferences of users. *Publication 3*: In the quantitative part of the study, NOSGER, BI, QUALIDEM, PW, MMSE, Short Form 12 Health Survey, Work Ability Index and statements for Kneipp therapy were collected and in the qualitative part the subjectively experienced changes were collected.

Results: *Publication 1*: An "integrative medical" program is feasible, however, time consuming. At 12 months, mean effect sizes for the Activities of Daily Living (ADLs) and quality of life were observed in comparison to routine care. *Publication 2*: In Berlin and Brandenburg is a high use of CAM: 61% of 400 asked older adults applied CAM. However, only 59% informed their general practitioner about these CAM use. In addition, more than 58% were not able to evaluate the side effects and interactions of their CAM supplements. Nevertheless, 65% of older adults

would prefer a combination of CAM and conventional medicine for their treatment. *Publication 3*: Positive effects on well-being were shown in the study. For the multimorbid and restricted in their ADLs, the well-being for the residents was supported by attention, care and the recognition of their lay knowledge about Kneipp and old home remedies. Because of the happier and calmer residents, the staff had more options for the basic care and experienced a positive impact on their well-being because of the self-determined freedom to act. The ability to work and the health related quality of life were higher than in the German comparison sample.

Conclusion: The parameters ADL and quality of life seem to be the most useful for larger studies (*publication 1*). Due to the high use of CAM by older adults a broader information about the risks (*publication 2*) is needed. Residents and caregivers of nursing homes perceived the Kneipp therapy positively (*publication 3*).

1 Einführung

Für die Komplementärmedizin (CAM) werden in Deutschland zahlreiche teilweise synonyme Begriffe wie Naturheilkunde, Alternativmedizin, Integrative Medizin etc. verwendet. (1) Einheitlich werden für die Komplementärmedizin eigene Therapiesysteme wie die Homöopathie, TCM, Kneipp-Therapie, Phytotherapie, usw. beschrieben. (2) Für diese Arbeit wurde die Definition von Frau Professor Dr. C. M. Witt zu Grunde gelegt:

> *„Komplementärmedizin umfasst eine Vielzahl von Verfahren, die zusätzlich zur konventionellen Medizin angewendet werden. Dazu gehören ganze Therapiesysteme wie beispielsweise die Chinesische Medizin, aber auch einzelne Vitamine und Spurenelemente wie Vitamin C oder Selen, die als Nahrungsergänzung eingesetzt werden.“* (3)

Die Akzeptanz und Anwendung komplementärmedizinischer Methoden und Arzneimittel in der deutschen Bevölkerung weist weltweit einen der höchsten Prozentsätze (75%) auf. (4) Aufgrund der genannten terminologischen Schwierigkeiten ist es nach Linde et al. (2014) jedoch problematisch, für die Nutzung von Komplementärmedizin exakte Zahlen zu allen Bereichen zu nennen. (5)

1.1 Wirksamkeit von CAM in Wohngemeinschaften (Publikation 1)

In Deutschland wurden von ambulanten Pflegediensten betreute Wohngemeinschaften seit Mitte der 1990er Jahre vermehrt zur neuen und beliebten Wohnoption von älteren Menschen. (6, 7) Eine aktuelle systematische Übersichtsarbeit wies nur fünf Artikel über die Verwendung von CAM in der Pflege in Seniorenwohngemeinschaften auf und folgerte, dass generell sehr begrenzt deskriptive Daten zum CAM Einsatz verfügbar waren. (8)

1.2 CAM Nutzung durch Senioren (Publikation 2)

In Deutschland haben viele Senioren lebenslange Erfahrungen mit pflanzlichen Präparaten und Hausmitteln. (9) Die Kombination dieser pflanzlichen Arzneimittel oder Vitamine mit verordneten Arzneimitteln stellt ein potentielles Risiko für Neben- und Wechselwirkungen dar. Wissenschaftlich ist die Verwendung von CAM durch die Senioren bisher nicht detailliert untersucht worden. So belegten frühere Studien nicht explizit die CAM-Nutzung von Senioren ab 70 Jahren. Weiterhin fehlen insbesondere Daten von pflegebedürftigen Senioren und Senioren unter gesetzlicher Betreuung weitgehend.

1.3 Komplementärmedizin in Pflegeheimen (Publikation 3)

Im Jahr 2007 haben einige Pflegeheime in Deutschland damit begonnen CAM als Prävention in Form von Kneipp-Therapie (KT) in die tägliche Grundversorgung zu integrieren. (2, 10) Die KT

besteht aus den fünf Elementen Hydrotherapie, Phytotherapie, Bewegung, gesunde Ernährung und Lebensordnung. (11) "Kneipp-Seniorenheime" unterschieden sich demnach durch die Angebote Hydrotherapie und Phytotherapie von den herkömmlichen Seniorenheimen.

2 Zielstellung

2.1 Wirksamkeit von CAM in Wohngemeinschaften (Publikation 1)

Das primäre Ziel der Pilotstudie war die Evaluation der Machbarkeit eines für in Seniorenwohngemeinschaften lebende Senioren entwickelten „integrativmedizinischen"-Programmes mit Elementen aus konventionellen und CAM-Therapien und der Vergleich zur Routineversorgung. Das sekundäre Ziel war die Überprüfung welche Parameter für eine spätere konfirmatorisch angelegte Studie geeignet wären.

2.2 CAM Nutzung durch Senioren (Publikation 2)

Das Ziel der Umfragestudie bestand darin, die Inanspruchnahme von CAM durch Senioren zu untersuchen.

2.3 Komplementärmedizin in Pflegeheimen (Publikation 3)

Das Ziel der Querschnittstudie war, Informationen über die Integration der Kneipp-Therapie in die tägliche Routineversorgung in den „Kneipp-Seniorenheimen" zu sammeln, den Gesundheitszustand von Bewohnern/-innen und Mitarbeitern/-innen sowie die jeweils angewandte Kneipp-Therapie zu erheben. Darüber hinaus wurden im qualitativen Studienteil Veränderungen des subjektiven Erlebens von Bewohnern/-innen und Mitarbeitern/-innen nach der Durchführung der Kneipp-Therapie untersucht. Ein weiteres Ziel dieser Studie bestand darin, die Ergebnisse als Grundlage zur Generierung von Forschungsfragen für weitere Studien zu nutzen, gut nutzbare Erhebungsbögen zu identifizieren und Erfahrungen in Bezug auf die Machbarkeit einer größeren Studie zu sammeln.

3 Methodik

3.1 Wirksamkeit von CAM in Wohngemeinschaften (Publikation 1)

Studiendesign

Es wurde eine zweiarmige, pragmatische, cluster-randomisierte Pilotstudie durchgeführt.

Stichprobe

Die Bewohner/-innen der Seniorenwohngemeinschaften waren mindestens 70 Jahre alt und erklärten schriftlich ihre Einwilligung. Ausgeschlossen wurden nur Bewohner/-innen mit einem Gesundheitszustand, der die Teilnahme absolut nicht erlaubte (z.B. palliativ).

Intervention

Das komplexe „integrativmedizinische"-Programm der Interventionsgruppe (IM) erfolgte über 12 Monate und beinhaltete ein Bewegungsprogramm, frisch gepresste Säfte, Heilkräutertees, Wickel und Auflagen sowie individualisierte homöopathische und ggf. schulmedizinische Arzneimitteltherapie. Die konventionelle Versorgung durch die Haus- und Fachärzte wurde beibehalten (= Routineversorgung). Die Kontrollgruppe erhielt nur Routineversorgung (= Routineversorgungsgruppe (RV)).

Parameter und Datenerfassung

Bei allen Bewohnern/-innen wurden zu Studienbeginn, nach drei, sechs und 12 Monaten standardisierte (geriatrische) Assessments erhoben. Die Ermittlung der Nurses Observation Scale for Geriatric Patients, des Barthel-Index, Quality of Life in Dementia und Profil des Wohlbefindens erfolgte anhand von Fremdbeurteilung. Bei den Bewohnern/-innen wurden das Assessment of Motor and Process Skills, den Mini Mental State Examination und Tinetti Test erhoben. Ferner erfolgte die Dokumentation der Anzahl der Stürze und Krankenhauseinweisungen sowie der verordneten Dauer- und Bedarfsmedikamente. Die Studienärzte erfassten zu Studienbeginn die soziodemographischen Daten und Krankheitsgeschichten. Während der gesamten Studie wurden unerwünschte Ereignisse und schwerwiegende unerwünschte Ereignisse erhoben.

Datenanalyse

Aufgrund des explorativen Pilotstudiendesigns wurden kein primärer Endpunkt und keine Hypothese definiert sowie keine formale Fallzahlberechnung durchgeführt. Alle Datenanalysen waren explorativ und erfolgten nach einem Intention-to-treat-Ansatz. Es erfolgte die Berechnung deskriptiver Analysen und jeder Zielparameter wurde separat durch allgemeine lineare Modelle analysiert.

3.2 CAM Nutzung durch Senioren (Publikation 2)

Studiendesign

Die Studie wurde als Querschnittstudie mit fünf Strata durchgeführt. Die Strata ergaben sich zum einen aus den verschiedenen Wohnformen der Senioren (selbstständig oder durch ambulanten Pflegedienst betreut in eigener Wohnung, im Seniorenheim). Zum anderen schlossen die ambulanten Pflegedienste und Seniorenheime Senioren sowohl mit, als auch ohne gesetzliche Betreuung in die Studie ein.

Stichprobe

Bei der Fallzahlberechnung wurde von Rücklaufquoten von 60% der selbstständig lebenden Senioren und 80% der Senioren mit ambulanter oder stationärer Pflege ausgegangen. Diese ergab demnach für die Gruppen „selbständig Lebende“, „mit ambulanter Pflege“, „Seniorenheim“ und „mit gesetzlicher Betreuung“ jeweils 96 benötigte Teilnehmer/-innen. An der Studie nahmen Senioren im Alter von mindestens 70 Jahren teil, die in den Bundesländern Berlin und Brandenburg lebten und einem der fünf Studienarme entsprachen. Ausgeschlossen wurden lediglich Senioren, deren gesetzliche Betreuer nach Information über die Studie der Erhebung widersprachen.

Parameter und Datenerhebung

Die Fragebögen erfassten soziodemographische Daten und die Verwendung von nicht-pharmakologischen Therapien. Des Weiteren wurden für die verwendeten CAM-Präparate Name, Dosierung, Grund für die Anwendung, die Entscheidungsgrundlage für den Einsatz erhoben. Zusätzlich erfolgte eine Erhebung zur Informierung der Hausärzte über die CAM-Nutzung ihrer Patienten. Die Senioren ohne gesetzliche Betreuung konnten zudem ihre subjektiven Meinungen und Einschätzungen über CAM: Erwartungen an und Erfahrung mit den Präparaten, geschätzte Nebenwirkungen und Risiken sowie ihre präferierte Behandlungsform äußern. Diese Senioren füllten den Fragebogen selbständig aus. Für die Senioren mit gesetzlicher Betreuung extrahierten die Pflegekräfte die Daten aus deren Pflegedokumentationen.

Datenanalyse

Deskriptive Analysen wurden berechnet und Gruppen, stratifiziert nach CAM-Nutzung (Ja/ Nein) mittels Chi^2- und t-Test verglichen. Für Senioren ohne gesetzliche Betreuung wurde die Wirkung von Variablen auf die CAM Nutzung mit einer multiplen logistischen Regression geschätzt.

3.3 Komplementärmedizin in Pflegeheimen (Publikation 3)

Studiendesign

Dieses Forschungsprojekt wurde als Querschnittstudie mit quantitativem und qualitativem Studienteil bei Bewohnern/-innen und Mitarbeitern/-innen der Pflegeheime durchgeführt.

Stichprobe

Die Bewohner/-innen waren mindestens 60 Jahre alt, zeigten adäquate kommunikative Fähigkeiten, erhielten seit mindestens drei Monaten regelmäßig Kneipp-Therapie (KT) und erklärten schriftlich ihre Einwilligung. Die Mitarbeiter/-innen waren mindestens 18 Jahren alt, wiesen eine allgemeine Berufserfahrung von mindestens drei Jahren auf, führten seit mindestens drei Monaten regelmäßig Kneipp-Therapie an den Bewohner/-innen durch und erklärten schriftlich ihre Einwilligung.

Parameter und Datenerfassung

Im quantitativen Studienteil erfolgte für die Bewohner/-innen die Ermittlung des Barthel-Index, Quality of Life in Dementia, Profil des Wohlbefindens und Short Form 12 Health Survey (SF-12) durch Fremderhebung vor Ort. Die Bewohner/-innen absolvierten den Mini Mental State Examination und wurden über ihr Wissen, ihre Meinung und Vorlieben, sowie die Auswirkung von KT auf ihr Wohlbefinden befragt. Die Erhebung der demographischen Daten, Pflegestufen, Diagnosen und Medikamente erfolgte aus den Bewohner/-innenakten. Für die Mitarbeiter/-innen erfolgte die anonyme und postalische Erhebung des Work Ability Index und SF-12. Zusätzlich wurden diese zur Dauer der Kenntnis der KT, nach der Verwendung für ihre eigene Gesundheit inklusive der Form und Häufigkeit sowie ihrer Vorliebe für bestimmte Formen der KT befragt. Ergänzend schätzten sie mögliche Effekte der KT ein und beurteilten die Integration in den Pflegealltag. Der qualitative Studienteil diente der Beschreibung der täglichen KT Praxis sowie der subjektiv wahrgenommenen Veränderungen nach der Implementierung der KT. Hierzu erfolgten in zwei Seniorenheimen teilnehmende Beobachtungen und halbstrukturierte Interviews während eines einwöchigen Beobachtungszeitraumes. Die Auswahl der Teilnehmer/-innen erfolgte unter den Mitarbeitern/-innen und Bewohnern/-innen, die während des Aufenthaltes vor Ort waren. In die Interviews wurden zusätzlich noch Heim- und Pflegedienstleitungen sowie Kneippgesundheitstrainer systematisch einbezogen.

Datenmanagement und statistische Analysen

Die qualitative Datenanalyse erfolgte mittels ANOVA und deskriptiv. Die Ergebnisse wurden als Mittelwert mit Standardabweichung, Median, absolute oder relative Häufigkeiten dargestellt. Die qualitative Analyse der Interviews folgte den Grundsätzen der Grounded Theory. (12)

4 Ergebnisse

4.1 Wirksamkeit von CAM in Wohngemeinschaften (Publikation 1)

Es nahmen je vier Seniorenwohngemeinschaften (WG) in der Interventions- (IM) und Routineversorgungsgruppe (RV) teil. Zu Baseline bestand die Interventionsgruppe aus 29 Bewohnern/-innen (davon n=27 mit gesetzlicher Betreuung, 86% weiblich, Durchschnittsalter 82,7±8,6 Jahre, im Durchschnitt sieben Bewohner/-innen pro WG). Die Routineversorgungsgruppe bestand aus 29 Bewohnern/-innen (davon n=21 mit gesetzlicher Betreuung, 48% weiblich, Durchschnittsalter 76,0±12,8 Jahre, im Durchschnitt acht Bewohner/-innen pro WG). In beiden Gruppen lebten multimorbide Senioren bei denen eine Multimedikation vorlag (IM-Bewohner/-innen 7,0±3,4 und RV-Bewohner/-innen 9,6±2,9 verschiedene Arzneimittel). Der Anteil der kognitiven Beeinträchtigungen (IM 55% vs. RV 48%) und die Anzahl der klassifizierten Krankheiten (IM 9,9±2,9 vs. RV 9,6±2,9) waren in beiden Gruppen vergleichbar. Im 12-monatigen Studienzeitraum wurde in der IM-Gruppe die durchschnittliche Anzahl von konventionellen Arzneimitteln pro Bewohner verringert (6,8±3,3 vs. 4,8±1,5), während sie in der RV-Gruppe gleichblieb (8,3±5,0 vs. 8,5±5,7). Es verstarben sieben Bewohner/-innen der IM-Gruppe und drei Bewohner/-innen der RV-Gruppe. Aus der RV-Gruppe zogen zudem drei Bewohner/-innen aus. Nach drei und sechs Monaten konnten keine deutlichen Unterschiede oder Trends zwischen IM- und RV-Gruppe beobachtet werden. Nach 12 Monaten zeigten sich im Gruppenvergleich Verbesserungen in mittleren Effektstärken in den Bereichen ADL, Lebensqualität, Wohlbefinden und spezifische affektive und soziale Funktionen zugunsten der IM-Gruppe. In dieser bestand ein höheres Risiko für Stürze im Vergleich zur RV-Gruppe (Odds Ratio (OR) 3,30; 95% Konfidenzintervall: 0,43; 25,26) allerdings waren die Krankenhauseinweisungen in beiden Gruppen vergleichbar (IM 0,7 ± 1,1; RV 1,0 ± 1,8). Insgesamt beurteilten die Studienärzte als durchführbar, aber arbeits- und zeitaufwendig.

4.2 CAM Nutzung durch Senioren (Publikation 2)

Die 400 Senioren lebten zu gleichen Teilen in den ländlichen Gegenden Brandenburgs und im Ballungsbereich Berlin. 79% waren weiblich. Die meisten Senioren (93%) waren gesetzlich krankenversichert und 58% hatten eine Pflegestufe. 61% der Senioren verwendeten mindestens ein CAM-Präparat. Am häufigsten nutzten sie Nahrungsergänzungsmittel und Phytotherapie. 3% der Senioren verwendeten CAM-Präparate von denen Wechselwirkungen mit anderen Arzneimitteln bekannt sind. Fast alle Senioren mit gesetzlicher Betreuung verwendeten vorwiegend von ihren Hausärzten verschriebene CAM-Präparate in Form von Nahrungs-

ergänzungsmitteln. Jedoch lag nur für die Hälfte der Fälle eine Dokumentierung des Verordnungsgrundes vor. Die CAM-Nutzer/-innen ohne gesetzliche Betreuung erwarteten von den Präparaten eine deutliche (45%) oder leichte Verbesserung (37%) der Beschwerden. 59% der Nutzer/-innen gaben eine gute Wirkung ihrer CAM-Präparate an. Die CAM-Nutzung basierte auf Empfehlung (31%) oder Eigeninitiative (27%) und nur bei 26% auf Verordnungen. 59% der CAM-Nutzer/-innen informierten von sich aus ihren Hausarzt. Mehr als die Hälfte (58%) gaben an, dass sie weder beurteilen können ob ihre CAM-Präparate Neben- und Wechselwirkungen haben, noch welche dies sein könnten. 65% der Senioren bevorzugte eine Kombination aus CAM und Schulmedizin. Die CAM-Nutzung wurde positiv durch die zwei Behandlungspräferenzen (nur CAM, OR 3,98, p-Wert 0,0042; CAM + Schulmedizin, OR 3,02; p-Wert 0,0028) und die Art der Krankenversicherung (gesetzliche, OR 3,57; p-Wert 0,0356) beeinflusst. Eine negative Beeinflussung erfolgte durch die zwei subjektiven Beurteilungen (CAM verursacht mit anderen Medikamenten Wechselwirkungen, OR 0,25; p-Wert 0,053; Ich kann Nebenwirkungen nicht beurteilen, OR 0,28; p-Wert 0,001). Die Nutzungshäufigkeit von mindestens einer nicht-pharmakologischen Therapie (z.B. Kneipp-Therapie) lag ebenfalls bei 61%. Die physikalische Therapie war die häufigste nicht-pharmakologische Therapie.

