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Titel der publikationsbasierten Dissertation

Zurück in den Alltag: Das Bewegungsverhalten älterer Personen mit kognitiven Einschränkungen in der poststationären geriatrischen Rehabilitation zielgruppenspezifisch erfassen und verbessern

vorgelegt von
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Prof. Dr. Gerhard Huber

Meiner geliebten Mutter.

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Hinweis:

Zu Gunsten einer besseren Lesbarkeit werden in der vorliegenden Arbeit Ausdrucksformen des männlichen Geschlechts, wie „Studienteilnehmer“ oder „Patienten“ verwendet. Dennoch sei explizit darauf hingewiesen, dass dabei immer auch „Studienteilnehmerinnen“ und „Patientinnen“ gemeint sind.

Inhaltsverzeichnis

Liste der Veröffentlichungen zur publikationsbasierten Dissertation

Publikation I:

Martin Bongartz, Rainer Kiss, Phoebe Ullrich, Tobias Eckert, Jürgen Bauer, Klaus Hauer (2017). Development of a home-based training program for post-ward geriatric rehabilitation patients with cognitive impairment: study protocol of a randomized-controlled trial. *BMC Geriatrics, 17* (214). doi: 10.1186/s12877-017-0615-0

Publikation II:

Martin Bongartz, Rainer Kiss, André Lacroix, Tobias Eckert, Phoebe Ullrich, Carl-Philipp Jansen, Manuel Feißt, Sabato Mellone, Lorenzo Chiari, Clemens Becker, Klaus Hauer (2019). Validity, reliability, and feasibility of the uSense activity monitor to register physical activity and gait performance in habitual settings of geriatric patients. *Physiological Measurement, 40* (9). doi: 10.1088/1361-6579/ab42d3

Publikation III:

Phoebe Ullrich, Christian Werner, **Martin Bongartz**, Rainer Kiss, Jürgen Bauer, Klaus Hauer (2019). Validation of a Modified Life-Space Assessment in Multimorbid Older Persons with Cognitive Impairment. *Gerontologist, 59* (2), e66–e75. doi:10.1093/geront/gnx214

Publikation IV:

Bastian Abel*, **Martin Bongartz***, Tobias Eckert, Phoebe Ullrich, Rainer Beurskens, Sabato Melone, Jürgen M. Bauer, Sallie E. Lamb, Klaus Hauer. Will we do if we can? Habitual Qualitative and Quantitative Physical Activity in Multi-morbid, Older Persons with Cognitive Impairment.

Zur Publikation eingereicht bei *Sensors*.
(*Bastian Abel und Martin Bongartz teilen Erstautorenschaft)

Publikation V:

Phoebe Ullrich, Tobias Eckert, **Martin Bongartz**, Christian Werner, Rainer Kiss, Jürgen M. Bauer, Klaus Hauer (2019). Life-space mobility in older persons with cognitive impairment after discharge from geriatric rehabilitation. *Archives of Gerontology and Geriatrics, 81*, 192–200. doi: 10.1016/j.archger.2018.12.007

Publikation VI:

Tobias Eckert, **Martin Bongartz**, Phoebe Ullrich, Bastian Abel, Christian Werner, Rainer Kiss, Klaus Hauer (2020). Promoting physical activity in geriatric patients with cognitive impairment after discharge from ward-rehabilitation: a feasibility study. *European Journal of Ageing, 17*, 309-320. doi: 10.1007/s10433-020-00555-w

Publikation VII:

Phoebe Ullrich, Christian Werner, **Martin Bongartz**, Tobias Eckert, Bastian Abel, Anton Schönstein, Rainer Kiss, Klaus Hauer (2020). Increasing Life-Space Mobility in community-dwelling older persons with cognitive impairment following rehabilitation: A randomized controlled trial. *The Journals of Gerontology: Series A*. doi: 10.1093/gerona/glaa254

Publikation VIII:

Tobias Eckert, Pamela Wronski, **Martin Bongartz**, Phoebe Ullrich, Bastian Abel, Rainer Kiss, Michel Wensing, Jan Koetsenruijter, Klaus Hauer. Cost-effectiveness and cost-utility of a home-based exercise program in geriatric patients with cognitive impairment.

Accepted in *Gerontology*.

Inhaltliche Kurzdarstellung / Abstract (Deutsch)

Gegenstand der vorliegenden publikationsbasierten Dissertation ist das habituelle Bewegungsverhalten von älteren, multimorbiden Personen mit kognitiven Einschränkungen in der poststationären geriatrischen Rehabilitation. In diesem Zusammenhang werden innovative sensor- und fragebogenbasierte Assessmentmethoden evaluiert und zur Erfassung des habituellen Bewegungsverhaltens eingesetzt. Darüber hinaus werden die Durchführbarkeit, die Effektivität und die Kosteneffektivität eines standardisierten, zielgruppenspezifischen Heimtrainingsprogramms analysiert.

Die Daten für die vorliegende Dissertation wurden im Rahmen der randomisierten, kontrollierten Studie „**Hei**mtraining bei **k**ognitiver **Ei**nschränkung" (HeikE) generiert. In Publikation I wird das Studienprotokoll der Studie dargestellt. Neben funktionellen Übungen zur Verbesserung der Kraft und der Gleichgewichtsfähigkeit inkludierte HeikE eine Motivationsstrategie, um eine Modifikation des Bewegungsverhaltens und eine regelmäßige, selbstständige Durchführung des Trainings zu erreichen. Im Rahmen dieses Projekts wurden neuartige Assessmentmethoden zur Erfassung unterschiedlicher Dimensionen des körperlichen Bewegungsverhaltens, wie die habituelle körperliche Aktivität, habituelle Gangparameter (z.B. Gangsymmetrie, Schrittregelmäßigkeit) und die Life-Space Mobilität von älteren Personen (82,3 ± 5,9 Jahre) mit kognitiven Einschränkungen erfolgreich validiert.

In Publikation II wird die Validität des Bewegungssensors uSense evaluiert. Bisherige ambulante Erfassungssysteme weisen bei dieser Zielgruppe hohe Messungenauigkeiten auf. Insbesondere die Validität von Messmethoden zur Erfassung von Parametern des Gangbildes sind bei der hier untersuchten Personengruppe bislang nur unter standardisierten Laborbedingungen nachgewiesen worden. Mithilfe des in dieser Arbeit genutzten uSense-Systems wurden Ganganalysen im Rahmen des habituellen Bewegungsverhaltens multimorbider, kognitiv eingeschränkter, geriatrischer Patienten valide im Alltag möglich. Publikation III stellt die Entwicklung und Validierung des fragebogenbasierten Life-Space Assessments für Personen mit kognitiven Einschränkungen dar. Durch diesen Fragebogen wird in dieser Zielgruppe erstmals eine valide Erfassung der räumlichen Ausprägung der Mobilität und das Ausmaß der dazu in Anspruch genommenen Hilfsmittel/ Hilfsperson möglich. Beide Erfassungsmethoden wurden an die spezifischen Charakteristika älterer Personen mit kognitiven Einschränkungen angepasst.

Querschnittliche Analysen der zuvor validierten Assessmentmethoden werden in den Publikationen IV und V durchgeführt. Mittels multipler, linearer Regressionsanalysen werden Determinanten des körperlichen Aktivitätsverhaltens (Publikation IV) und der Life-Space Mobilität (Publikation V) im habituellen Setting unmittelbar nach Rehabilitationsmaßnahmen ermittelt. Die Regressionsmodelle in Publikation IV zeigen, dass „körperliche Leistungsfähigkeit“ und in besonderem Maße „Parameter der Gangqualität“ in Zusammenhang mit dem „körperlichen Aktivitätsverhalten“ stehen. Dauer, Frequenz und Intensität des „körperlichen Aktivitätsverhaltens“ werden zu 40 – 68 % (adjustiertes R^2 = 0,40 – 0,68) von den genannten unabhängigen Variablen aufgeklärt. Die Ergebnisse in Publikation V zeigen, dass die Zielgruppe eine eingeschränkte Life-Space Mobilität aufweist. Das „körperliche Aktivitätsverhalten“, „die körperliche Leistungsfähigkeit“, „die Teilnahme an sozialen Aktivitäten“ und „männliches Geschlecht“ werden im Rahmen der Regressionsanalyse als spezifische unabhängige Determinanten identifiziert, die die Varianz der abhängigen Variable „Life-Space Mobilität“ zu 42 % (adjustiertes R^2 = 0,42) aufklären.

Neben den dargestellten Analysen des habituellen Bewegungsverhaltens werden notwendige Voraussetzungen für eine Implementierung des Heimtrainingsprogramms in die Gesundheitsversorgung von geriatrischen Patienten mit kognitiven Einschränkungen evaluiert. In Publikation VI wird eine hohe, initiale Adhärenz hinsichtlich der selbstständigen Trainingsdurchführung festgestellt. Dies ist mit Ergebnissen von vorangegangenen Studien vergleichbar, in denen kognitiv eingeschränkte Personen untersucht wurden, die bei der Trainingsdurchführung von Bezugspersonen unterstützt wurden. Trotz vornehmlich selbstständiger Trainingsdurchführung wird die soziale Unterstützung durch die Trainer von den Studienteilnehmern als effektivste Programmkomponente wahrgenommen.

In Publikation VII wird erstmals gezeigt, dass ein Heimtrainingsprogramm bei der Zielgruppe im Vergleich zu einer Placebo-Kontrollgruppe zu einer Steigerung des maximal erreichten Life-Space Bereichs und zu einer Reduktion der Inanspruchnahme von Hilfsmitteln bzw. Hilfspersonen führt. Die im Summenscore widergespiegelte verbesserte Life-Space Mobilität liefert initiale Evidenz für einen positiven, klinischen Effekt des Programms.

Die Kosten-Effektivitätsanalyse in Publikation VIII kommt zu dem Ergebnis, dass die Wahrscheinlichkeit für einen positiven inkrementellen Netto-Vorteil der HeikE-Intervention, ab einer theoretischen Zahlungsbereitschaft von 2000 € pro gesteigerter Einheit der Short Physical Performance Battery ein Maximum von 99 % erreicht. Dies deutet darauf hin, dass das Heimtrainingsprogramm hinsichtlich der Steigerung der körperlichen Leistungsfähigkeit im Vergleich zur Regelversorgung kosteneffektiv ist. Kostenträger können durch dieses Ergebnis dabei unterstützt werden, eine fundierte Entscheidung für oder gegen die Finanzierung dieses Interventionsansatzes zu treffen.

Zusammenfassend erschließt diese Dissertation wesentliche Aspekte des habituellen Bewegungsverhaltens von älteren, multimorbiden Personen mit kognitiven Einschränkungen in der poststationären geriatrischen Rehabilitation. Moderate bis gute Testgütekriterien wurden für zwei unterschiedliche Messverfahren des habituellen Bewegungsverhaltens gezeigt. Basierend auf diesen Methoden wurden Parameter der körperlichen Aktivität, der Gangqualität sowie die Life-Space Mobilität valide im Alltag der Zielgruppe erfasst. Durch das neue Heimtrainingsprogramm HeikE wurde eine kosteneffektive Intervention vorgestellt, die in der Zielgruppe durchführbar ist und mit der die Life-Space Mobilität von kognitiv eingeschränkten Personen in der poststationären geriatrischen Rehabilitation verbessert werden kann.

Inhaltliche Kurzdarstellung / Abstract (Englisch)

The aim of this thesis was to evaluate the psychometric properties of a sensor-based as well as a questionnaire-based assessment of habitual physical activity and movement behavior. In a second step, cross-sectional analyses of these parameters in geriatric patients with cognitive impairment (CI) were conducted to describe the status quo and to identify determining factors of the habitual physical behavior. The last step was to analyze the feasibility and the intervention effects of a standardized home-based training program in this target group after discharge from geriatric rehabilitation. Analyses of health-economic properties of the intervention were part of the program evaluation.

Data from the randomized, controlled trial „**Hei**mtraining bei **k**ognitiver **E**inschränkung" (HeikE) was used. Besides functional exercises to improve muscle strength and balance, the study included individually tailored motivational strategies to enhance activity behavior. Publication I illustrates the protocol of this study in detail. Within this project, validity of the assessment methods used to capture different dimensions of physical activity behavior was established for the first time in the everyday life of older, multimorbid people with CI (mean age 82,3 ± 5,9 years). The validity of an ambulatory sensor system (uSense) is shown in publication II, allowing long-term measurement of physical activity and qualitative gait parameters (e.g., gait symmetry, step regularity) under free-living conditions. Further, publication III depicts the development and validation of a questionnaire-based life-space assessment in geriatric patients with CI. Both assessment methods had been developed specifically for the use in target population, taking into account the specific movement characteristics of this population.

In publications IV and V habitual physical activity and life-space mobility of the study sample was thoroughly described using both assessments mentioned above, determinants of respective physical activity parameters under habitual conditions were analyzed. Multiple, linear regression models in publication IV showed that "motor performance" and especially "quality of gait" were the strongest determinants explaining 40-68 % (adjusted R^2 = 0,40 - 0,68) of the duration, frequency and intensity of the physical activity behavior respectively. Publication V indicated a substantially restricted life-space mobility in multimorbid, older persons with CI following geriatric

rehabilitation. A multiple, linear regression analysis identified “physical activity”, “physical performance”, “social activities” and “male gender” to explain 42 % (adjusted R^2 = 0,42) of the total variance of life-space mobility in this population.

Further, preconditions for the implementation of the standardized home-based training program into the current medical care of multimorbid, older patients with CI after discharge from geriatric rehabilitation have been analyzed. Publication VI indicated a high, initial adherence to self-performed physical training, comparable to results of studies with older persons with CI in which physical trainings had been conducted with caregiver support. Furthermore, adherence to motivational strategies was initially high. Despite the mainly self-performed training sessions in our study, the participants mentioned social support by trainers being the most effective component of the training program. Results of publication VII indicate the standardized home-based training program being effective to increase the maximal life-space and to reduce the use of assistive devices or help of a person. The improved composite score of life-space mobility indicates a positive clinical effect of the home-based training program.

Finally, a cost-effectiveness analysis in publication VIII demonstrated the probability of a positive incremental Net Monetary Benefit of the HeikE-intervention reached a maximum of 99 % at a willingness to pay of €2,000 per enhanced unit of the Short Physical Performance Battery. This shows the home-based training program being cost-effective to increase the physical performance as compared to the usual care. This result might be useful for the healthcare payers to make a decision for or against the financing of the presented HeikE program.

In conclusion, this thesis opens up essential aspects of the movement behavior in free living environments of multi-morbid patients with CI after discharge from geriatric rehabilitation. Good to moderate psychometric properties are shown for different assessment methods. Based on these methods, parameters reflecting the physical activity, quality of gait and life-space mobility are measured validly in the everyday-life of the target group. Further, a home-based training program is shown to be feasible and effective the enhance the life-space mobility. Additionally, from a health economical point of view the intervention is cost-effective to enhance the physical performance of patients with CI after discharge from geriatric rehabilitation.

Anmerkungen zum Studienprojekt

Die vorliegende publikationsbasierte Dissertation geht aus dem Projekt „**Hei**mtraining bei **k**ognitiver **E**inschränkung“ (HeikE) hervor, das von 2015 bis 2018 unter der Leitung von Herrn Prof. Dr. Klaus Hauer am AGAPLESION Bethanien Krankenhaus / Geriatrisches Zentrum der Universität Heidelberg durchgeführt wurde. Das Projekt baute auf erfolgreichen Vorarbeiten der Forschungsabteilung des AGAPLESION Bethanien Krankenhauses Heidelberg auf. Es stellte ein Modellvorhaben nach §45c SGB XI zur Weiterentwicklung der Versorgungsstrukturen und Versorgungskonzepte für an Demenz erkrankten Pflegebedürftigen sowie anderen Gruppen von Pflegebedürftigen dar. Die Finanzierung erfolgte über Drittmittel, die durch den „Kommunalverband für Jugend und Soziales Baden-Württemberg“ und durch die „sozialen und privaten Pflegeversicherungen” bereitgestellt wurden. Die Geldgeber nahmen keinen Einfluss auf das Studienkonzept, das Studiendesign, die Erfassung, Analyse und Interpretation der Daten sowie die Publikation der Studienergebnisse.

Gemäß §45c SGB IX verfolgte das HeikE-Projekt das Ziel, die poststationäre Versorgungssituation von geriatrischen Patienten mit kognitiven Einschränkungen unmittelbar nach geriatrischen Rehabilitationsmaßnahmen durch ein kostengünstiges, leicht in die bestehenden Versorgungsstrukturen integrierbares Heimtrainingsprogramm zu optimieren. Hochgradig von Pflegeheimeinweisungen bedrohte Patienten mit kognitiven Einschränkungen, die nach geriatrischen Rehabilitationsmaßnahmen ins häusliche Umfeld zurückkehrten, wurden zur eigenständigen Ausübung eines Heimtrainingsprogramms angeleitet und unter Einbeziehung von Techniken zur Verhaltensänderung (Behavior Change Techniques, kurz: BCTs) motiviert, die körperliche Leistungsfähigkeit, das körperliche Aktivitätsverhalten und die damit verbundene Selbstständigkeit zu steigern. Ein weiteres Projektziel bestand darin, innovative Messinstrumente zur Erfassung unterschiedlicher Parameter der körperlichen Aktivität für die vulnerable Zielgruppe geriatrischer Patienten mit kognitiven Einschränkungen zu modifizieren und hinsichtlich ihrer Testgütekriterien zu evaluieren.

Der Verfasser dieser Dissertationsschrift erarbeitete in Zusammenarbeit mit der Arbeitsgruppe die Studienkonzeption des Projekts und war anschließend für die praktische Durchführung und Koordination der umfangreichen Assessmentverfahren zu allen Messzeitpunkten, für die Auswertung der sensorbasierten Daten sowie für die auf diesen Daten basierenden Datenanalysen zuständig oder war an deren Erarbeitung beteiligt. Detaillierte Angaben zu den Beiträgen des Verfassers dieser Dissertationsschrift zu den entstandenen Publikationen sind Tabelle 1 in Anhang A zu entnehmen.

Einleitung und Kapitelüberblick

Diese publikationsbasierte Dissertation ist inhaltlich an der Schnittstelle von Bewegungswissenschaft, Rehabilitationswissenschaft und Geriatrie einzuordnen. Die im Rahmen der Dissertation erarbeiteten Manuskripte wurden auf Basis des HeikE-Projekts erstellt.

Strategien zur Behandlung von geriatrischen Patienten mit kognitiven Einschränkungen unterschieden sich lange nicht nennenswert von den Behandlungsstrategien, die bei kognitiv intakten geriatrischen Patienten angewendet wurden. Erste Studien zu Interventionsansätzen, die an die speziellen Charakteristika geriatrischer Patienten mit kognitiven Einschränkungen angepasst wurden, zeigten positive Effekte in Form von gesteigerter funktioneller Leistung sowie Reduktionen von Verhaltensauffälligkeiten, Verlegungsraten und Verweildauern (Hauer et al., 2012; Maier, Wachtler, & Hofmann, 2007; Schwenk et al., 2014; Zieschang et al., 2010). Dementsprechend kam es in den letzten Jahren zunehmend zu Neuausrichtungen von Behandlungsstrategien in der Akutversorgung, wodurch die spezifischen Charakteristika dieser Zielgruppe vermehrt Berücksichtigung fanden (Rosler et al., 2010). Dem Leitgedanken der International Classification of Functioning, Disability and Health (ICF) der Weltgesundheitsorganisation (WHO) aus dem Jahr 2001 folgend, muss der Gesundheitszustand einer Person als ganzheitliches Konzept angesehen werden. Neben Defiziten in Form klinischer Befunde, spielen auch vorhandene Ressourcen in Form funktioneller Fähigkeiten und gesundheitsrelevanter Verhaltensweisen eine wesentliche Rolle, durch die eine selbstbestimmte Lebensführung und eine gesellschaftliche Partizipation im Alltag der jeweiligen Personengruppe begünstigt werden. Ein wichtiger gesundheitsrelevanter Bereich ist in diesem Zusammenhang das habituelle Bewegungsverhalten. Die Untersuchung des individuellen habituellen Bewegungsverhaltens setzt eine zuverlässige Erfassung der Zielparameter in der zu messenden Personengruppe im Alltag voraus. Zuverlässige Erfassungsmethoden basieren demnach auf zielgruppenspezifischen Assessmentstrategien. Durch darauf aufbauende Analysen epidemiologischer Fragestellungen können darüber hinaus Erkenntnisse zum Zustandekommen des gesundheitsrelevanten Bewegungsverhaltens im Alltag der Zielgruppe gewonnen werden.