4.3 Komplementärmedizin in Pflegeheimen (Publikation 3)

Bewohner/-innen

Von den 64 Bewohner/-innen waren 83% weiblich mit einem Durchschnittsalter von 83,2±8,1 Jahren. Sie hatten im Durchschnitt 8±2,9 Diagnosen und 8±3,0 verordnete Medikamente. Die Mehrheit war in Pflegestufe 1 und 2 eingestuft und zeigte im Barthel-Index eine Hilfebedürftigkeit in den ADLs. Der MMSE wies bei über der Hälfte der Bewohner auf kognitive Einschränkungen hin im Vergleich dazu hatten 42% der Bewohner/-innen eine diagnostizierte Demenz. Die allgemeine Lebensqualität wurde anhand des QUALIDEM und Profil des Wohlbefindens als insgesamt gut bewertet. Die Ergebnisse des SF-12 deuteten darauf hin, dass die körperliche gesundheitsbezogene Lebensqualität eingeschränkt hingegen die psychische gesundheitsbezogene Lebensqualität nicht eingeschränkt war. Alle Bewohner/-innen erhielten mindestens einmal in der Woche Elemente der Kneipp-Therapie (KT). Die Bewohner/-innen verbanden mit ihr überwiegend Wasseranwendungen und bevorzugten diese als KT-Intervention. Die Mehrzahl berichtete eine positive Wirkung auf ihr Wohlbefinden.

Mitarbeiter/-innen

Die 29 Mitarbeiter/-innen waren weiblich, im Durchschnitt 42±11,7 Jahre alt und 10 Jahren in ihrem Beruf in Vollzeit oder Teilzeit tätig. Der Work Ability Index zeigten eine "gute"

Arbeitsfähigkeit. Der SF-12 deutet darauf hin, dass die körperliche und psychische gesundheitsbezogene Lebensqualität gut war. 93% verwendeten KT für sich selbst und berichteten von positiven Effekten auf ihr Wohlbefinden und ihre Gesundheit. Die Hydrotherapie war sowohl für die Selbstanwendung als auch die Anwendung am Bewohner die bevorzugte KT**.** Die Mitarbeiter/-innen äußerten Verbesserungen der Beziehung zu den Bewohner/-innen (90%) und des Verhältnisses zum Team (47%) sowie eine gute Integration der KT in den Pflegealltag (42%).

Qualitativer Studienteil

Insgesamt wurden 26 Interviews durchgeführt. Beide Seniorenheime zeigten eine ganzheitliche Umsetzung der KT Prinzipien. KT wird in täglichen Aktivitäten allen Bewohnern (Heim 1), aber auch als individuelle Behandlung (Heim 2) angeboten. Bewohner/-innen und Mitarbeiter/-innen assoziierten KT am häufigsten mit der Hydrotherapie. Es ließen sich zwei verschiedene Formen der KT-Umsetzung identifizieren: 1. Form: Eine spezialisierte Umsetzung durch den Kneippgesundheitstrainer, der die Anwendung zusätzlich zu den konventionellen Pflegeaktivitäten anbot. Die Bewohner/-innen nahmen die Behandlungen als außergewöhnliche Zuwendung, als Ausdruck eines persönlichen Geschenks verbunden mit der Absicht, ihr individuelles Wohlbefinden zu fördern wahr. 2. Form: Die KT wurde in die Grundversorgung integriert und von allen Mitarbeitern/-innen umgesetzt. Die Bewohner/-innen nahmen die KT als alltägliche Dienstleistung wahr. Beide Formen der Umsetzung wurden von den Bewohnern/-innen und Mitarbeitern/-innen als Förderung einer wesentlich aufmerksameren und individuelleren Pflege wahrgenommen. Die befragten Mitarbeiter/-innen stellten fest, dass die Integration von KT manchmal zu einem leicht erhöhten Zeitaufwand in der Grundversorgung führte, jedoch durch ruhigere Bewohner/-innen im gesamten Pflegealltag Zeit gespart wurde. Die Heim- und Pflegedienstleitungen betonten, dass die Integration von KT ohne zusätzliche personelle oder finanzielle Ressourcen möglich war. Als Vorteile für das Pflegeheim selbst benannten die Leitungen die Nutzung von KT als Marketing-Instrument und Alleinstellungsmerkmal. Außerdem bestehe das Potential für zufriedenere und gesündere Bewohner/-innen sowie Kosteneinsparungen im Hinblick auf Medikation und Körperpflegeprodukte. Die Mitarbeiter/-innen berichteten vor allem emotionale und funktionale Vorteile durch zufriedenere Bewohner/-innen. Außerdem schätzten sie die größere Abwechslung bei der Pflege und den erlebten erweiterten Handlungsspielraum. Als mögliche Grenzen wurden ein erhöhter Zeitaufwand, eine eingeschränkte Kontrollüberzeugung bei den Bewohnern/-innen und normative Zwänge im Team angeführt. Die Bewohner/-innen erlebten als Vorteile eine deutliche Zunahme an Zuwendung und Zufriedenheit. Darüber hinaus erfuhren sie mehr Abwechslung und

Individualität in ihrer Versorgung sowie ein Gefühl der Akzeptanz ihres Laienwissens über Kneipp und alte Hausmittel.

5 Diskussion

Die vorliegenden Publikationen beschäftigten sich unter Nutzung unterschiedlicher Methoden mit dem wenig erforschten Gebiet der Komplementärmedizin bei Senioren. Die explorative Pilotstudie (*Publikation 1*) wies darauf hin, dass ein komplexes „integrativmedizinisches" - Programm Lebensqualität und Alltagsfähigkeiten verbessern kann. Die Umsetzung war sehr aufwändig. Es wurden nach 12 Monaten Effekte zugunsten der Interventionsgruppe für ADL (Barthel Index, NOSGER), Wohlbefinden und Lebensqualität beobachtet, die als klinisch relevante Unterschiede zwischen den Gruppen angesehen werden können. Die Studie kann in Ermangelung vergleichbarer Daten weder in einen gesamtdeutschen noch internationalen Kontext gesetzt werden. Die explorative Interventionsstudie bediente sich eines pragmatischen Ansatzes, untersuchte das erste Mal ein zusätzliches komplexes „integrativmedizinisches" - Programm, das für Senioren in Seniorenwohngemeinschaften entwickelt sowie bei diesen angewendet wurde. Zwischen den beiden nach Seniorenwohngemeinschaften cluster-randomisierten Gruppen zeigten sich deutliche Altersunterschiede, für die adjustiert wurde. Dennoch schränkten diese die Aussagefähigkeit ein. Da es sich um eine komplexe Intervention aus mehreren Behandlungsmodulen handelte war es nicht möglich, die Auswirkungen auf einzelne Teile der Intervention zu beziehen. (13)

Durch die Umfragestudie (*Publikation 2*) konnte eine sehr hohe Inanspruchnahme von CAM mit mangelnder Kenntnis über deren Risiken nachgewiesen werden. Dabei zeigte es sich, dass die Senioren überwiegend Nahrungsergänzungsmittel und pflanzliche Zubereitungen ohne ein ärztliches Rezept verwendeten und CAM als wirksamen Therapieansatz mit geringen Risiken von Nebenwirkungen verstanden. Der Vergleich der Ergebnisse mit der bestehenden Forschung ist aufgrund der wenigen Publikationen, der unterschiedlichen Auswahlkriterien, Erhebungs-methoden und -zeiträume sowie heterogenen Definitionen schwierig. (8, 14) So bieten die veröffentlichten Daten zum Beispiel keine altersspezifischen Ergebnisse für den CAM-Einsatz oder identifizieren die Verwendung von Präparaten, welche in Deutschland nicht üblich sind (z.B. Megavitamine). (14) Die kurze Zeit später veröffentlichten Ergebnisse der Interviews im Rahmen der KORA-Age Studie ergänzten die Datenlage durch eine Frage zur Bekanntheit und zur Nutzung von CAM im Raum Augsburg (Bayern), diese zwei Fragen eigneten sich inhaltlich jedoch nicht für einen direkten Vergleich. (14) Eine weitere der KORA-Age Studie

entstammende Veröffentlichung zur Nutzung von Nahrungsergänzungsmitteln zeigte eine leicht höhere Nutzung von Nahrungsergänzungsmitteln im Vergleich zur vorliegenden Stichprobe (44% vs. 36%). Im Vergleich zu den Senioren ohne gesetzliche Betreuung der vorliegenden Studie nutzten die Senioren der KORA-Age Studie deutlich mehr Kombinationspräparate aus Vitaminen und Mineralien (5% vs. 44%). Die KORA-Age Studie zeigte ferner eine tendenziell höhere Nutzung von Magnesium und Vitamin D wobei ein direkter Vergleich nicht möglich ist, da keine Gesamtergebnisse berichtet wurden. Die in dieser Studie beschriebenen Ergebnisse bezogen sich ausschließlich auf die Nutzung von Nahrungsergänzungsmitteln und können daher größtenteils nicht mit der vorliegenden Studie in Beziehung gesetzt werden. (15) Die Senioren konnten die Wechselwirkungen von CAM-Präparaten bei gleichzeitiger Einnahme von verschreibungs-pflichtigen Medikamenten nicht einschätzen. (16) Da sich die Hausärzte unzureichend über die CAM-Nutzung ihrer Patienten informierten, können potentiell schädliche Wechselwirkungen von verschreibungspflichtigen Medikamenten mit Kräutern oder Nahrungsergänzungen nicht verhindert werden. Darüber hinaus stellte die gesetzliche Krankenversicherung die Erstattung von Aufwendungen für die CAM-Präparate 2002 ein, so dass eine ärztliche Verordnung nicht mehr nötig ist. Diese Faktoren führten dazu, dass das Risiko möglicher Neben- oder Wechselwirkungen von CAM-Präparaten mit anderen Medikamenten schwer einschätzbar geworden ist. Die Rekrutierungsstrategie der Umfragestudie erleichterte die Einbeziehung von multimorbiden Senioren. Die Direktansprache der Senioren führte zu einer hohen Rücklaufquote. Die in Berlin und Brandenburg erhobenen Daten können aufgrund unterschiedlicher Bevölkerungsstrukturen nicht auf die anderen Bundesländer übertragen werden.

Die Querschnittstudie mit Mixed Methods (*Publikation 3*) ermöglichte vielseitige Einblicke in die Anwendung der Kneipp-Therapie (KT) im Pflegealltag. Dadurch wurden die Hypothesen generiert, dass die Anwendungen bei den Bewohnern/-innen zur Reduzierung der Beschwerden führen und bei den Mitarbeitern/-innen eine höhere Arbeitszufriedenheit erzeugen. Die Querschnittstudie stellte erstmalig die Arbeit mit KT in Seniorenheimen für die Bewohner/-innen und Mitarbeiter/-innen systematisch dar. Die Ergebnisse zeigten, dass es möglich war, KT in den Tagesablauf der Pflegeeinrichtungen zu integrieren. Die Akzeptanz von KT und besonders der Hydrotherapie war hoch und vorteilhaft für das Wohlbefinden der Bewohner/-innen. Darüber hinaus wiesen die Mitarbeiter/-innen eine gute Arbeitsfähigkeit und Lebensqualität auf. Sie schätzten KT als Anwendung (z.B. Hydrotherapie, Bewegung) bei den Bewohnern/-innen und als Selbstanwendung hoch ein. Seit der Integration von KT wurden eine verbesserte Beziehung zu den Bewohnern/-innen und eine „ganzheitliche Konzeption“ der Versorgung wahrgenommen.

(17, 18) Der quantitative und qualitative Studienteil der Querschnittstudie ermöglichte ferner eine verbesserte wissenschaftliche Betrachtung der KT im Pflegeheim. Die Studie beschränkte sich als Pilotprojekt für eine Folgestudie auf eine kleine Stichprobe von Bewohnern/-innen und Mitarbeitern/-innen. Somit können die Ergebnisse nicht auf andere Bewohner/-innen und Mitarbeiter/-innen der Seniorenheime verallgemeinert werden. Der qualitative Studienteil fokussierte sich auf das Erleben der Integration von KT durch die Bewohner/-innen und Mitarbeiter/-innen von zwei der vier beteiligten Seniorenheime, daher ist es nicht möglich diese individuellen Einzelaussagen zu verallgemeinern.

Die Stärken der vorliegenden Publikationen lagen insgesamt im naturalistischen Setting, die erhobenen Daten entstammten der Lebenswirklichkeit der Senioren. Besonders die dementiell Erkrankten wurden somit keiner künstlich gestalteten experimentellen Situation ausgesetzt und demnach nicht in ihrem Handeln beeinflusst. „Nachteile der Beobachtung im *naturalistischen Setting* sind das Fehlen experimenteller Kontrolle und ihre mangelnde Generalisierbarkeit." (19)

Zukünftig sollten in der Geriatrie weitere komplexe Interventionen, die Bewegung, Ernährung, Arzneimittelreduktion und naturheilkundliche Strategien beinhalten, in prospektiven, kontrollierten Studien evaluiert werden. Um die Ergebnisse der Umfragestudie zu überprüfen, müsste die Nutzung von CAM durch Senioren auf Bevölkerungsebene genauer betrachtet werden. Auf Grundlage der Ergebnisse der Querschnittstudie wurde eine prospektive vergleichende Kohortenstudie zur Wirksamkeit der Kneipp-Therapie geplant und von 2013 bis 2014 durchgeführt. Weitere qualitative Forschung zur Kneipp-Therapie könnte zusätzliche Formen der KT-Umsetzung, Erfahrungen und Wahrnehmungen der Bewohner/-innen und Mitarbeiter/-innen aufdecken.

6 Schlussfolgerungen

Publikation 1: Die Parameter „Aktivitäten des täglichen Lebens" und Lebensqualität scheinen sich für groß angelegte Wirksamkeitsstudien zur Komplementärmedizin bei Senioren am besten zu eignen. Die Umsetzung eines „integrativmedizinischen"-Programmes ist möglich, jedoch zeitaufwendig. *Publikation 2:* Zur Reduzierung des potenziellen Risikos von Neben- und Wechselwirkungen bedarf es einer besseren Informierung der Hausärzte über die CAM-Nutzung ihrer Patienten und Aufklärung der Senioren über die Risiken einer zusätzlichen Verwendung von CAM-Präparaten. *Publikation 3:* Die Integration der Kneipp-Therapie im Seniorenheim ist durchführbar und wird von den beteiligten Bewohnern/-innen und Mitarbeitern/-innen positiv

wahrgenommen. Die Ergebnisse liefern eine geeignete Basis für zukünftige Wirksamkeitsstudien zur Kneipp-Therapie in Seniorenheimen.

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Eidesstattliche Versicherung

„Ich, Katharina Schnabel, versichere an Eides statt durch meine eigenhändige Unterschrift, dass ich die vorgelegte Dissertation mit dem Thema: *Komplementärmedizin bei Senioren* selbstständig und ohne nicht offengelegte Hilfe Dritter verfasst und keine anderen als die angegebenen Quellen und Hilfsmittel genutzt habe.
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Datum Unterschrift

Anteilserklärung an den erfolgten Publikationen

Katharina Schnabel hatte folgenden Anteil an den folgenden Publikationen:

Publikation 1:
Teut M, Schnabel K, Baur R, Kerckhoff A, Reese F, Pilgram N, Berger F, Luedtke R, Witt CM: Effects and feasibility of an Integrative Medicine program for geriatric patients - a cluster-randomized pilot study. Clinical Interventions in Aging 2013;8: 953-961

Beteiligung insgesamt etwa 50%.

Beitrag im Einzelnen:
Durchführung der Datenerhebung und Dateneingabe, Mitwirkung bei der Auswertung, Mitarbeit beim Verfassen des Manuskripttextes

Publikation 2:
Schnabel K, Binting S, Witt CM, Teut M: Use of complementary and alternative medicine by older adults – a cross-sectional survey. BMC Geriatrics 2014; 14:38

Beteiligung insgesamt etwa 60%.

Beitrag im Einzelnen:
Entwicklung von Fragestellung und Projektkonzept, Literaturarbeit, Entwicklung der Fragebögen, Durchführung Pretest für Fragebögen, Rekrutierung der Kooperationspartner, Projektkoordination, Durchführung der Dateneingabe, Interpretation der Ergebnisse, Verfassen des Manuskripttextes

Publikation 3:
Ortiz M, Soom Ammann E, Salis Gross C, Schnabel K, Walbaum T, Binting S, Fischer HF, Teut M, Kottner J, Brinkhaus B: Complementary Medicine in Nursing Homes - results of a mixed methods pilot study. BMC Complementary and Alternative Medicine 2014; 14:443

Beteiligung insgesamt etwa 30%.

Beitrag im Einzelnen:
Durchführung der Datenerhebung (quantitativer Studienteil), Mitwirkung bei der Auswertung, Literaturarbeit, Mitarbeit beim Verfassen des Abschlussberichtes und Manuskripttextes

Unterschrift, Datum und Stempel des betreuenden Hochschullehrers/der betreuenden Hochschullehrerin

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Unterschrift der Doktorandin

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Druckexemplare der ausgewählten Publikationen

Publikation 1

Teut M, Schnabel K, Baur R, Kerckhoff A, Reese F, Pilgram N, Berger F, Luedtke R, Witt CM. Effects and feasibility of an Integrative Medicine program for geriatric patients–a cluster-randomized pilot study. Clinical Interventions in Aging 2013;8: 953-961.

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ORIGINAL RESEARCH

Effects and feasibility of an Integrative Medicine program for geriatric patients–a cluster-randomized pilot study

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Background: Older adults often use complementary medicine; however, very few interventional studies have focused on them. The aim of this study was to evaluate the feasibility and to obtain preliminary data on effectiveness of an Integrative Medicine (IM) program compared to usual medical care.

Methods: The study consisted of older adults living in shared apartment communities including caregiving. The shared apartments were cluster-randomized to the IM program or Usual Care (UC). IM consisted of additional lifestyle modification (exercise and diet), external naturopathic applications, homeopathic treatment, and modification of conventional drug therapy for 12 months. The UC group received conventional care alone. The following outcomes were used: Nurses Observation Scale for Geriatric Patients (NOSGER); Assessment of Motor and Process Skills; Barthel Index; Qualidem; Profile of Wellbeing; and Mini-mental State Examination. Exploratory effect sizes (Cohen's d, means adjusted for differences of baseline values) were calculated to analyze group differences.