Diese Dissertation knüpft an den Paradigmenwechsel zur zielgruppenspezifischen, ganzheitlichen Behandlung geriatrischer Patienten mit kognitiven Einschränkungen an. Während bisherige Studien auf die Optimierung der stationären Behandlung geriatrischer Patienten im Akutkrankenhaus oder in Rehabilitationskliniken abzielten, generiert die vorliegende Arbeit neue Erkenntnisse für den Bereich der poststationären, ambulanten Nachsorge nach geriatrischen Rehabilitationsmaßnahmen.

Kapitel 1 stellt den theoretischen und empirischen Hintergrund der Forschungsthemen dar, die im Rahmen der vorliegenden Dissertation bearbeitet wurden. Dazu werden einleitend die allgemeine Relevanz des Forschungsfeldes der poststationären Gesundheitsversorgung nach geriatrischen Rehabilitationsmaßnahmen (Kapitel 1.1) und die spezifischen Charakteristika der Zielgruppe geriatrischer Patienten mit kognitiven Einschränkungen erläutert (Kapitel 1.2 und 1.3). Darauf aufbauend wird der Einfluss kognitiver Einschränkungen auf verschiedene Aspekte des Bewegungsverhaltens älterer Personen skizziert (Kapitel 1.4). Zum Abschluss von Kapitel 1 wird ein Überblick der aktuellen Forschungsstände von (a) Messverfahren zur Erfassung des Bewegungsverhaltens multimorbider, älterer Personen (Kapitel 1.5) und (b) der Durchführbarkeit und Effektivität von Heimtrainingsprogrammen bei multimorbiden, älteren Personen mit kognitiven Einschränkungen gegeben (Kapitel 1.6). Ein besonderer Fokus wird in Kapitel 1.6 auf die Notwendigkeit und Durchführung von gesundheitsökonomischen Evaluationen gelegt, denen für die Implementierung eines neuartigen Interventionsansatzes in die Versorgungswirklichkeit große Bedeutung zukommt. In Kapitel 2 werden die Fragestellungen und Ziele hergeleitet, die sich aus den zuvor dargestellten Forschungslücken ergeben. Die dieser Arbeit zugrunde liegenden Publikationen (Publikationen I – VIII) wurden in internationalen, für den Fachbereich relevanten, Fachzeitschriften veröffentlicht, um die dargestellten Forschungslücken zu schließen.

Kapitel 3 bietet Zusammenfassungen der Publikationen, die dieser Dissertation zugrunde liegen. Abbildung 1 stellt die inhaltlichen Zusammenhänge der einzelnen Publikationen dar. Nach der Dokumentation des Studienkonzeptes in Form eines Studienprotokolls sind die Publikationen folgenden Themenbereichen zugeordnet:

- Themenbereich 1: „Validierung innovativer Messmethoden zur Erfassung des habituellen Bewegungsverhaltens“ (Publikationen II + III)

- Themenbereich 2: „Charakteristika und Determinanten des habituellen Bewegungsverhaltens“ (Publikationen IV + V)
- Themenbereich 3: „Durchführbarkeit, Effekte und Kosteneffektivität eines Heimtrainingsprogramms“ (Publikationen VI + VII + VIII)

Themenbereich 1 stellt die Validierungen neuartiger, sensor- und fragebogenbasierter Messmethoden zur Erfassung unterschiedlicher Dimensionen des Bewegungsverhaltens von multimorbiden, älteren Personen mit kognitiven Einschränkungen dar. Diese werden erstmals im habituellen Setting dieser vulnerablen Personengruppe durchgeführt. Darauf aufbauend werden diese innovativen Messmethoden in Themenbereich 2 eingesetzt, um nach Wissen des Autors erstmalig Einblicke in das habituelle Bewegungsverhalten dieser Personengruppe zu gewinnen und potentielle Determinanten für das habituelle Bewegungsverhalten zu identifizieren. Abschließend stellt Themenbereich 3 Ergebnisse zur Evaluation der Durchführbarkeit der klinischen Effekte und der Kosteneffektivität des Heimtrainingsprogramms dar (s. Abbildung 1).

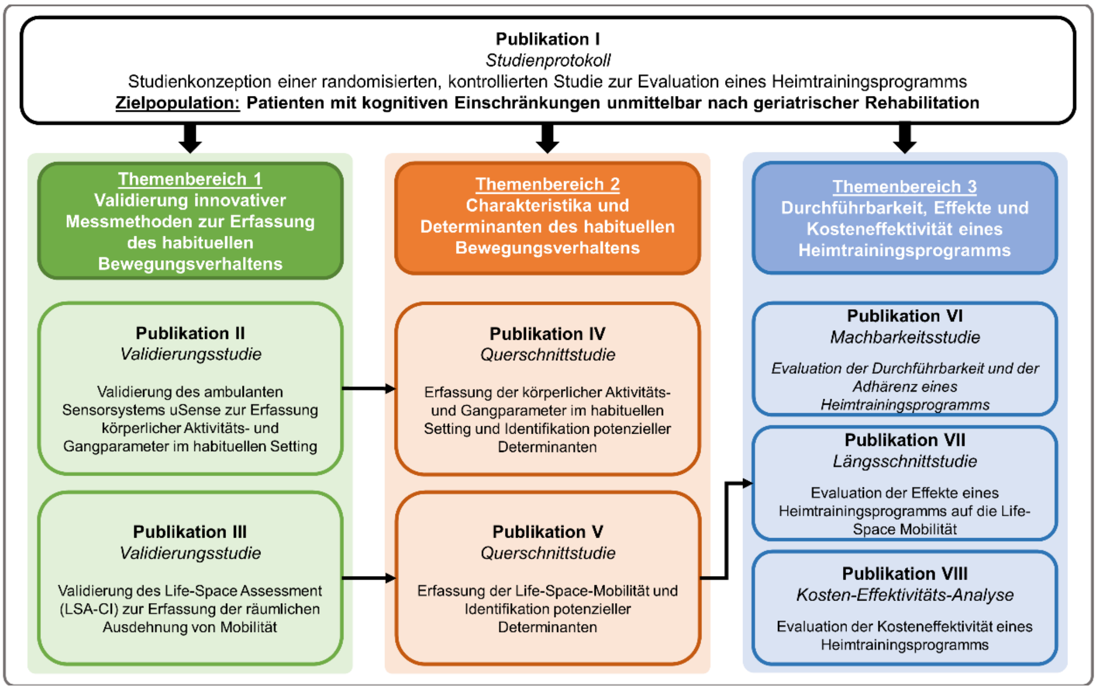

Abbildung 1: Schematische Übersicht der Publikationen (Publikationen I bis VIII), die dieser Dissertation zugrunde liegen

In Kapitel 4 werden die generierten Ergebnisse in den aktuellen Forschungszusammenhang eingebettet. Zum Abschluss erfolgt in Kapitel 5 ein inhaltliches Fazit der gesamten Arbeit und ein Ausblick auf weiterführende Forschungsfragen, die sich im Zusammenhang mit den neuen Erkenntnissen und den damit einhergegangenen veränderten Forschungslücken herauskristallisiert haben.

1 Theoretischer Hintergrund

1.1 Poststationäre Gesundheitsversorgung nach geriatrischer Rehabilitation – Relevanz des Forschungsfeldes

Der Anteil älterer Menschen an der Gesamtbevölkerung nimmt stetig und weltweit zu (WHO, 2015). In Deutschland wird für die kommenden Dekaden ein überproportionaler Zuwachs des Anteils von Menschen in hohem Lebensalter erwartet. Das statistische Bundesamt prognostiziert, dass der Anteil der über 67-Jährigen an der Gesamtbevölkerung Deutschlands von 2018 bis 2040 in Abhängigkeit von unterschiedlichen zugrunde liegenden Prognosemodellen von 19 % auf bis zu 27 % ansteigen wird, wobei die Zunahme an hochaltrigen über 80-Jährigen besonders stark ausgeprägt sein wird (Statistisches Bundesamt, 2019). Hohes Alter ist mit einer Zunahme chronischer Erkrankungen assoziiert (Barnett et al., 2012), wodurch die demographische Alterung zu einer steigenden Inzidenz der Multimorbidität in der Bevölkerung führen wird (Kuzuya, 2019). Gemäß des Grundsatzes „Rehabilitation vor Pflege“, der in den Sozialgesetzbüchern verankert ist, ist durch die demographische Alterung eine verstärkte Inanspruchnahme von allgemeinen Gesundheitsleistungen zu erwarten, was die Zunahme des Bedarfs an geriatrischen Rehabilitationsmaßnahmen einschließt (Robert Koch Institut, 2015). Für die Kostenträger wird die adäquate Allokation finanzieller Ressourcen zur Deckung des prognostizierten, erhöhten Bedarfs an Gesundheitsleistungen eine zu lösende Aufgabe darstellen. Die Leistungserbringer werden hingegen gefordert sein, Lösungsansätze in Form von effektiven, zielgruppenspezifischen Interventionsmaßnahmen anzubieten. Dies setzt eine, auf validen Assessmentmethoden basierende, wissenschaftliche Evaluation innovativer und effektiver Interventionsmaßnahmen voraus, die demnach im Interesse aller Akteure des Gesundheits- und Sozialsystems sind.

Bei der Entwicklung adäquater Interventionsmaßnahmen müssen auf der Basis der spezifischen Charakteristika geriatrischer Patienten Interventionsziele definiert werden. Die Ziele einer geriatrischen Rehabilitation bestehen nach der etablierten Definition von Kane et al. (1997) in einer Wiederherstellung funktioneller Fähigkeiten oder in einer Verbesserung der verbliebenen funktionellen Kapazität von älteren, multimorbiden Patienten. Cameron und Kurrle (2002) spezifizierten die Ziele der geriatrischen Rehabilitation auf die Fähigkeiten der möglichst selbstständigen Ausübung von Alltagsaktivitäten und Mobilität und rückten damit das individuelle Bewegungsverhalten in den Fokus der Zielsetzung. Per Definition liegt bei einem geriatrischen Patienten neben einem hohen Lebensalter gleichzeitig auch eine Multimorbidität vor, wodurch nicht jeder ältere Patient automatisch als geriatrischer Patient anzusehen ist (Borchelt, 2005). Multimorbidität ist bei gleichzeitig vorhandenem, niedrigem, funktionellem Status mit einem erhöhten Institutionalisierungs- und Mortalitätsrisiko assoziiert (Guido, Perna, Peroni, Guerriero, & Rondanelli, 2015). Im Verlauf von Krankenhausaufenthalten kommt es hinsichtlich des funktionellen Status zu einem Paradoxon zwischen der subjektiven Erwartungshaltung der geriatrischen Patienten und der objektiven Entwicklung ihrer Funktionsfähigkeit: Geriatrische Patienten erwarten, dass sich ihr funktioneller Status im Laufe des Krankenhausaufenthalts verbessert (Boltz, Capezuti, Shabbat, & Hall, 2010), wohingegen diese Patienten im Verlauf von Krankenhausaufenthalten häufig eine objektive Verschlechterung des funktionellen Status aufweisen (Gill, Allore, Gahbauer, & Murphy, 2010; Kortebein, 2009). Studienergebnisse zeigen, dass auch in der poststationären Phase nach dem Aufenthalt im Akutkrankenhaus ein reduzierter funktioneller Status vorliegt (Boyd et al., 2008; Gill et al., 2010). Ein Jahr nach der Entlassung aus dem Akutkrankenhaus erreichen lediglich 54 % der geriatrischen Patienten den gleichen funktionellen Status, den sie vor dem stationären Aufenthalt aufwiesen. Im Gegensatz dazu entwickeln 46 % eine Verschlechterung oder versterben (Boyd et al., 2008). Vor allem in der frühen poststationären Phase unmittelbar nach der Entlassung aus dem Akutkrankenhaus sind geriatrische Patienten hochgradig gefährdet, eine Pflegebedürftigkeit zu entwickeln, die eine Rückkehr in die eigene, häusliche Umgebung verhindert (Baztan, Suarez-Garcia, Lopez-Arrieta, Rodriguez-Manas, & Rodriguez-Artalejo, 2009). Nach dem Ergebnis einer Metaanalyse führen geriatrische Rehabilitationsmaßnahmen in der poststationären Phase unmittelbar nach der Entlassung aus dem Akutkrankenhaus kurzfristig zu einer Verbesserung des funktionellen Status und zu einer Reduktion von Pflegeheimeinweisungen sowie des Mortalitätsrisikos, mittel- bis langfristig schwächen sich diese positiven Effekte allerdings bereits nach 3 bis 12 Monaten ab (Bachmann et al., 2010). In Folge dessen wird die Entwicklung und Evaluation von rehabilitativen Maßnahmen empfohlen, die über die derzeit üblichen stationären Verweildauern geriatrischer Rehabilitationspatienten hinausgehen (Boyd et al., 2008; McGilton et al., 2016). Die poststationäre Versorgungsphase nach geriatrischer Rehabilitation benötigt demnach innovative, wissenschaftlich evaluierte Interventionsmaßnahmen, durch die positive Effekte von geriatrischen Rehabilitationsmaßnahmen langfristig gesichert und damit die Nachhaltigkeit der geriatrischen Rehabilitationsmaßnahmen optimiert werden. Aus diesem Grund wurde das HeikE-Projekt als poststationäres Versorgungskonzept initiiert (→ Publikation I).

1.2 Kognitive Einschränkungen bei älteren Menschen

Kognition ist die Gesamtheit aller informationsverarbeitenden Prozesse, bei denen das Gehirn als regulatives Zentrum fungiert, in dem die durch die sensorischen Systeme erfassten Informationen verstanden und interpretiert werden (Pezzulo & Cisek, 2016). Auf dieser Basis werden Interaktionen mit der Umwelt gesteuert, in deren Folge potenzielle Zustandsänderungen der Umgebung als neue Informationen von den sensorischen Systemen aufgenommen und erneut kognitiv verarbeitet werden (Pezzulo & Cisek, 2016). Aus diesem Prozess resultieren kognitive Leistungen, die in den Hauptbereichen Gedächtnis und Lernen, sprachlicher Ausdruck und Sprachverständnis, Exekutivfunktionen, sensorische und motorische Funktionen, Aufmerksamkeit sowie Selektion und Interpretation von sozialen Informationen erbracht werden (Wang & Dong, 2018). In der zweiten Lebenshälfte kommt es altersbedingt zu histologischen Veränderungen und zu einem Abbau von Hirnsubstanz (Kakimoto et al., 2016), die mit einer altersentsprechenden, physiologischen Reduktion der kognitiven Leistungen einhergehen (Morley, 2018). Pathologische Veränderungen in Form von leichten kognitiven Einschränkungen (Mild Cognitive Impairment, kurz: MCI) liegen vor, wenn die Reduktionen der kognitiven Leistungen höher sind, als es in Abhängigkeit von Alter und Bildungsniveau zu erwarten wäre. Die Aktivitäten des täglichen Lebens (u.a. Ankleiden, Körperhygiene, Einkaufen) können jedoch noch ohne oder mit geringen Einschränkungen selbstständig durchgeführt werden (Gauthier et al., 2006). Die Prävalenz von MCI steigt mit zunehmendem Alter an und liegt bei Personen im Alter von 60 – 64 Jahren bei 7 %, bei Personen im Alter von 80 – 84 Jahren bereits bei 25 % (Petersen et al., 2018). Epidemiologische Studien schätzen die

Gesamtprävalenz von MCI bei Personen über 60 Jahren auf 12 bis 18 % (Petersen, 2016). Die langfristige Entwicklung von MCI ist sehr variabel. Stabile, persistente Zustände oder gar Verbesserungen der kognitiven Fähigkeiten sind zwar möglich (Facal, Guardia-Olmos, & Juncos-Rabadan, 2015), im Vergleich zu kognitiv intakten Personen besteht bei Personen mit MCI jedoch ein deutlich erhöhtes Risiko, einen chronisch progredienten Rückgang der kognitiven Fähigkeiten zu erleiden (Mallo et al., 2019).

MCI können ein erster Hinweis auf eine beginnende Demenz sein (Petersen et al., 2018). Mehr als die Hälfte der Patienten mit MCI entwickeln innerhalb von fünf Jahren ein demenzielles Syndrom (Gauthier et al., 2006). Der Krankheitsverlauf von MCI zu einer Demenzerkrankung ist durch eine progressive Steigerung der kognitiven Einschränkungen gekennzeichnet, die mit zunehmenden funktionellen Einschränkungen, einem erhöhten Sturzrisiko, einer verringerten selbstständigen Ausführung von Alltagsaktivitäten und einem erhöhten Mortalitätsrisiko assoziiert ist (Allali & Verghese, 2017; Auyeung et al., 2008; McDonald, D'Arcy, & Song, 2018; Perna et al., 2015). Durch die progressive Verschlechterung der kognitiven Leistungsfähigkeit kommt es bei betroffenen Patienten zu einem hierarchischen Abbau bei der Ausführung von Aktivitäten des täglichen Lebens (Njegovan, Hing, Mitchell, & Molnar, 2001). Durch diesen hierarchischen Abbau können zunächst komplexe Aktivitäten (z.B. Einkaufen gehen, Finanzangelegenheiten regeln etc.) und im weiteren Krankheitsverlauf zunehmend einfache, automatisierte funktionelle Basisfähigkeiten der Selbstversorgung (Waschen, Anziehen, Essensaufnahme etc.) nicht mehr selbstständig ausgeführt werden (Njegovan et al., 2001).

1.3 Prävalenz und Charakteristika von Personen mit kognitiven Einschränkungen in der poststationären geriatrischen Rehabilitation

Bei geriatrischen Rehabilitationsmaßnahmen treten kognitive Einschränkungen bei einem hohen Anteil der Patienten auf. In Abhängigkeit der jeweils zu Grunde gelegten Grenzwerte für die Definition von kognitiven Einschränkungen liegt die Prävalenzrate bei 30 - 80 % (McGilton et al., 2012; Poynter, Kwan, Sayer, & Vassallo, 2011). Der kognitive Status ist stark positiv mit der funktionellen Verbesserung im Rahmen von Rehabilitationsmaßnahmen sowie mit der Wahrscheinlichkeit einer Entlassung in das häusliche Umfeld assoziiert (Zakharova-Luneva et al., 2020). Geriatrische Patienten mit kognitiven Einschränkungen weisen im Vergleich zu kognitiv intakten Patienten ein höheres Maß an Multimorbidität (von Renteln-Kruse et al., 2015), einen schlechteren funktionellen Status (Zekry et al., 2008), ein erhöhtes Sturzrisiko (Lach, Harrison, & Phongphanngam, 2016), eine höhere Institutionalisierungs- und Sterblichkeitsrate (Poynter et al., 2011) sowie schlechtere Rehabilitationsoutcomes (McGilton et al., 2016; Seematter-Bagnoud et al., 2013) auf. Ältere Personen mit gleichzeitigen körperlichen und kognitiven Defiziten haben ein besonders hohes Risiko, eine eingeschränkte Mobilität (Gill, Gahbauer, Murphy, Han, & Allore, 2012) bis hin zu hochgradiger häuslicher Gebundenheit zu entwickeln (Smith, Chen, Clarke, & Gallagher, 2016). Dies stellt eine Barriere dar, die sowohl die Teilhabe am gesellschaftlichen Leben, als auch die Inanspruchnahme von ambulanten Interventionsmaßnahmen erschwert oder verhindert. Innerhalb der Gruppe der geriatrischen Patienten stellen Patienten mit kognitiven Einschränkungen demnach ein besonders vulnerables, von Pflegebedürftigkeit bedrohtes Kollektiv dar.

Erstaunlicherweise berichten Achterberg et al. (2019), dass kognitive Einschränkungen in zahlreichen westlichen Nationen als Kontraindikation für die Durchführung von geriatrischen Rehabilitationsmaßnahmen gelten, was mit einer angeblich stark reduzierten Wiederherstellung funktioneller Fähigkeiten von Patienten mit kognitiven Einschränkungen begründet wird. Ungeachtet dessen haben erste Studien gezeigt, dass Patienten mit initial niedriger motorischer Leistung unabhängig vom kognitiven Status ein hohes Verbesserungspotenzial aufweisen (Hauer et al., 2012; Schwenk et al., 2014). Demnach gibt es keine evidenzbasierte Begründung dafür, Patienten mit kognitiven Einschränkungen von geriatrischen Rehabilitationsmaßnahmen auszuschließen.