Results: A total of eight shared apartment communities were included; four were allocated to IM (29 patients, median seven patients; [mean ± standard deviation] 82.7 ± 8.6 years) and four to UC (29 patients, median eight patients; 76.0 ± 12.8 years of age). After 12 months, effect sizes ≥0.3 were observed for activities of daily living on the NOSGER-Activities of Daily Living subscale (0.53), Barthel Index (0.30), Qualidem total sum score (0.39), Profile of Wellbeing (0.36), NOSGER-Impaired Social Behavior (0.47), and NOSGER-Depressed Mood subscales (0.40). Smaller or no effects were observed for all other outcomes. The intervention itself was found to be feasible, but elaborate and time consuming.

Discussion: This exploratory pilot study showed that for a full-scale trial, the outcomes of Activities of Daily Living and Quality of Life seem to be the most promising. The results have to be interpreted with care; larger confirmatory trials are necessary to validate the effects.

Keywords: Activities of Daily Living, complementary and alternative medicine strategies, NOSGER, older adults, caregiving, apartment-sharing communities, homeopathy

Background

In Western industrialized countries, the proportion of older adults is continually rising. This growing demographic is coupled with an increase of multimorbidity and nursing needs. The increase of patients with cognitive impairments poses a challenge to the health care system: presently, 1.2 million people are suffering from dementia in Germany. It is estimated that this number will increase to more than 1.4 million in 2020 and 2.3 million in 2050.[1,2] An increasing number of multimorbid and chronically ill older adults require new concepts in long-term medical care with regard to prevention

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and therapy.[3] In recent years, apartment-sharing communities with integrated care have become a new and more popular residential option among older people in Germany, adding to the traditional choices of late-life residences, such as nursing homes or home care. Usually, a group of older adults or their relatives rent an apartment and hire a caregiving service that provides medical care and assistance for services such as cooking, housekeeping, and other duties. Compared to the bigger nursing homes, this type of daily living is much closer to a usual family life.

To date, the integration of complementary and alternative medicine strategies (CAM) in geriatric care has not been systematically evaluated and tested with regards to feasibility and effectiveness. There are little data available in Germany regarding the use of and the reasons for the use of CAM by older adults. The Germany Allensbach inquiry (2010) highlights that 73% of the elderly population (above 60 years of age) have been using CAM drugs.[4] In the US, several surveys were carried out with older adults. A survey by Cheung et al[5] with 1,200 participants over 65 years of age showed that around two-thirds (62.9%) applied one or more (on average, three) CAM treatments at the same time. Eighty percent of users reported high satisfaction with these treatments. The maintenance of health and the treatment of health complaints such as arthritis and chronic pain were given as reasons for the use of CAM. Supplements (eg, vitamins and herbs), prayer, meditation, and chiropractics were predominantly applied. In the survey by Ness et al, 88% of those over 65 years of age applied CAM; CAM usage also increased with age.[6] The most frequently used CAM treatments were diet and chiropractic/manual medicine. Men applied CAM treatments less often than women. The majority of senior citizens did not inform their doctors about their CAM use and paid for the treatments largely out of pocket.[6] A recent systematic review searching for scientific literature about the use of CAM in care in aged residential communities in multiple scientific databases found only five articles, and concluded that very limited descriptive data is available on CAM use in general and much more research is needed due to this gap in information to inform policy and improve clinical practice.[7]

In theory, CAM therapies might add beneficial components to geriatric medical care because this care relies on lifestyle management strategies such as sports (eg, walking, swimming, gymnastics, yoga, tai chi, qi gong, and others) and nutrition. A complex treatment strategy combining elements of conventional and CAM therapies is called Integrative Medicine (IM). In a recently published study, IM was understood as a transitional term that can aid in removing barriers and opening up medical practice and research towards new forward-thinking health care delivery. Part of this vision is a clear focus on evidence building and patient orientation. IM may be the beginning of a general change from conventional medicine towards a true integration of different medical styles and practices, including an improvement in the patient–practitioner relationship, to ensure that patients receive the best care possible.[8]

The primary aim of this pilot study was to evaluate the feasibility of an IM program that was developed for older adults living in apartment-sharing communities, and to compare the effects of the program with conventional care. The secondary aim was to determine outcomes that would be suitable for a full-scale trial.

Methods

Design

This study was designed as a two-group, pragmatic, cluster-randomized pilot study. Since the intervention was designed for all inhabitants of an apartment-sharing community, we decided on a clustered randomization to allocate complete apartment-sharing communities to intervention or control. Randomization was carried out centrally by an independent statistician not further involved in the study. The randomized list was based on the "RANUNI" random number generator of the SAS/STAT® software (SAS Institute, Cary, NC, USA). Each apartment-sharing community received a number and was randomly allocated to intervention or control. The result of the randomization was concealed in an envelope for each apartment-sharing community; the study physicians were allowed to unblind the randomization allocation only after all included patients of a community received a complete baseline assessment of outcome parameters. Each study physician kept a log file with all randomized subjects. The study protocol was reviewed and approved by the Ethics Committee of the Charité University Medical Center, Berlin, Germany (EA1/118/09; 16.09.2009). The study was registered at ClinicalTrials.gov (NCT00974506).

Patients

The study was carried out in eight apartment-sharing communities with integrated nursing care. All older adults, regardless of their diseases and health state, were invited to participate. Older adults were enrolled by the study physicians. We originally planned to include only adults older than 70 years, but we had to change this criterion in the inclusion stage and amend the protocol as it became clear that some of the inhabitants being cared for

were younger than 70 years. We excluded only adults in a state of health which would absolutely not permit participation (eg, the patient was dying). All study participants or their legal guardians provided written informed consent before inclusion.

Intervention

The intervention for the IM group was designed by two experienced medical doctors specialized in internal medicine and general practice with further specialization in homeopathy, a naturopath specialized in naturopathic nursing care and self-help counseling, and a sports therapist. The complex IM program was designed with the aim to support self-healing and included lifestyle-changing elements, naturopathic care, and homeopathic treatment.[9,10]

The intervention took place over 12 months and consisted of:

- A weekly 60-minute exercise group, supervised by sport therapists. Exercise included: walking; ergometer training on a MOTOmed viva 2® device (Reck-Technik GmbH, Betzenweiler, Germany); exercise of muscular strength, motoric skills, balance, and coordination; as well as group communication. Patients that could not leave their beds due to disease received individual training in their beds.
- Naturopathic care, including the training of nurses by a naturopath about the use of herbal teas, naturopathic wraps and compresses, and the application of herbal massage oils.
- Freshly prepared fruit or vegetable juices regularly provided by caregivers.
- Individualized homeopathic treatment.
- Modification of conventional medication if needed.

The conventional care by family physicians or specialists was continued, but the homeopathic study physicians could change conventional medication if necessary; family physicians were regularly informed about these changes, and were asked to contact the study physicians if they disagreed.

The Usual Care group (UC) received conventional, usual care by family physicians, specialists, nurses, physiotherapists, and occupational therapists, without any influence due to the study.

Outcomes and data collection

All patients completed standardized geriatric outcome assessments at baseline and after 3 months, 6 months, and 12 months. Depending on the outcome, the assessments were either performed by a specialized geriatric occupational therapist or by the caregiving community nurse most familiar with the patient.

- Multidimensional geriatric assessment: the Nurses Observation Scale for Geriatric Patients (NOSGER) is a validated assessment instrument used in psychogeriatrics, consisting of 30 observable items of behavior and measuring impairments in six areas: memory, Instrumental Activities of Daily Living, Activities of Daily Living (ADL), mood, social behavior, and disturbing behavior (assessment by nurse).[11]
- Assessment of Motor and Process Skills (AMPS): a validated observational assessment allowing the simultaneous evaluation of motor and process skills and their effect on the ability of an individual to perform complex or instrumental and personal Activities of Daily Living. The AMPS comprised 16 motor and 20 process skill items (assessment by occupational therapist).[12,13]
- Activities of Daily Living: the Barthel Index (BI) is a validated assessment used to refer to daily self-care activities as a measurement of the functional status of a person. It comprises aspects like feeding oneself, bathing, dressing, grooming, and the ability to move on a scale from 0–100 (0, very dependent; 100, not dependent) (assessment by nurse).[14]
- Quality of Life: Qualidem is a validated dementia-specific Quality of Life instrument developed for use in residential care which consists of 37 items, divided in nine subscales regarding care relationship, restless tense behavior, positive and negative effects, positive self-image, social relations, having something to do, feeling at home, and social isolation (assessment by nurse).[15]
- Profile of Wellbeing: this unvalidated assessment tool aims to reflect the wellbeing of residents. Caregivers evaluate the patients' wellbeing subjectively within 14 indicators regarding signs of positive effects, communication, creativity, activity, cooperation, humor, and self-respect (assessment by nurse).[16]
- Cognition: the Mini-mental State Examination is a 30-point validated test measuring arithmetic, orientation, and memory functions (assessment by occupational therapist).[17]
- Falls: the Tinetti test is a validated test that assesses a person's static and dynamic balance abilities (assessment by occupational therapist)[18] as well as the absolute number of falls (assessment by caregivers/nurse).
- Medication list (assessment by nurse and occupational therapist).
- Hospital admissions (assessment by caregivers).

- Sociodemographic data and disease history (assessed at baseline by the study physicians).
- Adverse events and serious adverse events were monitored throughout the study by the caregivers and were critically reviewed by the study physicians and an occupational therapist.

The study physicians were asked to report and discuss their practical experiences and their thoughts on feasibility at the end of the trial.

Data analysis

To our knowledge, this is the first time an IM program including homeopathic treatment has been systematically evaluated. Due to the exploratory design of this study, no primary outcome was defined and no formal sample size calculation was performed. The decision to include eight apartment-sharing communities was based on practical feasibility that seemed appropriate according to funding and the personal resources available.

All data analyses were exploratory; 95% confidence intervals were only reported to help with the interpretation of results, not for confirmatory reasons. Each outcome parameter was analyzed separately by generalized linear models, which included treatment group, age, sex, and the respective baseline value as fixed factors and the apartment's identification as a random factor. Missing values were multiple imputed, which resulted in 20 different data sets. Each of the 20 data sets was analyzed separately with the abovementioned models; these results were adequately combined to provide adjusted estimates and 95% confidence intervals.

Results

Eight apartment-sharing communities were included; four were randomly allocated to the intervention IM and four to the control UC (Figure 1). The IM group consisted of 29 patients; the median group size was seven patients (range, 7–8), the mean age ± standard deviation of the patients was

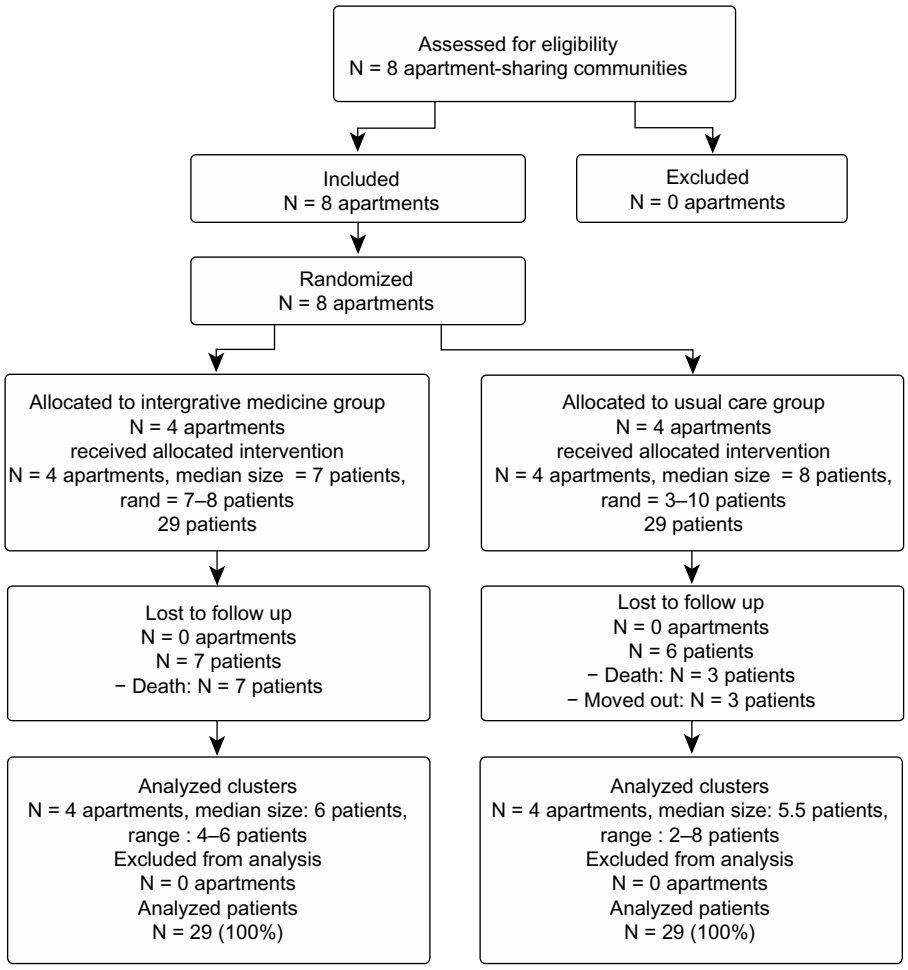

Figure 1 Trial flow chart.

82.7 ± 8.6 years (range, 65–102), 25 of 29 patients were female, and 27 had a legal guardian. The UC group consisted of 29 patients; the median group size was eight patients (range, 3–10), the mean age was 76.0 ± 12.8 years (range, 48–99), 14 of 29 patients were female, and 21 had a legal guardian. In the 12-month study period, seven patients in the IM group were lost to follow-up due to death; in the UC group, six patients were lost to follow-up, three due to death and three due to moving out of the apartment. Data on all patients were analyzed following an intention-to-treat approach.

At baseline, IM patients were on average 7 years older (82.7 ± 8.6) than UC patients (76.0 ± 12.8, Table 1) and were mainly female (86.2% versus 48.2%). Patients in both groups were typical geriatric patients with a high number of multiple diseases and multiple drug treatments. IM patients used 7.0 (±3.4) different drugs daily, compared to UC patients (9.6 ± 2.9). The percentage of patients with cognitive impairments and the number of classified diseases were comparable in both groups.

In the IM group, the mean number of conventional drugs per patient was reduced from 6.8 ± 3.3 at baseline to 4.8 ± 1.5 after 12 months (homeopathic drugs included), whereas it remained stable in the UC group (baseline: 8.3 ± 5.0; 12 months: 8.5 ± 5.7). All patients in the IM group received homeopathic treatment in various potencies, mostly LM potencies. LM represents the Roman numeral for 50,000 (quinquaginta-millesimal-potency); the dilution factor is 1/50,000 instead of the customary method of 1/100 dilution (C potencies). The most frequently prescribed homeopathic drugs were Hyoscyamus niger (n = 6), Lycopodium clavatum (n = 4), opium (n = 3), and phosphorus (n = 3); a total of 27 other homeopathic drugs were also prescribed.

Table 1 Sociodemographic data and characteristics of patients at baseline in both study groups

	Integrative Medicine group (n = 29)	Usual care group (n = 29)
Demographics		
Age, years (± SD)	82.7 (±8.6)	76.0 (±12.8)
Female, n (%)	25 (86.2)	14 (48.2)
Legal guardian, n (%)	21 (72.4)	27 (93.1)
Disease history		
Maximum level of care, n (%)	7 (24.1)	3 (10.3)
Number of ICD diagnoses, mean (± SD)	9.9 (±2.9)	9.6 (±2.9)
Cognitive impairment, n (%)	16 (55.1)	14 (48.2)
Apoplectic insult history, n (%)	2 (6.8)	6 (20.6)
Number of drugs taken, mean (± SD)	7.0 (±3.4)	9.6 (±2.9)

Abbreviations: ICD, International Statistical Classification of Diseases and Related Health Problems; n, number; SD, standard deviation.

Due to clinically relevant group differences at baseline for age and gender, the means, 95% confidence intervals, and the effect sizes (Cohen's d) were statistically adjusted.

After 3 and 6 months on an exploratory level, no clear differences or trends could be observed comparing outcomes of IM and UC (Table 2).

After 12 months, improvements with medium effect sizes ≥0.3 were noted in ADL, Quality of Life, Wellbeing, and specific affective and social functioning outcomes (see Table 2). This included BI (0.30 [0.03; 0.57]), Profile of Wellbeing (0.36 [–0.12; 0.84]), Qualidem total sum (0.39 [–0.20; 0.98]), Qualidem-having something to do (0.35 [–0.15; 0.86]), Qualidem-negative affect (0.33 [–0.16; 0.82]), Qualidem-positive affect (0.37 [–0.31; 1.05]), Qualidem-social relation (0.49 [–0.07; 1.05]), NOSGER-depressed mood (0.40 [–0.08; 0.89]), NOSGER-impaired ADL (0.53 [0.09; 0.97]), and NOSGER-impaired social behavior (0.47 [–0.08; 1.03]). There was a higher risk for falls in the IM than in the UC (odds ratio 3.30; 95% confidence interval: 0.43; 25.26), but hospital admissions were in general comparable for both groups (IM: 0.7 ± 1.1; UC 1.0 ± 1.8).

We observed seven deaths in the IM group caused by cardiovascular disease (three patients), cancer (three patients), and age (one patient, 102 years of age); three deaths in the UC group were caused by cardiovascular disease.

The study physicians discussed the feasibility of the trial every 3 months. Overall, they judged the intervention itself as feasible but found it elaborate and time consuming. The amount of adherence and identification with this study differed between the caregivers; generally, it seemed the female caregivers identified themselves very much with the study and observed good clinical results, whereas male caregivers were much more skeptical and supported the interventions to a lesser degree.

Discussion

To our knowledge, this is the first time that an additional complex IM program consisting of lifestyle change, naturopathic care, and homeopathic drug therapy was developed, applied, and evaluated in older adults in apartment-sharing communities. Exploratory effect sizes of ≥0.3 in favor for the IM intervention were observed after 12 months for ADL, Wellbeing, and Quality of Life.