1.4 Einfluss von kognitiven Einschränkungen auf das Bewegungsverhalten älterer Personen

Willkürliche Bewegungsausführungen wie zum Beispiel das Gehen stellen komplexe Prozesse dar, die die sensorische Aufnahme visueller, vestibulärer und propriozeptiver Informationen, deren zerebrale Verarbeitung sowie den efferenten motorischen Output beinhalten (van Iersel, Hoefsloot, Munneke, Bloem, & Olde Rikkert, 2004). Bei der Ausführung von Bewegungen werden sowohl bei der Verarbeitung sensorischer Informationen, als auch bei der Steuerung der Muskulatur kognitive Leistungen auf mehreren hierarchischen Ebenen des zentralen Nervensystems erbracht (Shumway-Cook & Woollacott, 2017). Kognitive Einschränkungen führen zu einer Störung der zerebralen Verarbeitung und Integration sensorischer Informationen in den motorischen Prozess, wodurch Bewegungsmuster entstehen, die nicht optimal an die jeweilige Situation angepasst sind (van Iersel et al., 2004). Derartige Störungen von motorischen Prozessen können unter anderem zu Veränderungen von Gangparametern führen, die mit einer Erhöhung der Sturzgefahr einhergehen (Tinetti, Speechley, & Ginter, 1988; van Iersel et al., 2004). Auch das körperliche Aktivitätsverhalten basiert auf willkürlichen Bewegungsausführungen und wird mit Gangparametern in Zusammenhang gebracht. Rubenstein (2006) weist auf die gesundheitsgefährdenden Folgen eines reduzierten körperlichen Aktivitätsverhaltens hin, das zu einer Dekonditionierung der Muskelkraft und zu abnormalen Veränderungen des Gehens beiträgt, wodurch das Sturzrisiko langfristig gesteigert wird. Körperliche Einschränkungen sind darüber hinaus mit Reduktionen von sozialen Aktivitäten, die außerhalb der eigenen Wohnung stattfinden assoziiert (Rosso, Taylor, Tabb, & Michael, 2013). Durch eine Verschlechterung der körperlichen Funktionen wird dieser Zusammenhang verstärkt. Unabhängig von körperlichen Einschränkungen ist auch ein reduzierter Life-Space, im Sinne der räumlichen Ausprägung des Bereichs, in dem sich eine Person bewegt, mit einer verringerten sozialen Teilhabe assoziiert (Rosso et al., 2013). Die soziale Teilhabe wird wiederum als wichtiger Bestandteil vom Wohlbefinden im Alter angesehen (Park et al., 2015). Diese Ergebnisse deuten darauf hin, dass vulnerable Personengruppen wie multimorbide, geriatrische Patienten mit kognitiven Einschränkungen besonders gefährdet sind, durch ein reduziertes Bewegungsverhalten weitreichende gesundheitliche Einschränkungen zu entwickeln.

Vor diesem Hintergrund werden im Folgenden die „körperliche Aktivität“, „Gangparameter“ und die „Life-Space Mobilität“ (LSM) als unterschiedliche gesundheitsrelevante Konstrukte des Bewegungsverhaltens und deren Charakteristika bei älteren Personen mit kognitiven Einschränkungen differenziert dargestellt.

1.4.1 Körperliche Aktivität

Körperliche Aktivität entsteht durch skelettmuskulär initiierte Bewegungen, die mit einer Steigerung des Energieverbrauchs einhergehen (Caspersen, Powell, & Christenson, 1985) und stellt ein multifaktoriell entstehendes, komplexes Verhalten dar, das hinsichtlich der Dimensionen Frequenz, Dauer und Intensität differieren kann (B. Ainsworth, Cahalin, Buman, & Ross, 2015; Condello et al., 2016; King et al., 2019). Es besteht eine allgemein anerkannte Evidenz für die positiven Effekte regelmäßiger körperlicher Aktivität auf die physische und mentale Gesundheit. Bei Personen bis ins hohe Alter von über 85 Jahren gezeigt, dass sowohl die Aufrechterhaltung, als auch die Aufnahme regelmäßiger körperlicher Aktivitäten zu einer Reduktion des Sterblichkeitsrisikos führen (Stessman, Hammerman-Rozenberg, Cohen, Ein-Mor, & Jacobs, 2009). Die WHO empfiehlt Personen über 65 Jahren mindestens 150 Minuten pro Woche moderate bis intensive körperliche Aktivitäten, um ihren Gesundheitszustand zu halten oder zu verbessern (WHO, 2010). Ungeachtet dieser evidenzbasierten Empfehlung wird dieses Mindestmaß an körperlicher Aktivität von der weit überwiegenden Mehrheit älterer Personen nicht erreicht (Keadle, McKinnon, Graubard, & Troiano, 2016; McPhee et al., 2016). Das Bewegungsverhalten von kognitiv eingeschränkten älteren Personen weist im Vergleich zu kognitiv intakten Personen Veränderungen auf, die teilweise durch gesteigerte, häufiger jedoch durch verminderte körperliche Aktivität gekennzeichnet sind. Ein gesteigertes Bewegungsverhalten kann in Form von unruhigem Umherlaufen („wandering“) auftreten (van der Linde, Matthews, Dening, & Brayne, 2017). Im Gegensatz dazu kam eine repräsentative, fragebogenbasierte Kohortenstudie zu dem Ergebnis, dass die überwiegende Zahl älterer Personen mit kognitiven Einschränkungen im Vergleich zu kognitiv intakten älteren Personen ein reduziertes Maß an körperlicher Aktivität aufweist (Kang & Xiang, 2020). Keadle et al. (2016) stellten fest, dass der Anteil der Personen, die die Mindestempfehlungen der WHO zur Durchführung von körperlicher Aktivität erreichen, von 41,7 % bei 65 – 74 Jährigen auf 18,4 % bei Personen über 85 Jahren sinkt. Innerhalb der Population älterer, körperlich unzureichend aktiver Personen stellen ältere Menschen mit kognitiven Einschränkungen demnach eine noch inaktivere Subgruppe dar, die in besonderem Maße von negativen Auswirkungen körperlicher Inaktivität gefährdet ist. Mangelnde körperliche Aktivität führt zu einer Verschlechterung der motorischen und funktionellen

Leistungsfähigkeit wodurch das Sturzrisiko erhöht (M. E. Taylor et al., 2019) und die selbstständige Ausübung instrumenteller Alltagsaktivitäten verringert wird (Kingston et al., 2012; Stessman et al., 2009). Bei älteren Personen kann ein niedriges körperliches Aktivitätsniveau altersbedingte Gesundheitsprobleme beschleunigen, wodurch die Gesundheitserwartung, d.h. die Anzahl der zu erwartenden gesunden Lebensjahre, reduziert wird (McPhee et al., 2016).

Die Kenntnis zielgruppenspezifischer, multifaktorieller Entstehungsfaktoren körperlicher Aktivität ist für die Konzeption zielgerichteter Therapieansätze zur Steigerung des körperlichen Aktivitätsverhaltens erforderlich (Brug et al., 2017). Im Rahmen einer umfangreichen, internationalen Studie erarbeitete ein Expertengremium ein theoretisches Rahmenkonzept, in dem Determinanten der körperlichen Aktivität über die Lebensspanne vom Kindes- bis zum Seniorenalter untersucht wurden (Condello et al., 2016). Die Autoren identifizierten 106 Determinanten des körperlichen Aktivitätsverhaltens, von denen die körperliche Leistungsfähigkeit und die Motivation körperlich aktiv zu sein als Faktoren dargestellt wurden, deren Einfluss auf die körperliche Aktivität über die gesamte Lebensspanne mit steigendem Alter zunimmt und die sich darüber hinaus durch einen hohen Grad an Modifizierbarkeit auszeichnen (Condello et al., 2016). In dem Rahmenkonzept werden auch kognitive Einschränkungen und der allgemeine Gesundheitsstatus als Faktoren beschrieben, die die körperliche Aktivität mit steigendem Alter zunehmend beeinflussen (Condello et al., 2016). Aus dieser langfristigen Betrachtungsweise vom Kindes- bis ins Seniorenalter lässt sich allerdings nicht ableiten, welche Determinanten der körperlichen Aktivität bei multimorbiden, älteren Personen mit kognitiven Einschränkungen relevant sind. Insbesondere für die Versorgungsphase nach geriatrischen Rehabilitationsmaßnahmen gibt es keine Studien, in denen Determinanten der körperlichen Aktivität für diese Zielgruppe untersucht wurden. In der vorliegenden Arbeit stellt dies eine zentrale Forschungsfrage dar (→ Publikation IV).

1.4.2 Gangparameter

Allgemein lässt sich das Gehen als das Ergebnis koordinierter Bewegungen unterschiedlicher Körpersegmente definieren, die durch einen komplexen Prozess des neuromuskuloskelettalen Systems entstehen und flexibel an unterschiedliche Umgebungsbedingungen angepasst werden (Mirelman, Shema, Maidan, & Hausdorff, 2018). Bei älteren Personen stellt das Gehen die am häufigsten ausgeführte Form der körperlichen Aktivität dar (Bootsman et al., 2018). Dies wird durch kaum notwendiges Equipment, niedrige Zugangsbarrieren und die Möglichkeit einer intuitiven, individuellen Intensitätssteuerung begünstigt (Brooks, Gunn, Withers, Gore, & Plummer, 2005; McPhee et al., 2016). Demnach weist das Konstrukt „Gehen“ Überschneidungen mit dem in Kapitel 1.4.1 dargestellten Konstrukt „körperliche Aktivität“ auf. Die Dauer, Intensität und Frequenz des Gehens umschreiben unterschiedliche Dimensionen des körperlichen Aktivitätsverhaltens. Im Gegensatz dazu werden Gangparameter durch einen detaillierten Einblick in einzelne Gangzyklen generiert, um damit zeitliche und räumliche Charakteristika der Gangzyklen zu quantifizieren und individuelle Gangmuster widerzuspiegeln. Wie in Abbildung 2 dargestellt, nehmen Del Din et al. (2016) eine Abgrenzung beider Konstrukte („körperliche Aktivität“ und „Gangparameter“) nach dem Grad der Detailliertheit der erfassten Parameter vor und unterscheiden zwischen Messungen auf der „Makro-Ebene“ und Messungen auf der „Mikro-Ebene“. Der Marko-Ebene wird das Konstrukt „körperliche Aktivität“ zugeordnet, da es ein übergeordnetes Bild des Bewegungsverhaltens mit einem geringen Grad der Detailliertheit widerspiegelt, wohingegen das Konstrukt „Gangparameter“ der Mikro-Ebene zugeordnet wird, da es Gangphasen im Detail quantifiziert (Abbildung 2) (Del Din et al., 2016).