Strengths of this study are the pragmatic and naturalistic approach, and the relatively large sample for a pilot study. The intervention was added to a naturalistic setting; we intended

Table 2 Outcome measures at baseline and after 3, 6, and 12 months (mean, 95% confidence intervals, Cohen's d/effect sizes, adjusted for baseline differences)

Outcome parameter	Results at 3 months			Results at 6 months			Results at 12 months		
	IM mean (95% CI)	UC mean (95% CI)	Effect size Cohen's d (95% CI)	IM mean (95% CI)	UC mean (95% CI)	Effect size Cohen's d (95% CI)	IM mean (95% CI)	UC mean (95% CI)	Effect size Cohen's d (95% CI)
Activities of daily living									
Barthel index	46.6 (37.3; 55.9)	42.4 (37.1; 47.8)	0.14 (−0.08; 0.37)	45.0 (35.3; 54.7)	42.4 (36.8; 47.9)	0.09 (−0.15; 0.34)	50.2 (39.6; 60.8)	41.4 (35.3; 47.4)	0.30 (0.03; 0.57)
AMPS motor skills	−0.3 (−0.7; 0.1)	−0.1 (−0.1; −0.1)	−0.12 (−0.36; 0.11)	−0.4 (−0.9; 0.1)	−0.1 (−0.1; −0.1)	−0.18 (−0.49; 0.13)	0.1 (−0.3; 0.6)	−0.1 (−0.1; −0.1)	0.12 (−0.16; 0.41)
AMPS process skills	−0.6 (−1.0; −0.2)	−0.6 (−0.8; −0.5)	0.04 (−0.21; 0.29)	−0.7 (−1.1; −0.2)	−0.6 (−0.8; −0.5)	−0.04 (−0.37; 0.30)	−0.7 (−1.2; −0.2)	−0.6 (−0.8; −0.5)	−0.06 (−0.49; 0.40)
Cognition									
Mini-mental state examination	11.7 (9.4; 13.9)	13.4 (12.1; 14.8)	−0.19 (−0.39; 0.01)	13.2 (11.2; 15.3)	13.8 (12.5; 15.0)	−0.06 (−0.26; 0.14)	15.4 (12.5; 18.2)	13.9 (12.1; 15.7)	0.15 (−0.13; 0.43)
Quality of life									
Profile of Wellbeing	14.3 (10.7; 17.9)	13.4 (10.5; 16.2)	0.14 (−0.16; 0.45)	12.5 (7.6; 17.5)	10.4 (7.0; 13.8)	0.33 (−0.23; 0.89)	15.5 (11.0; 20.0)	13.2 (9.9; 16.6)	0.36 (−0.12; 0.84)
Qualidem (total sum score)	56.6 (41.5; 71.8)	54.1 (42.7; 65.6)	0.14 (−0.39; 0.67)	51.6 (36.8; 66.3)	50.1 (39.9; 60.3)	0.08 (−0.50; 0.67)	56.0 (39.1; 72.8)	49.0 (36.1; 62.0)	0.39 (−0.20; 0.98)
Care relationship	9.8 (6.4; 13.2)	8.8 (6.2; 11.4)	0.27 (−0.33; 0.86)	8.2 (4.2; 12.2)	8.2 (5.4; 11.0)	−0.02 (−0.80; 0.77)	6.9 (2.5; 11.3)	6.3 (2.7; 10.0)	0.16 (−0.54; 0.87)
Feeling at home	5.3 (2.8; 7.8)	4.9 (3.3; 6.4)	0.13 (−0.48; 0.74)	4.1 (1.7; 6.5)	4.7 (3.2; 6.2)	−0.18 (−0.80; 0.44)	3.2 (1.3; 5.1)	3.6 (2.5; 4.7)	−0.11 (−0.60; 0.37)
Social isolation	3.5 (1.8; 5.2)	3.3 (2.3; 4.3)	0.07 (−0.57; 0.70)	3.6 (2.1; 5.2)	3.3 (2.2; 4.3)	0.15 (−0.40; 0.71)	3.9 (2.6; 5.2)	3.5 (2.5; 4.5)	0.15 (−0.34; 0.64)
Positive self-image	4.0 (2.0;5.9)	3.2 (2.1; 4.3)	0.30 (−0.29; 0.89)	3.3 (1.7; 4.8)	2.5 (1.5; 3.6)	0.28 (−0.22; 0.79)	3.4 (2.0; 4.9)	2.9 (1.9; 3.8)	0.23 (−0.25; 0.71)
Restless tense behavior	1.3 (0.2; 2.4)	2.3 (1.6; 3.0)	−0.51 (−0.96; −0.06)	2.6 (1.3; 3.9)	2.7 (1.8; 3.6)	−0.05 (−0.61; 0.52)	2.2 (0.8; 3.6)	1.7 (0.8; 2.6)	0.24 (−0.41; 0.90)
Having something to do	2.6 (1.7; 3.5)	2.2 (1.8; 2.7)	0.18 (−0.18; 0.54)	2.4 (1.3; 3.4)	2.2 (1.7; 2.7)	0.08 (−0.38; 0.54)	2.7 (1.6; 3.8)	2.0 (1.4; 2.5)	0.35 (−0.15; 0.86)
Negative affect	3.0 (1.6; 4.4)	2.8 (1.9; 3.8)	0.08 (−0.30; 0.46)	3.6 (2.1; 5.0)	3.2 (2.2; 4.1)	0.17 (−0.26; 0.60)	4.9 (3.3; 6.6)	4.2 (3.1; 5.3)	0.33 (−0.16; 0.82)
Positive affect	10.1 (8.3; 13.4)	10.8 (8.7; 12.8)	0.03 (−0.31; 0.36)	9.9 (6.1; 13.7)	9.0 (6.1; 11.9)	0.21 (−0.38; 0.80)	10.3 (5.9; 14.6)	8.7 (5.4; 12.0)	0.37 (−0.31; 1.05)
Social relation	8.0 (5.4; 10.7)	7.4 (5.4; 9.4)	0.17 (−0.22; 0.57)	8.4 (5.5; 11.3)	8.0 (6.2; 9.8)	0.10 (−0.48; 0.68)	8.3 (5.1; 11.4)	6.4 (4.3; 8.6)	0.49 (−0.07; 1.05)
Multidimensional NOSGER									
Depressed mood	4.8 (2.7; 7.0)	5.4 (3.5; 7.3)	0.17 (−0.22; 0.55)	5.2 (3.2; 7.3)	6.3 (4.5; 8.0)	0.31 (−0.09; 0.70)	4.1 (1.9; 6.2)	5.4 (3.8; 7.1)	0.40 (−0.08; 0.89)
Impaired activities of daily living	9.1 (6.0; 12.2)	10.6 (8.1; 13.1)	0.31 (−0.25; 0.88)	9.7 (7.0; 12.3)	11.6 (8.9; 14.3)	0.41 (0.02; 0.80)	8.3 (5.7; 10.9)	10.8 (8.3; 13.4)	0.53 (0.09; 0.97)

Impaired memory	11.7	12.5	0.18	9.6	11.4	0.40	11.3	11.6	0.08
	(8.1; 15.3)	(9.0; 16.0)	(−0.33; 0.69)	(5.9; 13.3)	(8.2; 14.6)	(−0.08; 0.88)	(6.7; 15.9)	(7.9; 15.4)	(−0.51; 0.66)
Impaired social behavior	8.9	10.1	0.21	8.4	9.8	0.25	8.8	11.4	0.47
	(5.5; 12.4)	(7.2; 13.0)	(−0.25; 0.67)	(4.9; 11.9)	(6.8; 12.7)	(−0.24; 0.74)	(5.2; 12.5)	(8.6; 14.3)	(−0.08; 1.03)
Disturbing behavior	5.3	6.5	0.36	4.7	5.3	0.20	3.8	3.9	0.03
	(2.2; 8.5)	(4.6; 8.4)	(−0.36; 1.07)	(1.7; 7.6)	(3.4; 7.3)	(−0.41; 0.82)	(1.1; 6.6)	(2.1; 5.7)	(−0.59; 0.64)
Impaired instrumental activities of daily living	14.7	14.5	−0.03	13.7	14.1	0.09	18.3	19.1	0.18
	(11.0; 18.4)	(11.0; 18.0)	(−0.43; 0.37)	(10.1; 17.3)	(10.6; 17.5)	(−0.30; 0.49)	(14.2; 22.4)	(15.4; 22.8)	(−0.36; 0.72)
Risk of falls									
Tinetti score	11.1	11.0	0.01	10.4	11.0	−0.07	11.0	10.7	0.04
	(8.7; 13.5)	(9.7; 12.3)	(−0.21; 0.23)	(7.7; 13.1)	(9.5; 12.4)	(−0.35; 0.20)	(7.8; 14.2)	(9.0; 12.4)	(−0.29; 0.37)

Abbreviations: AMPS, assessment of motor and process skills; CI, confidence interval; IM, Integrative Medicine; NOSGER, nurses observation scale for geriatric patients; UC, usual care.

to include all patients living in the apartments to avoid selection. It is important to understand that the intervention was not designed to evaluate specific effects of homeopathic drugs, but to test a holistic geriatric treatment approach that included homeopathic treatment philosophy with lifestyle change.[9] As this was a complex intervention consisting of several treatment modules, it is not possible to relate effects to single parts of the intervention (eg, exercise, reduction of conventional medication, naturopathic care, homeopathic treatment, or additional care offerings in general).

We chose a clustered randomization because it reflected best the typical setting for this complex intervention. It would not have been possible to provide lifestyle changes to only half of the patients in an apartment. However, cluster-randomized trials have drawbacks; it turned out that the clustered randomization resulted in group differences at baseline regarding age and gender. Therefore, we had to adjust in our exploratory data analyses for these baseline differences. By doing so and performing multiple imputations for missing values, we tried to provide more solid data while avoiding a confirmatory statement.

This was a study on older patients, who generally have a higher risk of passing away during the treatment or follow-up period. Moreover, this risk is considerably higher in more seriously ill patients. Consequently, we imputed missing values to have a more realistic result by including estimated values for the more seriously ill patients.

Although this study was a cluster-randomized trial, the number of clusters and patients was small. This generally bears the risk of group imbalances, and indeed it turned out that the groups differed in age and gender. We therefore decided to adjust our statistical analyses for these parameters. However, results with and without adjustments did not differ relevantly, although the group differences were generally somewhat smaller in unadjusted models (eg, standard mean difference of 0.14 versus 0.12 in the BI after 3 months). In general, we believe that adjusted models are more trustworthy, because they do have a lower risk of bias.

In the IM group, the mean age was 83 years, compared to 76 years in the UC group. The state of health for the whole IM sample might therefore have been more unstable compared to the UC sample. This hypothesis is supported by the group differences at baseline. More IM patients (24%) were receiving the highest level of care, compared to 10% of the control group. Systematic analyses of surveys of the elderly US population showed consistency of declines in any disability (−1.55% to −0.92% per year), instrumental activities of daily living disability (−2.74% to −0.40% per year),

functional limitations, and limited evidence on cognition and conflicting evidence on self-reported ADL (changes ranged from −1.38% to 1.53% per year).[19] Differences in age between the groups may also explain the higher rate of death and higher incidence of falls in the IM group. For future confirmatory trials, it should be estimated that approximately 20 percent of the study population may die naturally within a 12-month study period.

More falls were observed in the IM group. This could be explained solely by the age differences between the groups. But the fact that patients exercised could have contributed to this observation, although falls did not happen while patients were exercising. Nevertheless, falls would not have happened in patients without motivating caregivers to start walking with them again. This is an ethical dilemma: mobilizing patients is considered to be beneficial, and exercise training might increase autonomy and abilities of daily functioning in the elderly, but falls due to walking may have fatal consequences.

Generally, the adherence to the sports program was very high, as the training was implemented as a regular weekly group activity and was supervised by sports therapists recruited especially for this study. The adherence to nutritional changes and naturopathic therapies by the caregivers was substantially lower, and varied from apartment to apartment depending on the motivation of the caregivers. It turned out that it was not possible to practically measure these daily activities closely because caregivers and cooks could not be motivated to keep extra documentation on these activities.

The results of this trial indicate that such a complex treatment program might help older adults to improve ADL and Quality of Life as well as affective and social functioning. We consider the differences of the adjusted means of the BI and the NOSGER-impaired activities of daily living both after 12 months as clinically relevant group differences, justifying a larger trial with confirmatory design. However, it has to be emphasized that no relevant improvements were found after 3 or 6 months. If the improvements were due to the interventions, an effect can only be expected after a longer intervention time.

For a full-scale clinical trial, the following aspects should be considered: Activities of Daily Living (eg, BI or NOSGER) and Quality of Life after 12 months or even longer might represent the most promising outcomes for studies, including patients with different diseases in this age group. Reducing the outcome assessment to only a few assessments would also save resources. Focusing only on patients with a specific disease would reduce variance and sample size, and allow for a more disease-specific outcome, but it would introduce a more artificial setting because in apartment-sharing communities patients usually suffer from multiple and varying diseases. The study physicians subjectively had the clinical impression that the observed clinical effects were higher than shown in the results of the quantitative analyses. This impression was also supported by the observation of the caregivers responsible for the patients in the IM group.

Study physicians observed that the effects were higher in apartments where the caregivers identified with the IM program and actively supported the study. Both study physicians gave the opinion that for further projects, a high identification with IM and good clinical training of caregivers might be essential for obtaining good clinical results.

Conclusion

This exploratory pilot study showed that for a full-scale trial, the outcomes of ADL and Quality of Life seem to be the most promising. Although the IM program was feasible, it was elaborate and time consuming.

Author contributions

Study concept and design: MT, CMW, KS. Organization and data management: MT, KS. Design of intervention: MT, FR, NP, FB, AK. Study physicians: MT, RB. Exercise training: FR, NP, FB. Training of caregivers: AK. Geriatric assessments: KS. Statistical analysis: RL. Analysis and interpretation of data: MT, RL, CMW, KS. Obtained funding: MT, CMW. All authors drafted or revised, commented on, and approved the final manuscript.

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Disclosure

The authors report no conflicts of interest in this work.

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Use of complementary and alternative medicine by older adults – a cross-sectional survey

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Abstract

Background: Very little is known about complementary and alternative medicine (CAM) use by older adults in Germany. The aim of this study was to investigate the use of CAM and other health promoting substances (e.g., herbal teas) by older adults of at least 70 years of age.

Methods: A cross-sectional questionnaire study was conducted among persons of ≥70 years from metropolitan Berlin and rural parts of Brandenburg, Germany. Recorded were: demographics, current use of CAM, medical diagnoses, users' opinions and preferences.

Results: A total of 400 older adults, living as 'self-reliant' (n = 154), 'home care service user' (n = 97), or 'in nursing home' (n = 149), and with the legal status 'without guardian' (n = 355) or 'with guardian' (n = 45) were included (mean age 81.8 ± 7.4 years, 78.5% female). Any type of CAM used 61.3% of respondents (dietary supplements 35.5%, herbal medicines 33.3%, and external preparations 26.8%); 3.0% used drug-interaction causing preparations. Usage was based on recommendations (total 30.3%; in 20.0% by friends or family and 10.4% by pharmacists), own initiative (27.3%), and doctors' prescription (25.8%). Participants with legal guardian took almost solely prescribed dietary supplements. Of the others, only half (58.7%) informed their general practitioner (GP) of their CAM use. Participants expected significant (44.9%) or moderate (37.1%) improvement; half of them perceived a good effect (58.7%) and two-thirds (64.9%) generally preferred a combination of CAM and conventional medicine. More than half (57.9%) stated that they could neither assess whether their CAM preparations have side effects, nor assess what the side effects might be. Strongest predictors for CAM use were two treatment preferences (vs. 'conventional only': 'CAM only', OR = 3.98, p = 0.0042 and 'CAM + conventional', 3.02, 0.0028) and the type of health insurance ('statutory' vs. 'private', 3.57, 0.0356); against CAM use two subjective assessments predicted (vs. 'CAM causes no harm': 'CAM causes harmful drug interactions', 0.25, 0.0536 and 'I cannot assess side effects', 0.28, 0.0010).

Conclusion: Older German adults frequently use CAM. They perceived it as an effective complement to conventional medicine, but are not sufficiently informed about risks and benefits.

Keywords: Older adults, CAM, Dietary supplements, Nursing home, Residential care, Legal guardian

Background

Germany has a very long tradition of complementary and alternative medicine (CAM). Many older adults have lifelong experience with herbal medicine and other home remedies due to unavailable conventional care during their childhood. CAM therapies are often used as self-care to enhance wellbeing, to prevent and to cure illnesses [1]. However, the use of CAM by older adults in Germany has not been investigated extensively. In particular, data from older adults under legal guardianship or requiring nursing care are missing, largely, because these groups are hard to reach by conventional survey techniques such as questionnaires and telephone surveys, and health status may preclude responding. Previous studies exploring CAM use in Germany only investigated clients of one private health insurance company [2], excluded person of 70 [3] or 80 [4] years and older, or have not been evaluated specifically for the older adults [5], despite a high, and rising, rate of CAM users among this group (respondents of at least 60 years: 61% in 1970, 73% in 2010) [6,7].

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Polypharmacy is also a problem in the geriatric care in Germany and poses a risk for side effects and drug interactions. While seniors at the age of 60 years take 2–3 prescribed medications daily, the number increases among those over 80 years to more than 4–5 drugs per day [8]. Self acquired additional drugs such as herbal medicines or vitamins are not recorded in the statistics of the statutory health insurance because they are not covered. Many herbal drugs and products interactions and side effects are well known, e.g. (i.e., Ginkgo biloba, Valeriana officinalis, St. John's wort, and grapefruit juice [9,10].

Therefore we investigated the use of CAM and other health promoting substances (e.g., herbal teas) by older adults of at least 70 years, taking care to include under-researched areas such as rural areas or nursing homes.

Our survey solicited information regarding which form (s) of CAM is used and how its use is subjectively assessed, as well as medical context information. We asked for all natural products, drugs and therapies that were taken for treatment or prevention of diseases, this included not only drugs but also medically applied herbal teas and juices. To get the best possible representation of real-life conditions, we included older adults living with a variety of needs for care, living in either a metropolitan or a rural area, and with or without a legal guardian.

Methods

We conducted a cross-sectional questionnaire study from November 2010 through July 2012. Participation was anonymous and voluntary; participants expressed their agreement through completion of the questionnaire. For those under legal guardianship, the guardian provided legal consent. The study protocol was approved by the ethics committee of the Charité Universitätsmedizin Berlin (EA1/243/09, 2009-11-25 and 2010-12-16).

Older adults at least 70 years of age living in the states of Berlin (entire city) and Brandenburg (rural northeast, i.e., districts around Berlin including Oberhavel, Barnim, Uckermark and Märkisch-Oderland) were approached through care service providers, nursing homes, community clubs of older adults, or directly through the distribution of questionnaires in mailboxes of senior residential facilities (Berlin only). The care service providers and nursing homes were selected from the phone book and contacted in alphabetical order. The older adults lived in their own homes, either self-reliant or assisted by a home care service, or in a retirement or nursing home. Both home care service users and nursing home residents included older adults with, as well as without, a legal guardian, resulting in 5 study arms (Figure 1). Care service providers selected the clients to be approached by randomized weekday of service and nurse or caregiver, and nursing homes by randomized room numbers. Participants who were able to understand the questionnaires and who were legally permitted to be directly approached answered the questionnaires themselves, with assistance if necessary, and were rewarded with a medical self-care book. For the others (i.e., with legal guardians and not living independently), the caregivers extracted the data from their documentation. Here, no subjective assessments of the participants were asked; service providers or nursing homes received € 4 for every completed questionnaire.

The questionnaire asked for social and demographic data. In this study we also included non-medical health promoting substances such as vitamins or teas under CAM. We recorded for CAM preparations: Name and dosage, reason for the application, on what basis the decision for their use was made, and information regarding participants' general practitioners (GPs') knowledge about their patients' CAM usage. Further items covered the use of non-pharmacological treatments, and, for participants without legal guardians, their subjective opinions and assessments about CAM: expectations towards, experience with, and perceived effects and risks, as well as the generally preferred treatment.

Due to a lack of data about the prevalence of the use of alternative medical drugs in the studied population we assumed a prevalence of 50% of the use of CAM drugs in in the studied population. With an accuracy of 10% for a two-sided confidence interval of prevalence at the 95% level, 96 participants would be needed. In order to achieve this precision, 96 questionnaires would be needed for each of the four groups of older adults: living self reliantly, receiving homecare, living in nursing homes or having a legal guardian. We anticipated that 60% of the self reliant living older adults would return the questionnaires, in all others a return rate of 80% of the questionnaires. Thus the number of self reliant older adults to be contacted was n = 160, for all other groups n = 120. The total number of issued questionnaires thus was n = 520.

The answers from the questionnaires were entered into an electronic database (MS Access™) and checked for plausibility and quality. Descriptive analyses were calculated, and patient groups, stratified by CAM use (yes, no) were compared using chi-square (categorical variables) and t-test (continuous data). For participants without legal guardians, the effect of variables on CAM use was estimated with a multiple logistic regression. The variables were selected on the basis of the calculated p-values and frequencies, as well as an expert's opinion. Several potential predictor models were tested before the final logistic model was calculated. SPSS 19.0 and higher (© SPSS/IBM) and Statistical Analysis Systems 9.3 (© SAS Institute) were used for randomization and all analyses.

Results

We contacted 33 care service providers (Berlin 21, Brandenburg 12) and 19 nursing homes (Berlin 7,

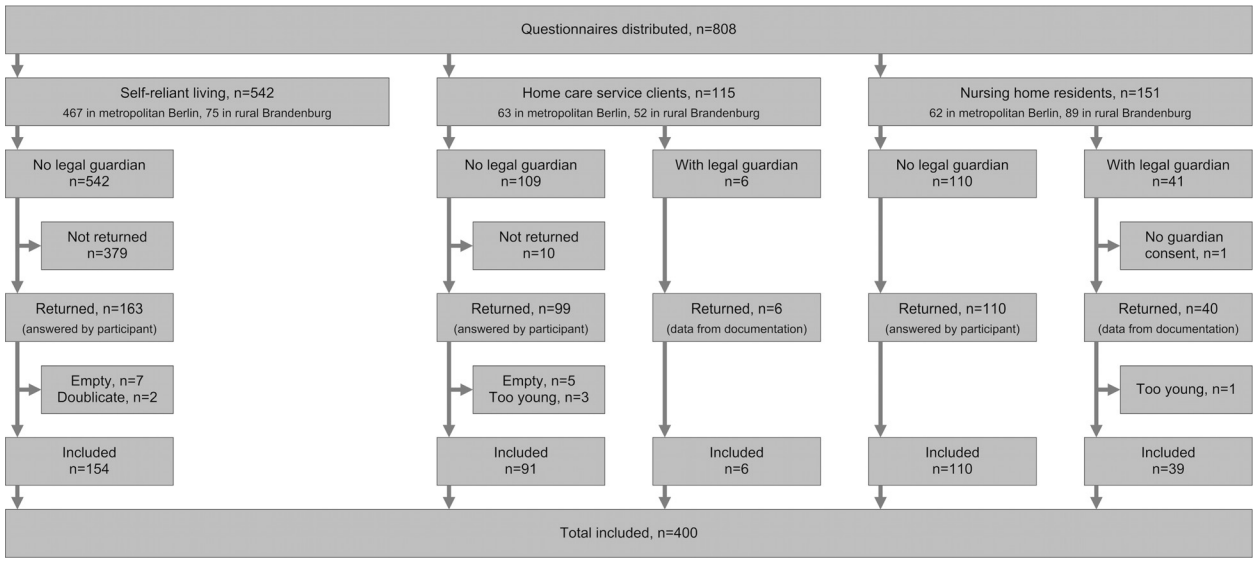

Figure 1 Recruitment, study arms, and inclusion.

Brandenburg 12), of which 6 care service providers (Berlin 3, Brandenburg 3) and 6 nursing homes (Berlin 2, Brandenburg 4) participated. Of the 761 questionnaires that were issued to older adults without legal guardian or their nurses, and the 47 questionnaires issued to nurses of older adults with legal guardian, a total of 418 (51.7%) were returned; 400 were entered into the final analysis (Figure 1). The demographic details of the included respondents are presented in Table 1. An equal proportion of included participants lived in rural and metropolitan areas, most were insured by the statutory health insurance, half were approved a care level of the German care insurance system, and three-quarters were female. From the groups without legal guardians, a higher education was more frequently reported in the self-reliant group (Table 1).

Nearly two out of three participants (61.3%) used at least one CAM preparation (Table 2). Both highest and lowest rates were seen in home care service clients (78.0% without, and 33.3% (2 of 6) with legal guardians). Most frequently they took dietary supplements (35.5%) and herbal medicines (33.3%). Physical therapy (41.3%) led the non-pharmaceutical therapies. Cardiovascular diseases were the most frequent reason for medication of any kind (26.8%), followed by chronic pain (24.5%). Table 2 shows details for all subgroups.

The CAM preparations most frequently used by older adults without legal guardians are listed in Table 3. Some of them are known to cause drug interactions (i.e., Ginkgo biloba, Valeriana officinalis, St. John's wort, and grapefruit juice [9,10]); such preparations were used by 3.0% of the participants (Table 3).

Of the older adults with legal guardians, 88.9% used CAM. In 92.9% of cases, their GPs prescribed the preparations but only 51.3% documented the reason. Users took predominantly dietary supplements: Vitamin D_3 (22.2%), vitamin B_{12} (20.0%), folic acid (13.3%), calcium (6.7%), magnesium (2.2%), and iron (2.2%) and only in 2.2% the herbal preparation, valerian. CAM users without legal guardians expected a marked (44.9%) or moderate (37.1%) improvement of their conditions; 11.7% did not state their expectations. More than half (58.7%) of the users experienced a good effect, 27.4% only a minor effect, and 6.0%, no effect.

CAM usage was in 31.3% based on recommendations (10.4% by pharmacists, 20.0% by friends or family) or as a result of one's own initiative (27.3%). Only a quarter (25.8%) of the total CAM uses were prescribed by medical or nonmedical practitioners (in Germany 'Heilpraktiker') (Table 4). More than half (58.7%) of CAM users informed their GPs of their CAM uses. Merely 16.6% of all participants were asked about their CAM usage by their GPs – the more dependent their living situation, the less frequently their GPs inquired (Table 4). Of the older adults without legal guardians, more than half (57.9%) stated that they could neither assess whether or not their CAM preparations would have side effects, nor what side effects these might be, and only 5.0% were aware of possibly harmful drug interactions (Table 4). Nearly two-thirds (64.9%) of this group preferred a combination of CAM and conventional medicine (Table 4).

The variables that predict the use of CAM preparations for participants without legal guardians are shown in Figure 2. Highest odds ratios predicting CAM use were found for two treatment preferences (CAM only, OR = 3.98, p = 0.0042; CAM + conventional, 3.02, 0.0028) and the type of health insurance (statutory, 3.57, 0.0356).

Table 1 Demographic data

Demographics	Total	Self-reliant	Home care service			Nursing home		
			Total	Without legal guardian	With legal guardian	Total	Without legal guardian	With legal guardian
	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)
Participants[a]	100.0 (400)	38.5 (154)	24.3 (97)	22.8 (91)	1.5 (6)	37.3 (149)	27.5 (110)	9.8 (39)
Age (years, mean ± SD)	81.8 ± 7.4	79.8 ± 7.1	82.1 ± 6.6	82.5 ± 6.1	76.0 ± 10.5	83.8 ± 7.7	83.7 ± 8.2	84.2 ± 6.3
Female	78.5 (310)	78.8 (119)	84.2 (80)	88.8 (79)	28.2 (11)	74.5 (111)	75.5 (83)	71.8 (28)
Living with partner	21.7 (76)	25.3 (38)	24.4 (22)	24.4 (22)	n/a	14.6 (16)	14.6 (16)	n/a
Approved care, any level[c]	58.4 (227)	9.7 (14)	70.5 (67)	70.8 (63)	66.7 (4)	98.0 (146)	98.2 (108)	97.4 (38)
Approved care level I[b,d]	52.4 (118)	85.7 (12)	58.2 (39)	58.7 (37)	50.0 (2)	46.5 (67)	55.7 (59)	21.1 (8)
Approved care level II[b,e]	39.1 (88)	14.3 (2)	38.8 (26)	38.1 (24)	50.0 (2)	41.7 (60)	44.3 (47)	34.2 (13)
Approved care level III[b,f]	8.4 (19)	0 (0)	3.0 (2)	3.2 (2)	0 (0)	11.8 (17)	0 (0)	44.7 (17)
Statutory health insurance	93.1 (359)	85.7 (126)	96.7 (87)	96.5 (82)	100.0 (5)	98.7 (146)	99.1 (109)	97.4 (37)
Private health insurance	6.8 (26)	15.3 (21)	3.3 (3)	3.5 (3)	0 (0)	1.4 (2)	0.9 (1)	2.6 (1)
>10 years of school	12.1 (42)	21.1 (31)	5.6 (5)	5.6 (5)	n/a	5.5 (6)	5.5 (6)	n/a
Metropolitan area (Berlin)	50.3 (201)	61.7 (95)	47.4 (46)	44.0 (40)	100.0 (6)	40.3 (60)	47.3 (52)	20.5 (8)
Rural area (Brandenburg)	49.7 (199)	38.3 (59)	52.6 (51)	56.0 (51)	0 (0)	59.7 (89)	52.7 (58)	79.5 (31)

Percent of valid answers of the respective group; [a]percent of total study population; [b]percent of older adults with approved care level.
[c]Care levels according to German law (§ 15 SGB XI). [d]Requires help ≥1×/d for ≥2 performances with body care, food or mobility, plus several times per week with household. The average duration of ≥90 min/d includes ≥45 min of basic care [11]. [e]Requires help ≥3×/d at different times with body care, food or mobility, plus several times per week with household. The average duration of ≥3 hrs/d includes ≥2 hrs of basic care [12]. [f]Requires help around the clock with body care, food or mobility, plus several times per week with household. The average duration of ≥5 hrs/d includes ≥4 hrs of basic care [13].

For those against CAM use, two subjective assessments were the strongest predictors (CAM causes harmful drug interactions, 0.25, 0.0536; I cannot assess side effects, 0.28, 0.0010). Gender (female, 0.6, 0.1340) and the degree of independence of the living situation (in nursing home, 1.22, 0.5554; using home care service, 2.31, 0.0360) were found to be weaker predictors.

Discussion

In an anonymous questionnaire survey in Germany of adults aged 70 years and older, we generally found a very high rate of CAM users. The older adults regarded CAM as an effective therapeutic approach with low risks of side effects. Predominantly dietary supplements and herbal preparations were applied, mostly without a physician's prescription.

One strength of this study is the coverage of naturalistic settings: metropolitan and rural areas in both former 'East' and 'West' Germany, a broad range of the need for care, and participants with and without legal guardians. Our recruitment strategy facilitated the inclusion of multimorbid older adults and thus reduced the selection bias for healthy respondents, which made it preferable to a phone survey or identifying possible participants through records from registration offices. The practice of directly approaching participants resulted in a high return rate in participants without legal guardianship, as has been suggested elsewhere [14].

The results obtained were collected in Berlin and Brandenburg (Germany). It is unclear whether they can be transferred to other German states. The recruitment of older adults with legal guardians was less successful than expected. The additional work for their nurses (obtaining guardian consent, data extraction) and possibly other concerns established an entry barrier that resulted in less than the 100 required participants; thus not all planned statistics could be calculated.

In all groups it is possible that some older adults listed all of their diseases as reasons for CAM use. Also, results from nursing homes may have been influenced by the fact that some of the homes offered CAM treatments, which may be interpreted as a distortion of the results or as part of the environment. A few respondents who were much younger than the intended inclusion age made it necessary to relax the strict intention-to-treat approach and exclude these untargeted extreme outliers.

A comparison of our results with the existing research is difficult because of the small body of literature and its different eligibility criteria. For Germany, only one anonymous questionnaire survey by Büssing et al. exists [2], which included only privately insured elderly without a legal guardian. Participants in that study were, on average, 17 years younger (mean age 64.7 ± 11.2 years) than our participants. These facts contribute to the other marked demographic differences between that and the present study: females were 30% of their respondents vs. 79% of ours, 53% (vs. 12%) had attended school

Table 2 Use of CAM preparations, non-pharmaceutical therapies, and underlying diseases

Use	Total	Self-reliant	Home care service			Nursing home		
			Total	Without legal guardian	With legal guardian	Total	Without legal guardian	With legal guardian
	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)
Use of CAM preparations								
Any preparation	61.3 (245)	52.6 (81)	75.3 (73)	78.0 (71)	33.3 (2)	61.1 (91)	57.3 (63)	71.8 (28)
Dietary supplements	35.5 (142)	31.2 (48)	45.4 (44)	48.4 (44)	0 (0)	33.6 (50)	22.7 (25)	64.1 (25)
Herbal therapy	33.3 (133)	35.7 (55)	52.6 (51)	56.0 (51)	0 (0)	18.1 (27)	23.6 (26)	2.6 (1)
External applications	26.8 (107)	16.9 (26)	41.2 (40)	41.8 (38)	33.3 (2)	27.5 (41)	34.5 (38)	7.7 (3)
Homeopathy	8.0 (32)	11.7 (18)	10.3 (10)	11.0 (10)	0 (0)	2.7 (4)	3.6 (4)	0 (0)
Juices (vegetable/fruit)	1.5 (6)	1.3 (2)	3.1 (3)	3.3 (3)	0 (0)	0.7 (1)	0.9 (1)	0 (0)
Other	1.5 (6)	1.9 (3)	0 (0)	0 (0)	0 (0)	2.0 (3)	1.8 (2)	2.6 (1)
Diseases for which medication is used								
Cardiovascular diseases	26.8 (107)	31.8 (49)	40.2 (39)	42.9 (39)	0 (0)	12.8 (19)	17.3 (19)	0 (0)
Chronic pain	24.5 (98)	27.9 (43)	38.1 (37)	39.6 (36)	16.7 (1)	12.1 (18)	15.5 (17)	2.6 (1)
Gastrointestinal diseases	14.0 (56)	16.2 (25)	24.7 (24)	26.4 (24)	0 (0)	4.7 (7)	6.4 (7)	0 (0)
Endocrine diseases	10.3 (41)	10.4 (16)	18.6 (18)	18.7 (17)	16.7 (1)	4.7 (7)	6.4 (7)	0 (0)
Psychological disorders	7.0 (28)	9.1 (14)	12.4 (12)	13.2 (12)	0 (0)	1.3 (2)	1.8 (2)	0 (0)
Metabolic diseases	3.3 (13)	5.8 (9)	3.1 (3)	3.3 (3)	0 (0)	0.7 (1)	0.9 (1)	0 (0)
Other	45.3 (181)	42.9 (66)	57.7 (56)	60.4 (55)	16.7 (1)	39.6 (59)	47.3 (52)	17.9 (7)
Not stated	5.0 (20)	n/a	0 (0)	n/a	0 (0)	13.4 (20)	n/a	51.3 (20)
Use of non-pharmaceutical therapies								
Any therapy	60.5 (242)	50.7 (78)	64.9 (63)	65.9 (60)	50.0 (3)	67.8 (101)	69.1 (76)	64.1 (25)
Physical therapy	41.3 (165)	50.6 (78)	49.5 (48)	49.5 (45)	50.0 (3)	20.1 (39)	23.6 (26)	33.3 (13)
Acupuncture/Chinese Medicine	4.5 (18)	9.1 (14)	4.1 (4)	4.4 (4)	0 (0)	0 (0)	0 (0)	0 (0)
Chiropractic/manual therapy/ osteopathy/physiotherapy	4.5 (18)	7.8 (12)	6.2 (6)	6.6 (6)	0 (0)	0 (0)	0 (0)	0 (0)
Occupational therapy/logopedics	2.8 (11)	n/a	1.0 (1)	n/a	16.7 (1)	6.7 (10)	n/a	25.6 (10)
Other	35.8 (143)	20.8 (32)	34.0 (33)	35.2 (32)	16.7 (1)	52.3 (78)	57.3 (63)	38.5 (15)

Percent of valid answers of the respective group. Multiple answers allowed.

for >10 years, 82% (vs. 22%) lived with a partner. More than two-thirds (68%) were healthy. The survey asked for prescribed drugs only. Private health insurance in Germany can cover all CAM expenditures, whereas statutory insurance does not, and a large number of our respondents were covered by statutory insurance. Therefore the differences in CAM use in the Büssing et al. study [2] to our results ought to be interpreted with great caution: More of the older adults they surveyed had used acupuncture/Chinese medicine (21% vs. 5%), homeopathy (21% vs. 8%), osteopathy/physiotherapy (12% and 19% vs. 5%), and fewer used phytotherapy (7% vs. 33%).

Another German survey of the general population included persons aged 18 to 79 years [4]. It allows a rough comparison of this age group with the CAM use of the general population, although the different survey methods prohibit detailed conclusions. We found a lower percentage of participants using homeopathy (8% vs. 17% in the last 12 months), acupuncture/Chinese medicine (4.5% vs. 6% in the last 12 months), or chiropractic/osteopathy (4.5% vs. 6% in the last 12 months). The motivation to use of natural/herbal medicines and homeopathy was much lower than in the general population. On their own initiative, 27% used any CAM, as opposed to 55% (CAM preparations excluding homeopathy) and 47% (homeopathy) in our study.

A general German population survey by the Allensbach Institute [7] also found that the risk of side effects of CAM was regarded as low.

Worldwide, only 5 studies on CAM use in residential care settings appear to have been published [15]. Their results are not comparable to our study because they include either a very small population (n = 6, assisted living, Australia [16]), or are restricted to specific ailments or treatments (dementia, Australia [17]; pain, UK [18]; T'ai chi, Taiwan [19]; TCM, Hong Kong [20]). For the

Table 3 CAM preparations used most frequently by older adults without legal guardians

CAM preparation	% (n)
Homeopathy	
Schuessler Salts	3.1 (11)
Dietary supplements	
Minerals	
Magnesium	13.5 (48)
Calcium	9.0 (32)
Zinc	2.5 (9)
Iron	2.0 (7)
Single vitamins	
Vitamin C	2.3 (8)
Vitamin B	1.4 (5)
Vitamin D	0.8 (3)
Combination (mineral/vitamin/other)	4.5 (16)
Herbs	
Without specific indication	
Chamomile (Matricaria recutita) tea	6.5 (23)
Unspecified "herbal" tea	5.1 (18)
Fennel, anise, caraway (Foeniculum vulgare, Pimpinella anisum, Carum carvi) tea	4.8 (17)
Peppermint (Mentha piperita) tea	3.7 (13)
Medicinal formulation	
Bronchial tea	2.8 (10)
Kidney-Bladder tea	2.5 (9)
Gastrointestinal tea	2.3 (8)
Ginkgo (Ginkgo biloba)	3.9 (14)
Valerian (Valeriana officinalis)	2.8 (10)
St. John's wort (Hypericum perforatum)	1.4 (5)
External applications	
Ointments	
Arnica (Arnica montana)	5.6 (20)
Calendula (Calendula officinalis)	3.1 (11)
Mountain pine (Pinus Montana) foot cream/balm/footbath	3.1 (11)
Rubbing alcohol	3.1 (11)
Juices	
Unspecified "vegetable" juice	0.6 (2)
Grapefruit (Citrus paradisi) juice	0.3 (1)

CAM (as defined in this study, see text) preparations that were most frequently used in the respective category. Percent of 355 older adults without legal guardian. Multiple answers possible; 751 answers in total.

other settings investigated in our study, we were able to identify 5 studies that were all conducted in the USA, where spiritual practices, mind-body techniques, and the use of megavitamins (uncommon in Germany) are subsumed under CAM, which limits comparability.