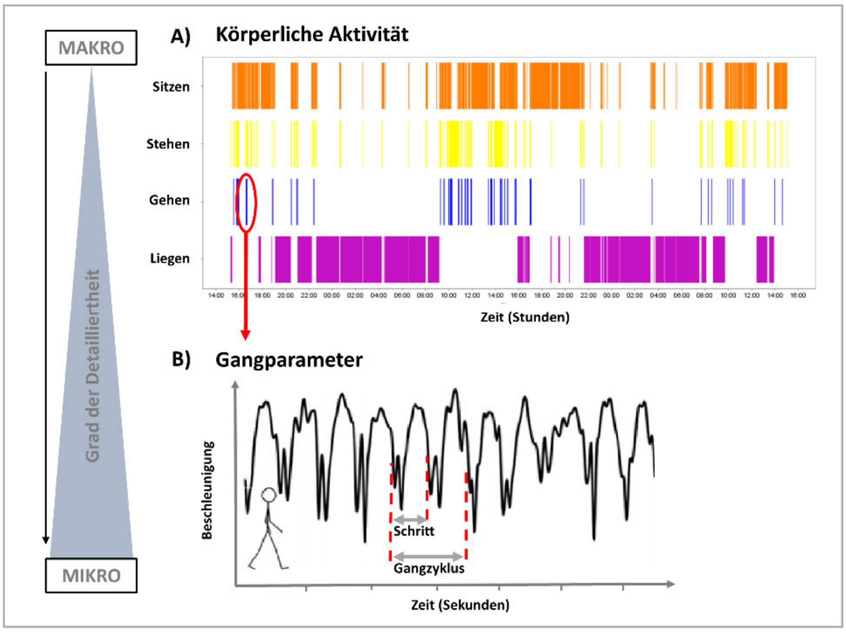

Abbildung 2: Abgrenzung folgender Konstrukte nach dem Grad der Detailliertheit: Konstrukt A) körperliches Aktivitätsverhalten, hier dargestellt in Form einer Messung des PAMSys Sensorsystems und Konstrukt B) Gangparameter, hier dargestellt in Form von Rohdaten der vertikalen Beschleunigungen (modifiziert nach Del Din et al., 2016).

Das Gehen erfordert kognitive Leistungen, deren Anforderungen mit zunehmender Komplexität der Umgebungsbedingungen steigen, um Gangmuster zu generieren, die optimal an die Umgebungsbedingungen angepasst sind (Mirelman et al., 2018). Ältere Personen mit kognitiven Einschränkungen weisen im Vergleich zu älteren Personen ohne kognitive Einschränkungen unter standardisierten Laborbedingungen spezifische Gangmuster auf (Bahureksa et al., 2017), die als Prädiktor für die Entstehung demenzieller Erkrankungen identifiziert wurden (Beauchet et al., 2016). Zu diesen spezifischen Charakteristika des Gehens gehören sowohl räumlich-zeitliche Gangparameter, wie eine Verlangsamung der habituellen Ganggeschwindigkeit (Bootsman et al., 2018; Montero-Odasso et al., 2014) und verkürzte Schrittlängen (Bahureksa et al., 2017; van Iersel et al., 2004), als auch zeitliche Gangparameter, wie verlängerte Bodenkontaktzeiten beider Füße (van Iersel et al., 2004) und eine Erhöhung der zeitlichen Variabilität aufeinander folgender Gangzyklen (Beauchet, Allali, Launay, Herrmann, & Annweiler, 2013; Beauchet et al., 2016). Sowohl Defizite in zeitlichen Gangparametern wie die zeitliche Variabilität und Symmetrie von Gangphasen sowie die Schrittfrequenz, als auch Limitationen von räumlich-zeitlichen Gangparametern wie der Ganggeschwindigkeit und Schrittlänge wurden als Prädiktoren für das Auftreten von Stürzen bei älteren Personen identifiziert (Rispens et al., 2016; van Schooten et al., 2016; Weiss, Herman, Giladi, & Hausdorff, 2014). Potenzielle Stürze durch defizitäre zeitliche und räumlich-zeitliche Gangparameter können wiederum zu einer drastischen Verschlechterung des Gesundheitszustandes älterer Personen führen.

1.4.3 Life-Space Mobilität

Vergleichbar mit dem in Kapitel 1.4.1. dargestellten Konstrukt der „körperlichen Aktivität" quantifiziert auch das Konstrukt der „LSM" ein von Personen ausgeführtes Verhalten. Während die körperliche Aktivität unterschiedliche Dimensionen explizit selbstständig ausgeführter Bewegungen, die mit einer Steigerung des Energieverbrauchs einhergehen, beschreibt, erfasst die LSM die räumliche Ausdehnung des Bereichs, in dem sich eine Person in einem definierten Zeitraum bewegt bzw. aufhält (May, Nayak, & Isaacs, 1985). Darüber hinaus spiegelt die LSM die Häufigkeit, in der die unterschiedlichen Bereiche erreicht werden und die dazu in Anspruch genommenen Hilfen wider (Baker, Bodner, & Allman, 2003). Modifikationen der LSM setzen räumliche Positionswechsel der Person voraus, wohingegen Veränderungen des körperlichen Aktivitätsniveaus auch ohne Ortswechsel erfolgen können (z.B. in Form einer Sitzgymnastik). Ein weiterer Unterschied zur körperlichen Aktivität besteht darin, dass Änderungen der LSM sowohl aktiv durch selbstständig ausgeführte Bewegungen (z.B. gehen), als auch passiv (z.B. als Beifahrer im Auto) erfolgen können. Sowohl Faktoren eines selbstbestimmten Lebens, wie die selbstständige Versorgung, als auch die gesellschaftliche Teilhabe setzen ein Mindestmaß an Mobilität voraus und stehen mit der LSM in Verbindung (Baker et al., 2003; Chung, Demiris, & Thompson, 2015; Rosso et al., 2013). Ältere Personen mit kognitiven Einschränkungen weisen im Vergleich zu kognitiv intakten älteren Personen eine reduzierte LSM auf (Tung et al., 2014) und sind in der Folge in besonderem Maße gefährdet, die Möglichkeit einer selbstständigen Lebensführung zu verlieren.

Die Konzeption von Interventionsmaßnahmen zur Modifikation der LSM setzt die Kenntnis über mögliche beeinflussende Faktoren voraus. Als theoretisches Rahmenmodell definierten Webber et al. (2010) LSM als multifaktorielles Konzept, bei dem sowohl persönliche (z.B. physische und psychische Gesundheit) als auch umweltbezogene (z.B. Umgebung oder Kultur) Faktoren Einfluss auf die LSM nehmen. Mehrere Studien stellen die körperliche Leistungsfähigkeit als denjenigen Faktor dar, der am stärksten mit der LSM älterer Personen assoziiert ist (Baker et al., 2003; Peel et al., 2005). Kuspinar et al. (2020) fanden in einer aktuellen Studie drei unabhängige Faktoren, die in besonderem Maße die Varianz im LSM von älteren Personen ohne kognitive Einschränkungen erklärten: die Möglichkeit des Autofahrens, die soziale Unterstützung und die habituelle Ganggeschwindigkeit. Da es nach Kenntnisstand des Autors bislang keine Studien gibt, in denen die Determinanten der LSM von multimorbiden älteren Personen mit kognitiven Einschränkungen untersucht wurden, widmet sich diese Arbeit unter anderem dieser Fragestellung (→ Publikation V)

1.5 Methoden zur Erfassung des Bewegungsverhaltens älterer Personen

Die körperliche Aktivität, Gangparameter und die LSM stellen, wie in Kapitel 1.4. erläutert, gesundheitsrelevante Konstrukte des Bewegungsverhaltens älterer Personen dar. Die Erfassung dieser Parameter basiert auf geeigneten Messmethoden, die sowohl zu wissenschaftlichen Zwecken eingesetzt werden können, als auch eine direkte Translation der Messmethoden in therapeutische Settings ermöglichen, um beispielsweise Therapieerfolge zu überprüfen. Die Auswahl einer geeigneten Messmethode hängt von dem zu messenden Parameter, der Zielpopulation und dem Setting, in dem der jeweilige Parameter gemessen werden soll, ab. Darüber hinaus müssen ausreichende Testgütekriterien des Messinstruments, wie die Validität und Reliabilität der Messung des jeweiligen Parameters in der Zielpopulation und in dem Setting, nachgewiesen werden (Dowd et al., 2018; Schmitz-Hubsch et al., 2016). In den letzten beiden Dekaden ist die Entwicklung und die Bandbreite von Sensorsystemen zur Messung von Parametern des körperlichen Aktivitätsverhaltens sowie von Gangparametern deutlich angestiegen, wobei die Testgütekriterien von zahlreichen entwickelten Sensorsystemen bislang nicht wissenschaftlich überprüft wurden (Arvidsson, Fridolfsson,

& Borjesson, 2019; Erdmier, Hatcher, & Lee, 2016). Demnach scheint die sportwissenschaftliche Forschung der rasanten Entwicklung technischer Sensorsysteme zur Erfassung des Bewegungsverhaltens nicht Schritt halten zu können. Der geringe Validierungsgrad existierender Sensorsysteme kann jedoch auch durch unterschiedliche Motive zwischen den Unternehmen, die im Bereich der Entwicklung technischer Sensorsysteme aktiv sind und den Akteuren der sportwissenschaftlichen Forschung begründet sein. Während Unternehmen mit der Entwicklung sensorbasierter Messsysteme wirtschaftliche Motive verfolgen, setzt die sportwissenschaftliche Forschung bei der üblichen und notwendigen Vernetzung mit nicht-sportwissenschaftlichen Teildisziplinen im Kern eine sportwissenschaftlich relevante Fragestellung voraus (Willimczik, 2011). Demnach ergibt sich die Notwendigkeit der Validierung neu entwickelter Sensorsysteme aus sportwissenschaftlicher Sicht nicht durch die reine Existenz eines neu entwickelten Sensorsystems, sondern durch die fachliche Beurteilung, ob eine erfolgreiche Validierung des Sensorsystems dazu führen würde, dass wissenschaftlich relevante, neuartige Fragestellungen durch die innovative Messmethode überprüfbar werden. Ungeachtet derartiger wissenschaftstheoretischer Grundsätze deckte ein systematischer Review methodische Defizite von zahlreichen Studien auf, in denen bei der Population älterer Menschen unterschiedliche Sensorsysteme zum Einsatz kamen: Lediglich in 63 % der Interventionsstudien zur Steigerung der körperlichen Aktivität wurden valide und reliable Messmethoden zur Erfassung der körperlichen Aktivität eingesetzt, von denen bei 57 % bzw. 66 % die Reliabilität bzw. Validität der Methoden in der untersuchten Zielgruppe wissenschaftlich belegt ist (Falck, McDonald, Beets, Brazendale, & Liu-Ambrose, 2016).