A cross-sectional survey by Cherniack et al. [14] with 421 interviewees found a 12 month CAM use prevalence of 58%. Female gender, higher education, and thyroid disease or arthritis correlated with CAM use. The cross-sectional questionnaire survey by Cheung et al. [21] among 1200 randomly selected metropolitan adults aged ≥65 years recorded 63% CAM users. In our study, use was lower for nutritional supplements (36% vs. 44% and 28% megavitamins) and chiropractic (5% vs. 18%), but higher for herbal medicine (33% vs. 21%). Although 80% of the Cheung et al. participants were satisfied with CAM, only 53% (vs. 59%) informed their physicians of the use.

Another cross-sectional analysis by Cohen et al. [22] from a geriatrics outpatient department found that 64% of the participants reported the use of dietary supplements or herbs, but use was documented for only 35%. Another Australian study investigated the use of complementary and alternative medicines in a group of older rural Australian attending a multi-disciplinary health screening clinic. Three-quarters (78%) of respondents had used at least one CAM product within the past 12 months and 66% had visited a CAM practitioner. Almost half (46%) had not discussed their use of CAM with their doctor and only 15% had discussed their CAM use with a pharmacist [23]. The Ginkgo Evaluation of Memory (GEM) study [24] also recorded the use of CAM drugs and dietary supplements, but its exclusion criteria prohibit detailed comparisons. Its participants predominantly used dietary supplements, whereas our population used these and herbal preparations (mostly teas) in equal proportion.

A randomized subsample (n = 1099) of the 2000 wave of the Health and Retirement Study [25] answered questions about their CAM use. The evaluation included subgroups in the age ranges of 65–79 (43%) and 80 years or older (14%). The use of CAM was more frequent than in our study (87% of the first group, 92% of the latter, vs. 61%), but included lifetime prevalence for chiropractic and alternative practitioner consultations. Non-herbal dietary supplements were much more frequently used than in our study (60%, 70% vs. 36%), most often multivitamins (48%, 51%, not seen in our study), vitamin A (12%, 9%, ditto), vitamin C (30%, 35% vs. 2%), vitamin D (15%, 13% vs. 1%), vitamin E (35%, 39%, not seen in our study), calcium (31%, 38% vs. 9%). Magnesium was an exception (13%, 12% vs. 14%). Herbal therapies (21%, 8%) and supplements (20%, 18%) were less commonly used (33% of our participants). Higher age correlated with the use of dietary supplements, higher education with the use of dietary and herbal supplements.

In our study we found none of the predictors for, or correlations with, the use of CAM preparations or therapies that had been seen in some of the more or less differing populations cited above [25], but we observed a general similarity that raises concerns about drug safety. More than half of our study participants stated that they could neither assess whether their CAM preparations would have side

Table 4 Considerations, decision, and information about CAM use

	Total	Self-reliant	Home care service users			Nursing home residents		
			Total	Without legal guardian	With legal guardian	Total	Without legal guardian	With legal guardian
	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)
Participants' assessment of side effects of CAM preparations								
Cannot assess	57.9 (187)	54.2 (71)	48.2 (40)	48.2 (40)	n/a	69.7 (76)	69.7 (76)	n/a
No harm	23.5 (76)	15.3 (20)	36.1 (30)	36.1 (30)	n/a	23.9 (26)	23.9 (26)	n/a
Mild side effects	13.6 (44)	24.4 (32)	10.8 (9)	10.8 (9)	n/a	2.8 (3)	2.8 (3)	n/a
Harmful in combination with other drugs	5.0 (16)	6.1 (8)	4.8 (4)	4.8 (4)	n/a	3.7 (4)	3.7 (4)	n/a
General treatment preference								
CAM and conventional medicine	64.9 (209)	73.9 (96)	59.3 (51)	59.3 (51)	n/a	58.5 (62)	58.5 (62)	n/a
Only conventional medicine	18.9 (61)	19.2 (25)	15.1 (13)	15.1 (13)	n/a	21.7 (23)	21.7 (23)	n/a
Only CAM	16.2 (52)	6.9 (9)	25.6 (22)	25.6 (22)	n/a	19.8 (21)	19.8 (21)	n/a
CAM preparation use is based on								
Recommendation - total	31.3 (125)	30.5 (47)	43.3 (42)	46.2 (42)	0 (0)	24.2 (36)	32.7 (36)	0 (0)
- by pharmacist	10.4 (36)	9.3 (14)	n/a	12.4 (36)	n/a	n/a	10.4 (11)	n/a
- by friends and family	20.0 (69)	14.7 (22)	n/a	25.8 (23)	n/a	n/a	22.6 (24)	n/a
Own initiative	27.3 (109)	26.6 (41)	44.3 (43)	45.1 (41)	33.3 (2)	16.8 (25)	22.7 (25)	0 (0)
Prescription	25.8 (103)	20.1 (31)	25.8 (25)	27.5 (25)	0 (0)	47 (31.5)	19.1 (21)	66.7 (26)
GP information about CAM preparation use								
Participant informed GP[a]	58.7 (138)	62.3 (48)	49.3 (34)	48.5 (33)	50.0 (1)	62.9 (56)	45.9 (28)	100.0 (28)
GP inquired about use	16.6 (53)	21.1 (27)	19.5 (16)	19.5 (16)	n/a[b]	9.2 (10)	9.2 (10)	n/a[b]

Percent of valid answers of respondents, [a]Percent of 245 users. [b]Prescription mandatory for all medicines including CAM. For definition of 'CAM' in this study see text.

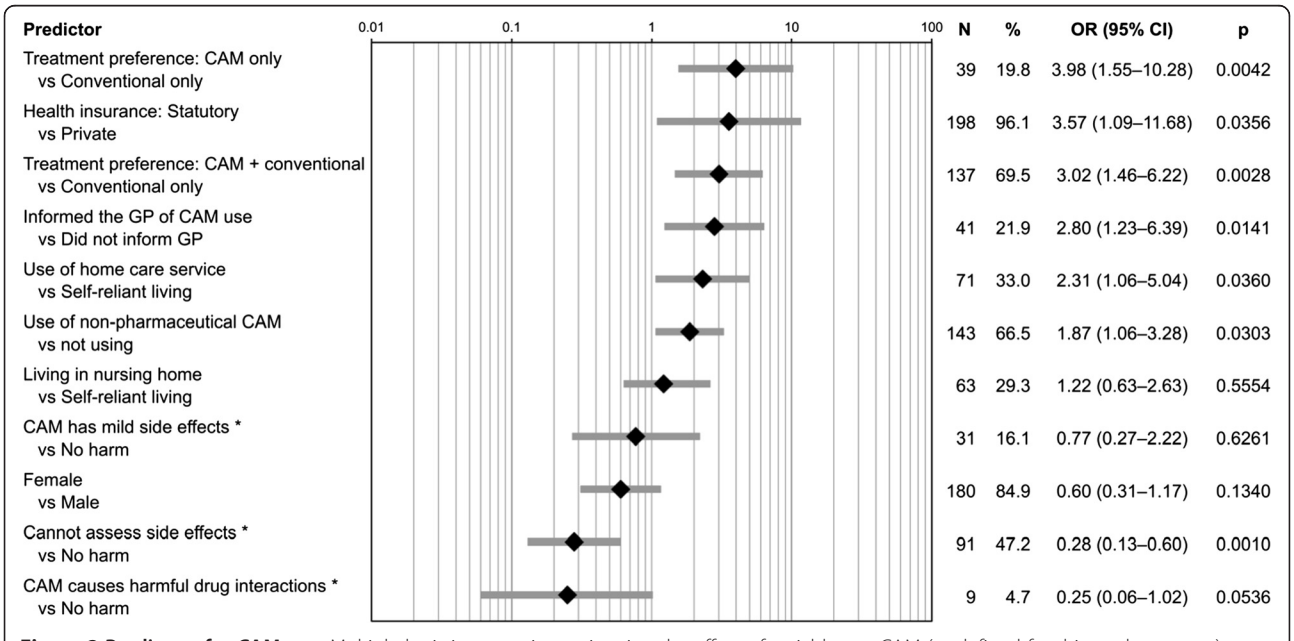

Figure 2 Predictors for CAM use. Multiple logistic regression estimating the effect of variables on CAM (as defined for this study, see text) use. Results for participants without a legal guardian, * = participants' assessment. Predictor model selected on the basis of p-values and frequencies as well as an expert's opinion. Log scale; OR = odds ratio; CI = confidence interval.

effects, nor assess what side effects might arise. Only 5.0% were aware of possibly harmful drug interactions. In many of those cases the primary care physicians were also insufficiently informed about the use of CAM preparations [21]. If they are not aware of this "substantial concomitant use of prescription drugs and dietary supplements" [24], harmful interactions of drugs with herbs or supplements cannot be prevented. Conversely, physicians who prescribe CAM treatments may meet the needs of older adults. This can be seen as a typical problem for health systems where CAM medications or CAM therapies are not included in the statutory health insurance system and thus their use cannot be sufficiently monitored. One way to increase the safety of CAM drug use in Germany would be to reimburse the expenses for CAM medication by the statutory health insurance system, as it was common in Germany until 2002. GPs would again be able to inform patients and also control CAM medication at least to a certain degree, which could help to minimize the risk of potential side effects or drug interactions.

Conclusion

In this first study that included participants in living situations involving various degrees of independence we found a high rate of users of CAM preparations and dietary supplements among German older adults. Self-reliant older adults primarily use dietary supplements, herbal medicines and external preparations. For the most part they follow recommendations by pharmacists, friends or relatives or make their own decisions, whereas older adults with legal guardians or a high need for care take prescribed vitamins and minerals. General practitioners were insufficiently informed about CAM usage. Older adults perceived CAM as an effective complement to conventional medicine, but were not sufficiently informed about risks.

Competing interests

The authors declare that there are no conflicting interests regarding the publication of this article. This study was funded by the Karl and Veronica Carstens Foundation (Essen, Germany).

Authors' contributions

KS participated in study concept and design, data collection, statistical analysis, data interpretation, and manuscript drafting. SB did the statistical analysis and participated in data interpretation and manuscript drafting. MT participated in study concept and design, data interpretation, and manuscript drafting. CMW participated in study concept and design, data interpretation, and manuscript drafting. All authors read and approved the final manuscript.

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RESEARCH ARTICLE Open Access

Complementary medicine in nursing homes - results of a mixed methods pilot study

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Abstract

Background: 'Kneipp Therapy' (KT) is a form of Complementary and Alternative Medicine (CAM) that includes a combination of hydrotherapy, herbal medicine, mind-body medicine, physical activities, and healthy eating. Since 2007, some nursing homes for older adults in Germany began to integrate CAM in the form of KT in care. The study investigated how KT is used in daily routine care and explored the health status of residents and caregivers involved in KT.

Methods: We performed a cross-sectional pilot study with a mixed methods approach that collected both quantitative and qualitative data in four German nursing homes in 2011. Assessments in the quantitative component included the Quality of Life in Dementia (QUALIDEM), the Short Form 12 Health Survey (SF-12), the Barthel-Index for residents and the Work Ability Index (WAI) and SF-12 for caregivers. The qualitative component addressed the residents' and caregivers' subjectively experienced changes after integration of KT. It was conceptualized as an ethnographic rapid appraisal by conducting participant observation and semi-structured interviews in two of the four nursing homes.

Results: The quantitative component included 64 residents (53 female, 83.2 ± 8.1 years (mean and SD)) and 29 caregivers (all female, 42.0 ± 11.7 years). Residents were multimorbid (8 ± 3 diagnoses), and activities of daily living were restricted (Barthel-Index 60.6 ± 24.4). The caregivers' results indicated good work ability (WAI 37.4 ± 5.1), health related quality of life was superior to the German sample (SF-12 physical CSS 49.2 ± 8.0; mental CSS 54.1 ± 6.6). Among both caregivers and residents, 89% considered KT to be positive for well-being.
The qualitative analysis showed that caregivers perceived emotional and functional benefits from more content and calmer residents, a larger variety in basic care practices, and a more self-determined scope of action. Residents reported gains in attention and caring, and recognition of their lay knowledge.

Conclusion: Residents showed typical characteristics of nursing home inhabitants. Caregivers demonstrated good work ability. Both reported to have benefits from KT. The results provide a good basis for future projects, e.g. controlled studies to evaluate the effects of CAM in nursing homes.

Keywords: Hydrotherapy, Kneipp, Complementary and alternative medicine, Elderly care, Nursing homes, Mixed methods research

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Background

Current demographic changes in ageing societies are a major challenge for health care systems as well as for the social communities in all industrialised countries. An increasing number of care-dependent disabled older adults demands new concepts in preventive medicine, long-term treatment, and hospital care [1,2]. In 2011, about 2.5 million individuals in Germany were care-dependent, and approximately 30% of them lived in nursing homes [3]. Chronic cardiovascular, musculoskeletal and metabolic diseases are common. Dementia is one of the most commonly diagnosed diseases in care-dependent older adults living in nursing homes: nearly two thirds suffer from it [4]. Therefore, a focus on prevention and maintenance of functioning levels is urgently needed to maintain quality of life (QoL) and to reduce morbidity in the elderly population. Experts in the field of Complementary and Alternative Medicine (CAM) suggest that CAM might offer preventive potential for senior citizens [5].

In 2007, some nursing homes for the elderly in Germany started to integrate CAM in the form of Kneipp Therapy (KT) in the daily basic care of their clients. KT is a form of prevention and treatment in the field of CAM and represents an important part of traditional European medicine, especially in the German-speaking parts of Europe. CAM KT methods are well known in the German population [6]. They can be traced back to the European medicine traditions and were formulated mainly by Sebastian Kneipp, a Catholic priest and a non-professional medical practitioner living in the 19th century. He developed a large range of self-help and therapeutic strategies including hydrotherapeutic interventions, herbal medicine, mind-body medicine, physical activity, and healthy nutrition [7]. In Germany, the approximately 160,000 member Kneipp Association keeps this CAM tradition alive and provides professional education in KT.

'Kneipp nursing homes' implement those interventions in daily care and are mostly differentiated from conventional nursing homes through offers referring to hydrotherapy and herbs. For minor ailments, often simple herbal teas or aromatherapy are offered by the nursing staff. Many 'Kneipp nursing homes' maintain herb beds and organic vegetable gardens. In the field of hydrotherapy, various applications are offered by trained personnel such as wraps, layers, foot or arm baths, treading water and dry brush. Nutrition in Kneipp nursing homes relies on healthy, fresh, seasonal, whole food with a high proportion of fruits and vegetables. Elements of mind-body medicine range from relaxation to creative therapy offers. Physical activity is offered in groups (e.g. gymnastics class, garden walks) or as individualized physiotherapy or occupational therapy. The idea of KT is mostly to regulate or stimulate body and mind functioning via frequent mild stimuli, e.g. from hydrotherapy or physical activity but also from mind-body elements. The intention is to improve physical functions and quality of life, taking into account the well-being of the individual.

To achieve certification as a 'Kneipp nursing home', the management must provide a concept of integration of KT in daily routine care, which has to be validated by the Kneipp Association. At least three persons on the staff have to be trained in KT by the Academy of the Kneipp Association. Kneipp trainers are, together with the nursing home management, responsible for implementing KT in the nursing homes' daily living and care routines. To date there are 18 'Kneipp nursing homes' in Germany.

The aim of this research project was to gather information about the integration of KT in daily routine care in four Kneipp nursing homes, and to report on the health status of the residents and caregivers who received respectively applied KT. In addition, after the implementation of KT, changes subjectively experienced by residents and caregivers were investigated in the qualitative research component.

One underlying aim of this study was to use the findings as a basis to generate adequate research questions, identify feasible and relevant assessment tools, and gather experience in terms of feasibility for conducting a further study on the effects of KT.

Study design

This research project was performed as a cross-sectional, mixed methods study including a quantitative (part 1) and a qualitative (part 2) component in a convergent parallel design [8]. It was conducted between September and December 2011 in four certified Kneipp nursing homes in two German states (Bavaria (n = 2) and North Rhine-Westphalia (n = 2)). The study was performed in accordance with the Declaration of Helsinki and was approved by the ethics commission at the Charité - Universitätsmedizin Berlin (EA1/147/11; 22th June of 2011). Trial registration: DRKS00006800 (25th September of 2014).

Methods - part 1: quantitative component

Nursing homes

At the time this study began, there were four certified Kneipp nursing homes in Germany. All of them could be recruited for our study. Nursing home A was located in a rural area in Bavaria, and had at the time of study entry 136 residents and 117 employees. Nursing home B was located in North Rhine-Westphalia in the center of a city and had 74 residents and 87 employees. Nursing home C was located in a small town. At the time of the study it had 63 residents; 70 persons were employed.

Nursing home D was located in a rural area of Bavaria and had 44 seniors and 35 employees. Every nursing home provided outside and inside facilities for Kneipp hydrotherapy, medicinal herb beds, space for exercise and relaxation therapy, and in-house kitchens for meal preparation for the residents. KT was offered regularly by parts of the caregiver teams or therapists.

With the help of the respective Directors of Nursing, we conducted a pre-screening of the residents on the basis of the main in- and exclusion criteria. On the basis of this screening, we were able to contact legal guardians for residents under guardianship and inform them about our study before we initiated interviews. Caregivers and residents (and, if necessary, legal guardians) were informed verbally as well as in written form about the study content. Caregivers and residents who provided written informed consent and fulfilled inclusion criteria were included in the study. Assessments for residents were performed by specially trained and experienced study personnel. Caregivers received questionnaires by letter. All assessments and questionnaires were documented in case report forms for each study participant.

Study population

Inclusion criteria for residents were an age of at least 60 years, the ability to answer questions adequately, written and oral informed consent (for those under legal guardianship, guardians had to provide consent) and regular (daily or weekly) individualised KT for at least 3 months. Inclusion criteria for caregivers were an age of at least 18 years, regular and routine delivery of KT in the nursing home for at least 3 months, and at least 3 years general professional experience.