Möglichkeiten und Grenzen der zur Verfügung stehenden Messmethoden zur Erfassung der gesundheitsrelevanten Konstrukte „körperliche Aktivität“, „Gangparameter“ und „LSM“ werden im Folgenden detailliert aufgezeigt, da deren Kenntnis essentiell ist, um geeignete Messmethoden auswählen und weiterentwickeln zu können.

1.5.1 Erfassungsmethoden der körperlichen Aktivität

In Studien werden in Abhängigkeit von der zu überprüfenden Fragestellung die unterschiedlichen Dimensionen Frequenz, Dauer, Intensität oder die Art der körperlichen

Aktivität über verschiedene Zeiträume (Tage, Wochen, mehrere Monate etc.) gemessen (B. Ainsworth et al., 2015). Aktuell stehen zur Messung aller genannten Dimensionen der körperlichen Aktivität einerseits subjektive Methoden zur indirekten Messung (Fragebögen, Interviews oder Bewegungstagebücher), andererseits sensorbasierte, objektive Methoden zur direkten Messung (Pedometer, Akzelerometer, komplexe Sensorsysteme in Form kombinierter Sensorarten) zur Verfügung (B. Ainsworth et al., 2015; Arvidsson et al., 2019). Die Vorteile indirekter, fragebogenbasierter Methoden bestehen in einer geringen Belastung und einer hohen Akzeptanz aus Sicht der Befragten sowie in der kostengünstigen Durchführung, die den Einsatz in epidemiologischen Studien mit großen Fallzahlen ermöglicht (Dowd et al., 2018; Strath et al., 2013). In einem aktuellen systematischen Review werden 40 Fragebögen zur Erfassung der körperlichen Aktivität älterer Personen identifiziert und hinsichtlich der Testgütekriterien Reliabilität und Validität bewertet (Sattler et al., 2020). Die Autoren kommen zu dem Ergebnis, dass alle identifizierten Fragebögen methodische Mängel aufweisen. Lediglich die Fragebögen „Physical Activity Scale for Ederly“ und „Physical Activity and Sedentary Behaviour Questionaire“ weisen laut den Autoren eine hinreichende Validität und Reliabilität auf, um deren Einsatz zu empfehlen, bis Fragebögen mit besseren Testgütekriterien zur Verfügung stehen (Sattler et al., 2020). Bisherige Studienergebnisse haben gezeigt, dass mittels indirekter, fragebogenbasierter Methoden moderate bis intensive körperliche Aktivitätsphasen erfasst werden können, leichte bis moderate Intensitäten hingegen nicht zuverlässig gemessen werden (Strath et al., 2013).

Im Rahmen retrospektiver Befragungen werden häufig überhöhte Angaben zur durchgeführten körperlichen Aktivität gemacht (B. Ainsworth et al., 2015; Arvidsson et al., 2019). Gründe für diesen Messfehler sind fehlende detaillierte Erinnerungen an vor allem im leichten Intensitätsbereich durchgeführte körperliche Aktivitäten, Missverständnisse und verfälschte Antworten infolge sozialer Erwünschtheit (B. Ainsworth et al., 2015; Arvidsson et al., 2019).

Im Gegensatz zu subjektiven, fragebogenbasierten Methoden haben objektive, sensorbasierte Messsysteme das Potenzial, Parameter der körperlichen Aktivität mit höherer Validität und Reliabilität zu erfassen (Dowd et al., 2018). Durch den höheren technischen und zeitlichen Aufwand kommen sie im Gegensatz zu fragebogenbasierten Methoden jedoch nur selten in großen epidemiologischen Studien zum Einsatz (Dowd et al., 2018). Die objektiven Methoden zur direkten Erfassung der körperlichen Aktivität reichen von einfachen bis hin zu komplexen Sensorsystemen (Arvidsson et al., 2019). Pedometer stellen die einfachste Art der objektiven Methoden zur Erfassung der körperlichen Aktivität dar und sind auf die Messung der Schrittanzahl beschränkt (Rao, 2019). Akzelerometer messen Spannungsveränderungen durch Beschleunigungen in bis zu drei Bewegungsebenen. Durch Algorithmen werden diese Rohdaten konvertiert, wodurch Parameter generiert werden, die neben der Anzahl der Schritte, auch die Intensitäten der körperlichen Aktivitäten zeitlich erfassen (Westerterp, 2014). Komplexe Sensorsysteme kombinieren Akzelerometer mit weiteren Sensoren, die beispielsweise physiologische Reaktionen wie Herzfrequenz oder Hauttemperatur messen. Im Vergleich zu ausschließlich auf Akzelerometern basierenden Systemen, weisen komplexe Sensorsysteme eine erhöhte Genauigkeit bei der Messung der Intensität körperlicher Aktivitäten sowohl bei jüngeren, als auch bei gesunden, älteren Erwachsenen auf (O'Driscoll et al., 2020; Van Remoortel et al., 2012). Nachdem ein systematisches Review im Jahr 2012 zu dem Ergebnis kam, dass die Validität von Sensorsystemen zur Erfassung der körperlichen Aktivität unzureichend in der Zielgruppe der älteren Personen mit gesundheitlichen Einschränkungen überprüft wurde (Van Remoortel et al., 2012), kam es in den Folgejahren vermehrt zur Überprüfung der Testgütekriterien von bestehenden Sensorsystemen in dieser Zielgruppe (Straiton et al., 2018; Westerterp, 2014). Im Ergebnis führen altersbedingte Bewegungseinschränkungen, wie langsame Ganggeschwindigkeiten oder ungleichmäßige Gangmuster, bei aktuell bestehenden Sensorsystemen immer noch zu hohen Messfehlern (Straiton et al., 2018). Demnach besteht ein erhöhter Bedarf an der Entwicklung und wissenschaftlichen Evaluation von Sensorsystemen zur Messung der körperlichen Aktivität, die an die spezifischen Charakteristika von älteren Personen mit gesundheitlichen Einschränkungen angepasst sind.

1.5.2 Erfassungsmethoden von Gangparametern

Im Rahmen von Ganganalysen werden Charakteristika des Gehens quantifiziert. Dazu werden entweder die Bewegungen der unterschiedlichen Körpersegmente in Form kinematischer Parameter oder die zugrunde liegenden Prozesse, aus denen diese Bewegungen resultieren, in Form kinetischer Parameter oder muskulärer Aktivitäten erfasst (Tao, Liu, Zheng, & Feng, 2012). Die Identifikation von Auffälligkeiten innerhalb eines Gangmusters mittels Ganganalysen ermöglicht eine objektive Überwachung von Krankheitsverläufen sowie von Effekten therapeutischer Interventionen, macht optimierte individuelle Trainingsplanungen möglich und kann zusätzliche Hilfestellungen für differentialdiagnostische Entscheidungen geben, da Veränderungen von Gangparametern Hinweise auf die zugrunde liegenden pathologischen Ursachen liefern (Gordt, Gerhardy, Najafi, & Schwenk, 2018; Mirelman et al., 2018; Schniepp, Mohwald, & Wuehr, 2019). Darüber hinaus werden Auffälligkeiten in Gangmustern hohe prognostische Aufklärungswerte für die Entstehung von kognitiven Einschränkungen (Abellan van Kan et al., 2009), für zukünftige Stürze (Abellan van Kan et al., 2009; Mirelman et al., 2018) sowie für die Lebenserwartung älterer Personen beigemessen (Studenski et al., 2011). Dadurch können Ganganalysen auch in der Primär- und Sekundärprävention zum Einsatz kommen, um sturzgefährdete Personen zu identifizieren und geeignete Maßnahmen zur Reduktion des Sturzrisikos zu ergreifen (Vienne, Barrois, Buffat, Ricard, & Vidal, 2017). Das Ziel der Messungen und die dafür zu erfassenden Parameter und haben maßgeblichen Einfluss auf die Auswahl einer passenden Erfassungsmethode, zu denen aktuell Elektromyographien, Kraftmessplatten, optoelektronische Ganganalysesysteme und ambulante Sensorsysteme gehören. Diese Messsysteme generieren unterschiedliche Rohdaten, die bei den meisten Systemen mittels Algorithmen in quantifizierbare Gangparameter transformiert werden (Caldas, Mundt, Potthast, Buarque de Lima Neto, & Markert, 2017). Elektromyographien messen muskuläre Aktivitäten während des Gehens in Form elektrischer Potenziale, wodurch Innervationsstörungen der arbeitenden Muskulatur identifiziert werden können (Tao et al., 2012). Der Fokus aktueller Ganganalysesysteme liegt jedoch auf der Erfassung von räumlich-zeitlichen Gangparametern (Mirelman et al., 2018). Kraftmessplatten messen kinetische Bodenreaktionskräfte, wodurch die Positionen der Füße und deren Abrollbewegung während des Gehens räumlich und zeitlich exakt erfasst und daraus räumlich-zeitliche Gangparameter wie beispielsweise Schrittlänge, Schrittdauer, Geschwindigkeit oder Bodenkontaktzeit beider Füße abgeleitet werden können (Ambrozy, Palma, Hasenoehrl, & Crevenna, 2020; Schniepp et al., 2019). Den Gold-Standard für die kinematische Erfassung räumlich-zeitlicher