Assessments

The activities of daily living (ADLs) were measured with the Barthel-Index. This questionnaire is a recommended assessment and often used in healthcare to refer to daily self-care activities as a measurement of the functional status of a person [9]. ADLs include feeding oneself, bathing, dressing, grooming and the ability to move; the Barthel Index scores ADLs on a scale from 0 to 100 (0 = very dependent, 100 = not dependent) [10,11]. The Quality of Life in Dementia (QUALIDEM) is a dementia-specific QoL instrument, which was developed for use in residential care. We used the version for people with mild to severe dementia which consists of 37 items, divided in 9 subscales regarding care relationship, restless tense behavior, positive affect, negative affect, positive self-image, social relations, having something to do, feeling at home, and social isolation. It is rated by professional caregivers or proxies. Results can be described as points or percents of the scale for each item [12]. The Profile of Well-being is a tool that reflects the well-being of residents. Caregivers evaluate residents' well-being subjectively within 14 indicators regarding signs of positive affect, communication, creativity, activity, cooperation, humour, and self-respect [13]. The Short Form 12 Health Survey (SF-12) describes the health-related QoL including physical and mental health aspects [14-16]. To assess cognition, we performed the Mini Mental Status Examination (MMSE), which is a 30-point test measuring arithmetic, orientation, and memory functions [11,17,18]. In addition, the residents were asked about use, knowledge, meaning, preferences, and the perception of KT regarding their well-being. Demographic and further variables like care level (it defines the grade of care dependency from grade I to III), diagnoses, medication were taken from the nursing records. Predetermined questions about KT were asked of the residents in a standardized way, and the Mini Mental Status Examination was carried out face-to-face between residents and the study staff. All other assessments were external assessments and performed with the help of the respective caregivers who had to reflect on the situation of their clients to answer the questionnaires.

The following variables were assessed in caregivers: The Work Ability Index (WAI) Short Form evaluates work ability and comprises 10 questions including aspects of physical and psychological work demands, health status, and reserve capacity. The WAI yields a continuous score ranging from 7 to 49 points, where higher scores indicate better work ability. WAI scores can be categorized as excellent (44–49 points), good (37–43 points), moderate (28–36 points) or poor (7–27 points) [19-21]. To evaluate overall health-related QoL we used the SF-12 self-evaluation form [14,15,16]. In addition, caregivers were asked how long they have been familiar with KT, if they use KT for their own health issues, what kind of KT they deliver and how often, and their preference for particular forms of KT for self-treatment and for the treatment of residents. Additionally, caregivers were asked if KT is supposed to have effects or not for their own health or the health of residents, if and how KT changes the relationship between caregiver and resident, and how KT can be integrated in usual care in terms of feasibility. All caregivers received questionnaires by letter and returned them to the study secretary.

Data management and statistical analyses

Data management was conducted according to ICH-GCP guidelines. All data for residents and caregivers were analysed descriptively with R Development Core Team (Vs. R 2.14 [22]) and SAS (Vs. 9.2). Results for continuous data were reported as means and standard deviations or medians, and for nominal data as absolute or relative frequencies.

Results - part 1: quantitative component

Residents

The pre-screening on the basis of the main in- and exclusion criteria identified 133 out of 317 residents (the total of all residents of the four nursing homes) as eligible for inclusion in the study. In a second screening step we identified again 46 residents not fulfilling the inclusion criteria, 16 residents declined to participate, one died, one was at the hospital and three legal guardians could not be contacted. In the end, 66 residents were included. Two residents dropped out, thus 64 residents were considered for the analyses (Figure 1 Study participants´ flow chart). More than two thirds (83%) of the assessed residents were female with a mean age of 83.2 (SD ±8.1) years (Table 1). The number of diagnoses ranged between 3 and 14 with a mean of 8 (SD ±2.9) diagnoses per

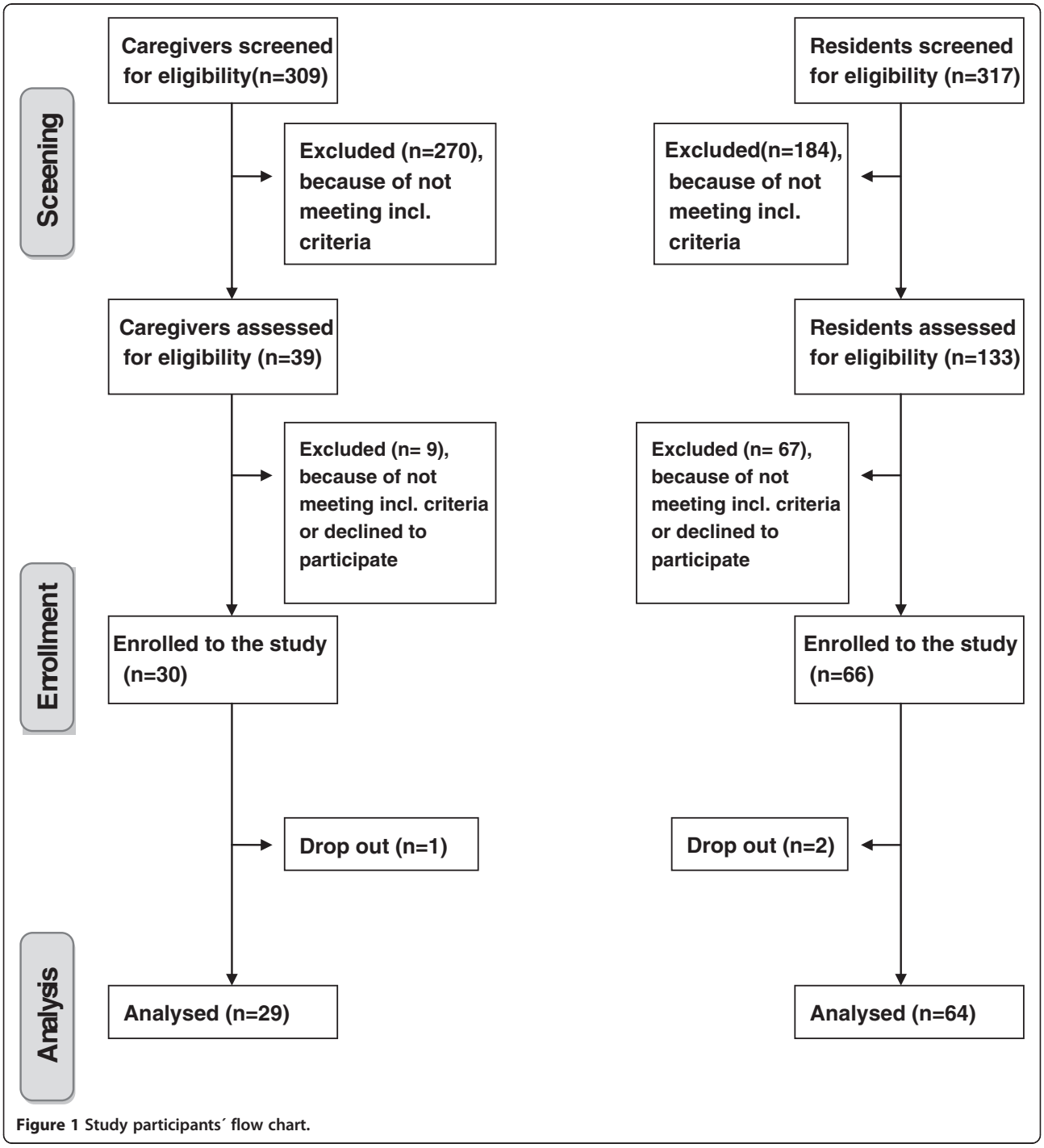

Figure 1 Study participants´ flow chart.

Table 1 Socio-demographic data of residents and caregivers (quantitative component)

	n	Gender female	Age (years)*	Height (cm)*	Weight (kg)*	BMI (kg/m^2)*
Residents	64	n = 53 (82.8%)	83.2 ± 8.1	161.9 ± 9.3	72.1 ± 16.1	27.4 ± 5.4
Caregivers	29	n = 29 (100%)	42.0 ± 11.7	166.7 ± 6.2	76.3 ± 16.6	27.3 ± 5.9

BMI = Body Mass Index, SD = Standard Deviation, n = Number, *Mean ± SD.

resident. The diagnoses documented most frequently were hypertension (56%), musculosceletal diseases (51%), metabolic diseases such as diabetes (31%), coronary heart disease (25%), dementia (42%) and depression (25%). Residents took on average 8 (SD ±3.0) different drugs daily, mainly for cardiovascular diseases (38%), gastrointestinal diseases (14%), for psychiatric disturbances (12%) and for pain (8%). Residents in our study were distributed along a care continuum (as defined by the German Social Code Book XI) ranging from 6% at no care level, 55% at care level 1, 33% at care level 2, and 6% at care level 3.

The mean of the Barthel Index was 60.8 points (SD ±24.4) (13% had a Barthel Index between 0 and 30 (severe disability), 64% between 35 and 80 (moderate disability), and 23% more than 85 points (nearly no disability). The cognition test (the MMSE) resulted in an average of 22.3 points (SD ±6.3) (29% between 0 and 18 points (severe to moderate cognitive impairment), 29% between 19 and 24 (mild cognitive impairment) and 42% more than 25 points (no cognitive impairment). The results of the SF-12 showed an average of 43.2 (SD ±8.1) for the physical component summary scale and 56.9 (SD ±8.2) for the mental component summary scale.

Table 2 Outcome parameter of residents (quantitative component)

	n	Mean (±SD)	Scale range (points)
Barthel-Index	64	60.8 ± 24.4	0-100
MMSE	52	22.3 ± 6.3	0-30
QUALIDEM			
Nursing relationship	64	18.5 ± 3.5 (88%)	0 - 21
Positive affect	64	15.9 ± 3.0 (88%)	0 - 18
Negative affect*	64	7.2 ± 1.7 (80%)	0 - 9
Restless, tense behaviour*	64	5.3 ± 1.4 (58%)	0 - 9
Positive self-perception	64	7.1 ± 2.3 (78%)	0 - 9
Social relationships	64	14.1 ± 3.8 (78%)	0 -18
Social isolation*	64	8.0 ± 1.6 (89%)	0 - 9
Feeling familiar	64	11.0 ± 2.2 (91%)	0 - 12
Having something to do	64	3.4 ± 2.0 (56%)	0 - 6
Profile of Well-being	64	25.2 ± 3.1	0-28
SF-12 Physical Comp. Sum. Scale	64	43.2 ± 8.1	0-100
SF-12 Mental Comp. Sum. Scale	64	56.9 ± 8.2	0-100

MMSE = Mini Mental Status Examination, SF = Short Form, SD = Standard Deviation, n = Number.
*higher rating means less marked.

The highest ratings on the QUALIDEM subscales were gathered for 'feeling familiar' (91%), 'social isolation' (89%) and 'positive affect' (88%) (high ratings for 'social isolation' means less marked). The Profile of Well-being showed an average of 25.2 points (SD ±3.1) (Table 2). All residents received each of the different elements of KT once or twice a week. When asked about what they think KT consists of, residents primarily associated KT with hydrotherapy (88%), followed by herbal treatments (53%) and physical activity (45%). Among residents, 43% were aware of KT since adulthood; 26% KT since childhood; 23% since their move into the Kneipp nursing home, 8% could not answer the question. Among residents, 71% preferred hydrotherapy as their primary KT intervention. The majority of residents (89%) perceived KT as positive for well-being.

Caregivers

The pre-screening identified 39 caregivers out of a group of 309 staff members (drawn from all professional fields in the nursing home) as eligible for study participation because they regularly applied KT to residents (Figure 1). Nine caregivers could not be included because they were not available (n = 4) at the time of evaluation, refused study participation (n = 2), or did not respond (n = 3). Thirty caregivers were included in the study, but one did not return the assessment forms. In the end, the data provided by 29 caregivers was analysed. All caregivers were female and on average, 42 years old (SD ±11.7) (Table 1). Caregivers had worked an average of 10 years in their professions, 55% full-time, 41% part-time, and two-thirds worked as shift workers.

The Work Ability Index of the caregivers showed an average of 37.4 (SD ± 5.1) points, reflecting a 'good' work ability. The SF-12 of the caregivers showed an average of 49.2 (SD ± 8.0) for the physical component summary scale and 54.1 (SD ± 6.6) for the mental component summary scale (Table 3). When starting their work in the Kneipp nursing home, 48% of the caregivers first came into contact

Table 3 Outcome parameters of caregivers (quantitative component)

	n	Mean (± SD)	Scale range
SF-12 Physical Comp. Sum. Scale	28	49.2 ± 8.0	0-100
SF-12 Mental Comp. Sum. Scale	28	54.1 ± 6.6	0-100
Work Ability Index	23	37.4 ± 5.1	7-49

SD = Standard Deviation, n = Number.

with KT; 93% used KT for themselves, mainly in the of hydrotherapy or physical activity. Among caregivers, 96% reported subjective positive effects of KT on their well-being and health. Caregivers preferred hydrotherapy (65%) and mind-body methods (44%) for resident care (multiple answers could be given). The majority of the caregivers (90%) stated that their relationship to the residents had improved since implementing KT. About 47% stated an improved relationship to the caregiver team as a result of KT and 42% stated that KT could be easily integrated into their daily work.

Methods - part 2: qualitative component

The qualitative study component aimed at describing everyday KT practice in nursing homes and residents' and caregivers' subjectively perceived changes following the implementation of KT. We approached this aim by doing a rapid appraisal based on ethnographic fieldwork techniques (including participant observation and semi-structured interviews) in two of the above-mentioned nursing homes. Both nursing homes were similar in size, resident population and organizational structure, one located in a small town (nursing home C) and one in a rural area (nursing home D). During a one-week observation period in each of the two nursing homes, residents and caregivers were accompanied by an ethnographically trained researcher (ESA, a social anthropologist experienced in researching health and care organizations but not in CAM or KT) who observed them in their daily KT activities from early morning to the evening. During this one-week observation period, semi-structured interviews focusing on subjective experiences of change were conducted with selected residents and caregivers, as well as with KT trainers, heads of nursing and directors of the two nursing homes. Participants were selected by theoretical sampling among those caregivers and residents being present during the one-week field stay. In addition, directors, heads of nursing and the KT trainers responsible for KT implementation were systematically included. In total, 26 interviews were conducted. Participant observation and interviewing focused on pre-defined aspects of subjective perspectives (Table 4), which were transformed into practice-oriented open questions and collected in a field manual. The questions were mainly directed at generating narrative accounts on experiences with KT. Analysis of the interview transcripts and field notes were adapted to the explorative character of the study design and loosely followed the principles of Grounded Theory (open, axial and selective coding by the researcher who did the fieldwork) [23,24].

Results - part 2: qualitative component

Both nursing homes included in the qualitative component of this study showed an integral implementation of KT principles, including individual care, group therapies, social activities, nutrition, and a specific arrangement of spaces allowing for spontaneous Kneipp activities. Implementing KT in this kind of holistic approach is in accordance with the certification requirements of the German Kneipp Association, which, as the directors and heads of nursing stated, is associated with an intense reflection on how the nursing home organizes care and daily activities and with what aims (see Table 5, second box on 'conceptual focus'). KT is integrated into daily activities directed at all residents, such as healthy menu planning, collective meals, social gatherings, moderate physical activities (e.g., going for a walk in fresh air, group activities), and also offered as individual treatment. Kneipp activities and treatments are thus in one or another form available to every resident – and, to a certain extent, also to the caregivers – in the nursing home. Residents and staff most commonly associated KT with individually applied forms of hydrotherapy such as washing, baths, gushes, and massages.

The qualitative component identified two different types of KT implementation showing effects on how KT is perceived (Table 5): Type 1 is characterized by a specialized implementation: The nursing home employs a KT trainer, who is responsible for applying KT in addition to the conventional care activities of caregivers. In this implementation type, treatments are perceived by the residents as an exceptional care activity, applied with the intention to foster their individual well-being. This leads to a resident's perception of KT as a personal gift (i.e. a transaction focusing on long-term reciprocity [25]) and thereby

Table 4 Aspects of subjective perspectives of residents and caregivers (qualitative component)

Residents	Caregivers
• Experience of care and naturopathic applications	• Experience of care and naturopathic applications
• Therapeutic relationship	• Relationship with residents
• Health complaints	• Professional self-concept
• Illness experience	• Illness perceptions and concepts
• Illness perceptions and concepts	• Working conditions, job satisfaction
• Self-efficacy, control of reinforcement, sense of coherence	• Stress
• Perspectives on the future	• Identification with the employing organization
	• Motivation
	• Quality of care, caring competencies
	• Co-operation within the caring team
	• Self-experiences with naturopathy

Note: These items were pre-defined and informed a set of practice-oriented open questions collected in a field manual. Questions were situationally adapted to meet the interviewee (be it nursing home directors, heads of nursing, nurses, nurses' aides or residents).

Table 5 Systematic overview of interpretive categories re implementation (qualitative component)

Nursing home C	Nursing home D
Type, specialized implementation'	**Type, integrative implementation'**
Individual KT treatments conducted by a KT trainer (→ specialized knowledge)	individual KT treatments conducted by all nurses and nurses' aides (→ generalized knowledge)
Conceptual focus on attentive dimensions:	**Conceptual focus on physical-sensual dimensions:**
'I think that Kneipp is a conception sensitizing us for things we already do in elder care. To let us have a closer look on how we do things in care and what effect we want to achieve. For example the right nutrition, or being there for someone. Yes, it's a holistic view on care. Everyone is talking about holistic care, but this is a hazy expression, what can you do with it? And I think that the Kneipp concept is describing what holism is.' (head of nursing)	*'I do think that Kneipp is giving the whole thing a name, or a roof. A bit of orientation, so that the staff knows what is important to us, and the residents know it as well, their relatives, everyone knows that we have a slightly different way of working here, another kind of consciousness about care.' (director)*
'I think what makes a difference is that care is done in a conscious manner. There are a lot of things one already does in care, but it is not done consciously, although it is at the same time a Kneipp treatment. It's about the attention given in that moment, by the nurses. For example at lunch, when they feed someone, if you do it with ease, take a chair and sit next to the resident instead of standing and pushing the spoon in – this would also be a treatment in the Kneipp way, feeding with consciousness and ease and giving attention through it.' (KT trainer)	*'Maybe it works so well because it's so normal. I mean, I could just as well work with any kind of sound therapy or scents or whatever, but that's rather special. Kneipp, instead, is down-to-earth, I do not have to explain it to the residents, they know it and they understand it.' (director)*
'Well, it is simply part of our profession that we work here under a high tension, that we do not always have the inner calmness necessary to transfer our attention to the resident. For example, if we do not feel comfortable and calm ourselves, we could do Kneipp ten times and it would not reach the residents. No, it would only become hectic and have no effect for the resident.' (a nurse)	*'Simply as far as skin care is concerned, or decubitus prophylaxis, Kneipp treatments are just the optimal thing. Washing with cold water and brushing the skin is but perfect, better than all those ridiculously expensive skin products we used in other nursing homes to enhance the blood circulation of the skin, we do not need those things here! We do very simple things that don't cost anything.' (head of nursing)*
	'I think that Kneipp makes a difference about care because we have slightly more time for the residents. For example when we brush the skin, you need to take your time to brush every part of the hand or the arm, and with the washrag you always to it tatata and done. If you use the brush, it's a little more time you give. And, after all, it's not the same thing every day! One day you brush, one day you wash with cold water, one day you prepare a bath. And we would all get fed up with having to eat spinach and eggs every day, don't we? And it's the same with basic care.' (a nurse)
Holism: the entire organization is 'doing Kneipp'	
Explanation of symbolic order: director, head of nursing and KT trainer	explanation of symbolic order: director and head of nursing
Keepers of specialized knowledge: KT trainer and a few nurses/nurses' aides externally trained in KT	keeper of specialized knowledge: head of nursing (who is a trained KT trainer)
Knowledge transfer: voluntary internal schooling by KT trainer	knowledge transfer: compulsory element of job introduction for nurses and nurses' aides
Application of KT treatments: KT trainer (according to trainer's treatment plan)	application of KT treatments: care staff (according to residents' treatment plans)
Additional KT activities: care staff (voluntary, within daily basic care activities); attendants (individual attendance in daily activities); therapists and social workers (their activities are integrated into the KT concept); kitchen crew (cooking healthy menus)	additional KT activities: nurses' aides, attendants and volunteers (group activities and individual attendance in daily activities); therapists (their activities are integrated into the KT concept)
Personalized application, complex treatments	**Pragmatic application, simple treatments**
KT treatments are done by the KT trainer, in a manner that stresses individual attention (giving time, serving the individual needs of the resident)	Head of nursing instructs the staff how to apply KT
Therapist applies complex, time-consuming treatments, which are popular among the residents (hot/cold baths, massages, hot rolls etc.)	Each staff member applies KT according to pragmatic instructions
Nurses and nurses' aides are invited to apply KT as well, but do it seldom because they do not feel in a position to give the same amount of time and individual attention as the KT trainer does	Treatments are chosen that integrate well into the daily tasks and routines of care (washings, gushes, brushing, simple baths etc.)
A few nurses and nurses' aides punctually apply single elements in basic care (e.g. brush massages) and in treatment of indispositions (e.g. herbal teas, poultices)	Residents get a fixed treatment plan compulsory for staff

Table 5 Systematic overview of interpretive categories re implementation (qualitative component) *(Continued)*

Application of KT in the mode of a gift	**Application of KT in the mode of a standard service**
No time pressure: KT treatments can be done in a careful, individually adapted manner and therefore stress the attentive aspects. Only the KT trainer does treatments; frequency and regularity is hard to achieve.	KT treatments are done regularly, several times a week. This requests planning, offers liability for residents, and obliges staff to apply KT.
Treatments have an enchanted character; they are individual gifts of absolute attention.	Treatments have a pragmatic, everyday character; they are part of the standard services.
Treatments focus on well-being and indulging.	Focus on simplicity (cold washes, gushes) and regularity also leads to observable physiological effects; therefore, residents and staff tend to be convinced about positive long-term effects on health.
Treatments and the person of the therapist are very popular among residents.	'Cold' treatments are regarded as unpopular among residents, which leads some team members to replace unpopular treatments by more appreciated ones (such as the brush massages); this brings in the gift dimension (cf. organization C).
Nurses and nurses' aides acknowledge that 'doing Kneipp' is 'something beautiful' they do not have the possibilities to do in their daily care work.	
Residents' agency: non-negotiable, gratitude	**Residents' agency: negotiable, a right**
Residents may co-determine KT within the concrete interactions during a treatment since treatments focus on situational needs of the residents.	Residents have a therapy plan in their rooms and know what treatments they are supposed to get. Treatments are therefore part of standard services the residents have a right to.
Treatments are closely tied to the person of the therapist and tend to be experienced as personal and comprehensive 'caring about'.	Residents may claim treatments on the basis of this plan, they may also negotiate situational changes in treatments (e.g. receiving a brush massage instead of a cold washing). They may, however, not influence who does the treatment (i.e. KT is not person-bound).
Residents have no explicit claim to receive treatments; they are perceived as occasional gifts, not regular services.	The power to define KT lies with the head of nursing (who puts up the treatment plan); the power to apply KT lies with the staff, but is negotiable for the residents.
The power to define and to apply KT treatments is not perceived to be available to residents.	
Outcome for the residents: gain in attention and well-being	
'Sometimes they treat you here as if you were a piece of wood. And Ms. X (the KT trainer) is always very kind. One day she makes me a hot roll, another day a hot-cold foot bath. And I somehow feel better afterwards.' (a resident	*'When I came here and saw those pictures of Mr. Kneipp hanging everywhere – we had them at home as well when I was a child! Yes, Kneipp was always present at our home, and certainly this helped me get so old. Just today I had one of those cold washings – freezing it was, I thought I am not going to survive it! But now I feel so well, so warm.' (a resident)*
'It always feels good. It's good if you get an opportunity to relax, one feels less stiff, I can move better, blood circulation is better, this does a lot. And I like Ms. X (the KT trainer), her entire personality is good.' (a resident)	*'Well, the dry brushing, this is great, really. It releases, and it wonderfully stimulates blood circulation, and it feels very well. I am always looking forward to this!' (a resident)*
	'Yes, one is grateful for that, if it itches at your back, if someone washes or brushes you there. And one can have such nice talks with the nurses while they're doing it.' (a resident)
Outcomes for the organization: uniqueness and secondary gains from more contented residents	
Gains for organization: uniqueness, i.e. the Kneipp nursing home is a better place to reside and a better place to work; more continuity in staff; lower material costs (medication, skin care products)	
Gains for staff: emotional and functional gains from more contented residents; wider scope of action (especially nurses' aides), more variety in basic care	
Limitations: time; compulsion to 'do Kneipp'	
'Since Kneipp is so multifaceted there are so many possibilities to apply something, small but sometimes powerful. Be it with teas for example, doing small things with big effects.' (a nurses' aide)	*'I am in a position to offer something to the residents, so that they feel like: Now they're doing something special for me." (a nurses' aide)*
'Take for example a fever: before you grab the paracetamol, you can try to do a calf packing, which is not a big thing.' (a nurse)	*'Well, to be honest, a contented resident also uses his bell less often.' (a nurse)*
'And if you do some Kneipp and see how much joy they get from what you do for them, then (laughs) you want to have more of that!' (a nurse)	*'If someone is contented, if I was able to help him or her with small things, then this helps me as well. I can stay with other work, I am more contented as well, everyone is happier!' (a nurses' aide)*
'When Mrs. W. gets her depressions, for example, she does not call us when she needs to go to the toilet. And when she feels well – and Kneipp is good for her psyche – she also cooperates better in care.' (a nurse)	*'If you see reactions from residents you did not expect, it's joyful, it's nice, somehow. That's the kick in nursing the elderly, it makes you happy if you get reactions, and if you get appreciation for what you do.' (a nurse)*

promoting an exclusive relationship between the resident and the KT trainer. Type 2 is an implementation type focused on including KT in basic care, where treatments are delivered by all the caregivers. This implementation type gives rise to KT being perceived as an everyday service (i.e. a commodity) and tends to de-personalise the way KT is experienced (each person working in care is capable of delivering it, while in Type 1 the experiences associated with KT are closely related to the individual person of the KT therapist). On the other hand, type 2 empowered residents to actively request KT since it was perceived as part of the standard service to which each resident has equal access. As this brief characterization of the observed implementation types shows, there are diverse implementation possibilities for KT in nursing home care, but each has crucial consequences for the experiences of residents and caregivers and for the ways in which KT is perceived.

The two observed types of KT implementation in institutional elder care also differ in their focus either on personalised attention or physiological aspects of KT: Treatments as individual gifts tend to emphasize attention, while treatments perceived as everyday commodities allow for regular applications promising better effects on the body. However, both types of implementation have been perceived by the residents and the caregivers as fostering a substantially more attentive and more individualised culture of caring. '*We are now explicitly allowed to give attention, to sit next to the bed and hold a hand*', a nurses' aide has put it. The interviews with residents furthermore clearly showed that residents receiving individual KT treatments experienced them as unique and personal (see also Table 5). Moreover, KT is described by the residents and the caregivers as being compatible with the lay knowledge of the residents and with their perceptions of what is good for their health and well-being. The fact that the nursing home is trying to do something good to their health and well-being by using KT is therefore tangible and understandable for the residents. Some of the residents also stated that they were aware of their own possibilities "to do Kneipp" and live healthy. However, the fact that nursing home residents are of advanced age, live with a severely restricted health and must rely on care from other persons clearly restricted their sense of agency and self-determination.

Although some caregivers state that the integration of KT results in a slightly increased expenditure of time in basic care activities, others also observe time gains resulting from the less time-consuming behavior of more content and quieter residents. The directors and heads of nursing of both participating nursing homes stated that integration of KT was possible without increasing the personal or financial resources needed for care.

The analysis of the data collected in participant observation and interviews showed that the integration of KT generated benefits in three respects: for the nursing home itself, for the caregivers and the residents (see also Table 5): First, as the responsible actors (directors, heads of nursing) stated, the nursing home as an organization enjoys the benefit of leveraging KT as a marketing tool, distinguishing the Kneipp nursing home from other homes. From an organizational perspective, KT is perceived to offer the security of a frame of reference for all actors involved. Furthermore, there is the potential for more content and possibly healthier residents, as well as cost savings with regard to medication and personal care products. Besides that, the planning and conceptualization of KT integration is a highly appreciated opportunity for in-depth organizational self-reflection since KT implementation is not simply about adding treatments. Second, residents potentially experience the following benefits: As stated by both caregivers and residents, there is a clear gain in attention and contentedness for the residents, especially for those receiving regular individualized KT. Furthermore, residents experience more variety and individuality in care (e.g. when washing in the morning is done in different ways on specific days, according to an individual weekly treatment plan). Since KT uses treatment elements which are widespread in local folk medicine, residents also state a feeling of acceptance of their lay knowledge. Third, caregivers mainly report experiencing emotional and functional gains through more contented residents. Furthermore, caregivers appreciate the larger variety in caring procedures. Due to this and due to the possibilities of KT to ease discomfort in many ways, caregivers also state that they experience a widened scope of action through the integration of KT. Furthermore, KT offers a legitimization for attentive aspects of caring since giving attention is a fundamental element of good care according to KT and not a potential waste of time.

Limitations that were mentioned first include the expenditure of time by management and staff to implement KT in the organization. Second, residents referred to a restricted sense of control since they are in constant need of care. Third, as some caregivers stated, the integration of KT, due to its holistic dimensions affecting all dimensions of working in a nursing home, may also be experienced as a normative compulsion by some team members.

Discussion

To our knowledge, this is the first study that evaluated residents and caregivers in nursing homes working with KT. Considering the overall lack of caregivers in elder care in Germany and the rising demographic of aged persons the perspective of caregivers who call for a

different, multi-dimensional and more self-determined routine care is an especially promising aspect. To generate further research questions and to gain as much and as complex information as possible about residents and caregivers, in this study we combined a quantitative with a qualitative approach. This mix of methods allows eclectic insight into the research topic from a more generalizable viewpoint (quantitative) as well as from the perspective of the involved individuals (qualitative). Due to space limitations, it is not possible to report every detail of the different study components, however, publications are planned to address additional detail of the individual components.

A limitation of the quantitative component was that the inclusion criteria limited the study sample to a small group of residents and caregivers. We did not expect that only a relatively small number of the caregivers applied individualized KT. Although there were elements of KT (e.g. nutrition, group activities) applied to all residents, only some of the residents received individual KT treatments (e.g. hydrotherapy) regularly. Thus the results cannot be generalized to other caregivers and residents of the nursing homes. A further limitation is the external rating for most of the residents' assessments. Data might be biased due to varying qualifications of the raters. In addition, more recent studies show that the QoL of the raters may also influence external ratings [26].

The qualitative component of our project was focussed on an exploratory appraisal of how KT integration is experienced by residents and caregivers in two nursing homes. It might be possible that further qualitative research would reveal additional integration types with distinct effects on experiences and perceptions of residents and caregivers.

Finally, the design of this project does not allow conclusions about any effects at all of integrating KT. Indeed some of the interviewed caregivers stated potential benefits in the qualitative component of the study, which allowed us to develop new research questions and outcomes for future studies, but it is of course not possible to generalize those individual statements.

The results derived from both components of the study demonstrate that it seems possible to integrate KT in the daily routine of the nursing homes although residents were clearly restricted. Furthermore, the acceptance of KT, and especially for hydrotherapy, was high and considered to be beneficial for well-being by most of the study participants. In addition, the caregivers demonstrated a good work ability and quality of life. They appreciated KT both in applying it to the residents and using it for themselves. Favored treatments for self-care among caregivers were hydrotherapy and exercise. Among caregivers, 90% stated an improved relationship to their clients because of the changes perceived since the integration of KT.

In terms of age, gender, multi-morbidity and polypharmacy, the sample of the quantitative component was comparable to the overall German nursing home population [27,28]. Activities of Daily Living (Barthel Index) demonstrated clear restrictions [10]. Although restricted activities of daily living often have a negative impact on QoL, we found relatively good results for the QoL assessments. The QUALIDEM scores for the subscales 'feeling familiar', 'social isolation', 'care relationship', and 'positive affect' were rated high in comparison to other studies [29]. These results are consistent with the results of the qualitative component reporting subjectively perceived gains in attention and well-being for the residents.

The 'Profile of Well-being' is a rarely used multidimensional instrument for evaluating QoL by a caregiving team. Compared to residents in shared housing arrangements, well-being scores were high [30]. Also the results for health-related QoL measured by the SF-12 were on average superior to the German sample >70 years (physical component summary scale and 38.8 (SD ±10.6), mental component summary scale 52.3 (SD ± 9.2)) [14]. But it has to be stated critically that there are no comparable data for an externally evaluated SF-12, so this may also have an influence on the distinctive results for the mental sum scale. QoL might be related to several determinants such as depression, neuropsychiatric symptoms (e.g. irritability, anxiety, and aggressiveness), psychiatric drug use and restricted activities of daily living [31-33]. While the role of cognition is discussed, this may have influenced our results for QoL because the results for the MMSE reflected only moderately impaired cognition; 42% even had MMSE scores >25. Maybe the inclusion of residents who were 'able to answer questions adequately' influenced the results for the MMSE. Nearly 70% of the residents knew KT before they moved to the nursing home, which may had an influence on evaluating it to be beneficial for well-being. However, the residents interviewed in the course of the qualitative component all stated that KT was not the main reason to choose the nursing home.

The results for the 29 participating caregivers indicated on average a 'good' work ability (WAI) in the sample comparable to other German nursing homes and health care settings [34,35], while the health-related QoL represented by the SF-12 was superior to the German sample for healthy women for both the mental and physical component summary scale [14,19]. A great majority of caregivers used elements from KT for their own health and well-being, which shows the possible impact of KT for primary or secondary prevention as well as for overall health awareness.

The results of the qualitative component showed that the integration of KT in nursing homes did not simply add a therapeutic element, but tended to change the

culture of care in the nursing homes in general [36] (see also Table 5), shifting the focus from professionalism, efficiency and quality measures to a holistic perspective stressing attention, sensitivity and well-being. Integrating the Kneipp naturopathy concept in a long-term care facility seems to be associated with intense reflections on how care can become compatible with the central principles of KT. Integration therefore fosters changes, not only by adding hydrotherapeutic treatments and herbal medicine, but also in promoting moderate physical activity, healthy eating, and elements structuring the social lives and mental balance of residents. Although different types of KT implementation have been observed, having different effects on how KT is perceived, the cultures of care in Kneipp nursing homes seem to contribute to a 'holistic conception' of care that can be traced back to the early 1960s nursing theorists [37]. This also involves an explicit legitimacy of the attentive and emotional aspects of caring, such as giving time, respecting individual moods and preferences, and having fun, as well as enjoying attention and tactile care, possibly without increasing the personal or financial resources needed for care. As a recent systematic review of qualitative studies has shown, attentive caring and an explicit focus on relationship-centered approaches to care seem to be of considerable importance for residents' well-being in nursing homes [38]. Furthermore, KT relates to well-known traditional concepts of folk medicine, which were reported by both residents and caregivers to convey a sense of acceptance of the lay knowledge and the life experiences of the residents. KT seems to be a well-understood therapeutic concept working with simple and everyday means. Therefore, KT has a certain potential to foster residents' interactive health literacy and co-determination, although only within the restricted scope of action of individuals in need of care.

Although both residents and caregivers stated that KT primarily produces benefits for the residents, there are also indirect gains for the caregivers, as has been reported. Contented residents not only contribute to lighter workloads, but their well-being and the gratitude that often is expressed after a Kneipp treatment is also perceived as positive feedback and appreciation for the caring personnel. With their focus on personal attention and their legitimation for attentive aspects of care, Kneipp nursing homes practice a relationship-centered approach, which has been well established as having an important role in dealing with future challenges in long-term care [1,38-40]. In sum, the subjectively perceived changes induced by KT implementation in nursing homes point to a concept with the potential to develop new cultures of care focusing on the residents' well-being and on their health promotion – an orientation that appears to hold promise in coping with the present and future challenges in long-term care [1,38].

For further studies it might be interesting to find out if benefits, including increased care and attention paid to the residents, as well as a reduction of residents' complaints, may not only satisfy residents but also lead to higher job satisfaction among caregivers and improve the subjective conceptualization of caregivers' roles [41,42]. Therefore, the integration of CAM interventions in routine care may lead to an increasing job diversity and differentiation, thus making work in nursing homes attractive to more people [43,44]. Due to the shortage of caregivers in Germany, particularly in nursing homes for older adults, this could be advantageous.

Conclusion

The results of this study including quantitative as well as qualitative research components suggest that the integration of KT in nursing homes is accompanied by a high acceptance among the involved residents and caregivers. Caregivers demonstrated a good work ability and health related QoL. Residents suffered from a restricted health status. Both residents and caregivers reported that KT was perceived as positive on residents' well-being and on the attention they received in care. Results provide a sufficient basis for future research projects including controlled studies to evaluate the effects of KT in nursing homes.

Competing interests

The authors MO, BB, ESA, CSG, SB, JK, TW, HFF, KS, MT declare that they have no competing interests.
RS is the Executive Director of the Centre for Quality in Care.

Authors' contributions

MO coordinated and supervised the quantitative study component. ESA and CSG were our cooperating partners from the University of Bern for the qualitative study component. ESA carried out the qualitative field studies and analysed the results with support and supervision from CSG. MO and ESA mainly drafted the manuscript, supported by CSG and BB. KS carried out all geriatric assessments in the quantitative study component. TW supported KS in collecting data from study participants and nursing records. SB was responsible for the data management in the quantitative study component, supported by HFF. MT participated in the design of the study and with JK and RS, served as advisors to the study. BB developed with MO the design of the overall project as well as the quantitative study and served as the principal investigator throughout all phases of these projects. All authors read and approved the final manuscript.

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Mein Lebenslauf wird aus datenschutzrechtlichen Gründen in der elektronischen Version meiner Arbeit nicht veröffentlicht.

komplette Publikationsliste

Promotion

1. Teut M, Schnabel K, Baur R, Kerckhoff A, Reese F, Pilgram N, Berger F, Luedtke R, Witt CM. Effects and feasibility of an Integrative Medicine program for geriatric patients–a cluster-randomized pilot study. Clinical Interventions in Aging 2013;8: 953-961.

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