Gangparameter stellen momentan optoelektronische Ganganalysesysteme dar, mit denen dreidimensionale Bewegungsanalysen mittels Signalreflektionen von Markern, die an definierten Körperstellen der Versuchsperson angebracht sind, erfasst werden (Schniepp et al., 2019). Die Durchführung von optoelektronischen Ganganalysen mit entsprechenden Systemen ist durch den enormen personellen und technischen Aufwand nicht nur sehr kostenintensiv, sondern auch auf das Laborsetting limitiert (Mirelman et al., 2018). Im Gegensatz zu laborbasierten, stationären Ganganalysesystemen ermöglichen ambulante Sensorsysteme kostengünstige Langzeitmessungen von habituellen Gangmustern im Alltag älterer Personen. Über mehrere Tage oder Wochen kommen kabellose Sensoren, die an Oberschenkel, unterem Rücken, Hüfte, Sternum oder Handgelenk getragen werden, zum Einsatz ohne dass das normale Bewegungsverhalten beeinflusst wird (Caldas et al., 2017; Mirelman et al., 2018; Schniepp et al., 2019; Tao et al., 2012). Die im Alltag über mehrere Stunden oder Tage erfolgende Datenerfassung mittels ambulanter Sensorsysteme erweitert das Spektrum der messbaren Parameter durch dynamische Gangmessungen der Variabilität und Regelmäßigkeit zahlreicher, aufeinander folgender Gangzyklen, die im Laborsetting aufgrund der Beschränkung auf kurze Gehstrecken und wenige Gangzyklen nur eingeschränkt oder gar nicht erfasst werden können (Hausdorff, 2007; Kobsar, Olson, Paranjape, Hadjistavropoulos, & Barden, 2014). Die momentan hohe Heterogenität der generierten Parameter muss bei der Interpretation und dem Vergleich von Studienergebnissen berücksichtigt werden, da vielfach noch keine Normwerte dieser innovativen Parameter existieren (Del Din et al., 2016; Schniepp et al., 2019; Vienne et al., 2017). Aktuell werden ambulante Sensorsysteme in Form von Akzelerometern und „Inertial Measurement Units“ (IMU) unterschieden. Akzelerometer basieren auf der Messung von Beschleunigungen, die in den unterschiedlichen Phasen des Gangzyklus in spezifischer Ausprägung in Richtung der anterior-posterioren, medio-lateralen und vertikalen Achsen entstehen. IMU kombinieren innerhalb eines Sensors mehrere Sensorarten, um detailliertere Ganganalysedaten zu generieren (Mirelman et al., 2018; Tao et al., 2012). Neben Akzelerometern werden Gyroskope zur Messung von Winkelgeschwindigkeiten, die bei Drehungen entstehen, sowie Magnetometer, die die Lage des Sensors im Verhältnis zur Vertikalachse erfassen, in IMU integriert (Tao et al., 2012). Systematische Reviews kommen zu dem Ergebnis, dass Ganganalysen mittels ambulanter Sensorsysteme im habituellen Setting einerseits das Potenzial haben, innovative Gangparameter und dadurch neuartige Einblicke in die Gangmuster älterer Personen zu generieren, die im Labor nicht messbar sind (Benson, Clermont, Bosnjak, & Ferber, 2018). Diese Möglichkeit bleibt andererseits jedoch meist ungenutzt, da die meisten Studien, in denen ambulante Sensorsysteme genutzt werden, unter standardisierten Laborbedingungen durchgeführt werden (Vienne et al., 2017). Eine mögliche Begründung für die überwiegende Anzahl laborbasierter Studien liegt nach der Ansicht von Vienne et al. (2017) darin, dass die meisten Sensorsysteme und Algorithmen für die Messung unter standarisierten Laborbedingungen entwickelt wurden, wodurch deren Validität im habituellen Umfeld nicht sichergestellt ist. Die aktuelle Studienlage zur Überprüfung der Testgütekriterien von ambulanten Sensorsystemen zur Durchführung von Ganganalysen bei älteren Personen unterstützt die Vermutung von Vienne et al. (2017), da Validierungsstudien bislang ausschließlich unter standardisierten Laborbedingungen durchgeführt wurden. Wie im Folgenden dargestellt, kamen bisherige Studien zur Validierung von ambulanten Sensorsystemen bei älteren Personen mit und ohne gesundheitliche Einschränkungen zu heterogenen Ergebnissen.

Mancini et al. (2016) untersuchten die Validität eines ambulanten IMU-Systems zur Messung von zeitlichen Parametern, die den ersten Schritt einer Gangphase bei Parkinsonpatienten charakterisieren. Die Autoren kamen zu dem Ergebnis, dass das IMU-Messsystem unter Laborbedingungen hohe Korrelationen mit vergleichbaren Parametern aufweist, die zeitgleich durch Kraftmessplatten und direkte Observation erfasst wurden, woraus eine hohe Validität abgleitet wurde. Analog dazu wurde in einem Review festgestellt, dass ambulante Ganganalysesysteme bei Parkinsonpatienten vor allem zeitliche Parameter (zeitliche Variabilität und Symmetrie von Gangzyklen) mit hoher Validität messen (Del Din et al., 2016). Bei Personen mit zerebraler Gangataxie wurde im Labor eine hohe Validität eines ambulanten Sensorsystems bei der Messung zeitlicher Gangparameter nachgewiesen, wohingegen die Erfassungen räumlicher Gangparameter im Vergleich zu stationären Ganganalysesystemen niedrige Testgütekriterien aufwiesen (Schmitz-Hubsch et al., 2016). Im Gegensatz dazu kam eine Studie bei älteren Personen ohne chronische Gesundheitseinschränkungen zu dem Ergebnis, dass räumlich-zeitliche Gangparameter (Ganggeschwindigkeit, Kadenz und Schrittlänge), die simultan mit einem ambulanten Sensorsystem und einem stationären

Ganganalysesystem unter Laborbedingungen gemessen wurden, hohe Übereinstimmungen zeigten, wohingegen die Messung des zeitlichen Gangparameters Gangvariabilität eine geringe Übereinstimmung zwischen den Messsystemen aufwies (Hartmann, Luzi, Murer, de Bie, & de Bruin, 2009). Die Aussagekraft der Ergebnisse zu Gangparametern wie der zeitlichen Variabilität von Gangzyklen wird dadurch eingeschränkt, dass die Messungen längerer Gangphasen bedürfen, die unter Laborbedingungen nicht möglich sind (Hausdorff, 2007). Unter Berücksichtigung dieser Einschränkungen und unter dem Vorbehalt möglicher Einflüsse, die durch die Variabilität der unterschiedlichen Populationen entstehen können, deuten die Ergebnisse darauf hin, dass ambulante Sensorsysteme zeitliche Gangparameter zuverlässiger messen als räumlich-zeitliche Gangparameter. Die Heterogenität der Ergebnisse untermauert jedoch insgesamt die Notwendigkeit, dass die Testgütekriterien von Sensorsystemen sowohl in dem Setting, als auch in der Population evaluiert werden müssen, in denen die ambulanten Ganganalysen durchgeführt werden sollen. Bislang gibt es keine Studien, in denen die Testgütekriterien von ambulanten Sensorsystemen zur Ganganalyse im habituellen Setting von älteren Personen mit kognitiven Einschränkungen evaluiert wurden. Aus diesem Grund wurden im Rahmen der vorliegenden Arbeit die psychometrischen Testgütekriterien des ambulanten Bewegungssensorsystems uSense überprüft, das speziell für diese Zielgruppe konzipiert wurde (→ Publikation II).

1.5.3 Erfassungsmethoden der Life-Space Mobilität

Die ersten Erfassungsmethoden des Life-Space entstanden zu einem Zeitpunkt, in dem sensorbasierte Methoden zur ambulanten Messung von Parametern des körperlichen Bewegungsverhaltens noch nicht existierten. May et al. (1985) entwickelten einen fragebogenbasierten Ansätze zur Erfassung des Life-Space, mit dem die räumliche Ausprägung des Bereichs, in dem sich eine Person in einem definierten Zeitraum bewegt bzw. aufhält gemessen wurde. Diese Methode misst demnach ausschließlich die räumliche Ausprägung des Life-Space, ohne zu berücksichtigen, ob dieser Raum selbstständig oder durch die Nutzung von Hilfsmitteln bzw. Hilfspersonen erreicht wird. Insbesondere bei älteren Personen, die von einem Verlust der Selbstständigkeit bedroht sind, ist die Kenntnis über die Nutzung von Hilfsmitteln oder Hilfspersonen von hoher Relevanz, um den Grad der Selbstständigkeit einzuschätzen. Daher hat sich bei der Messung älterer Personen in der Folge zunehmend eine umfassendere und differenziertere Betrachtungsweise des Life-Space durchgesetzt, nach der über die räumliche Ausprägung hinaus das Ausmaß an Hilfestellungen und die Häufigkeit, in der dieser Raum erreicht wird, erfasst wird (Baker et al., 2003). Durch diese erweiterte Betrachtungsweise wird das Life-Space-Konzept nach May et al. (1985) durch detaillierte mobilitätsbezogene Aspekte ergänzt, wodurch Einschränkungen hinsichtlich der selbstständigen Mobilität älterer Personen identifiziert werden können. Dieses erweiterte Life-Space-Konzept wird treffender als LSM bezeichnet. In der vorliegenden Arbeit wird dieser Betrachtungsweise gefolgt.

Analog zur körperlichen Aktivität lassen sich auch bei der Erfassung des Life-Space und der LSM sensor- und fragebogenbasierte Messmethoden unterscheiden. Sensorbasierte Global Positioning System (GPS)-Messungen wurden durchgeführt, um den Life-Space außerhalb des Hauses von Personen mit kognitiven Einschränkungen zu messen (Tung et al., 2014). In Pflegeheimen wurde eine drahtlose Vernetzungstechnologie verwendet, um den Life-Space der Pflegeheimbewohner innerhalb des Gebäudes zu erfassen (Jansen, Diegelmann, Schnabel, Wahl, & Hauer, 2017). Die genannten sensorbasierten Technologien müssten demnach kombiniert werden, um den Life-Space sowohl innerhalb, als auch außerhalb des Gebäudes (Outdoormobilität) zu messen. Darüber hinaus messen beide Technologien ausschließlich räumliche Ausprägungen des Life-Space und erfassen daher nicht die LSM. Im Vergleich zu sensorbasierten Methoden sind fragebogenbasierte Methoden für die Messung der LSM besser geeignet, da hierbei sowohl die räumliche Ausprägung des Life-Space inner- und außerhalb des Gebäudes, als auch der Grad der Selbstständigkeit, die Nutzung von Hilfsmitteln und Hilfspersonen erfasst werden kann. Fragebogenbasierte Erfassungsmethoden der LSM nutzen das Grundkonzept von May et al. (1985). Zur Messung der räumlichen Dimension, in der sich eine Person bewegt, bzw. aufgehalten hat, werden Life-Space Bereiche in Form von konzentrischen Zonen, beginnend innerhalb des Hauses mit dem Schlafzimmer, hin zu Zonen außerhalb des Hauses, wie die Nachbarschaft und der Wohnort etc. eingeteilt (May et al., 1985). Erfasst werden die erreichten Zonen, die Häufigkeit, in der die Zonen erreicht wurden sowie die dabei in

Anspruch genommenen Hilfsmittel und Hilfspersonen. Abbildung 3 stellt unterschiedliche Operationalisierungen des LSM Konzepts nach dem Prinzip der konzentrischen Zonen dar (siehe Abbildung 3).

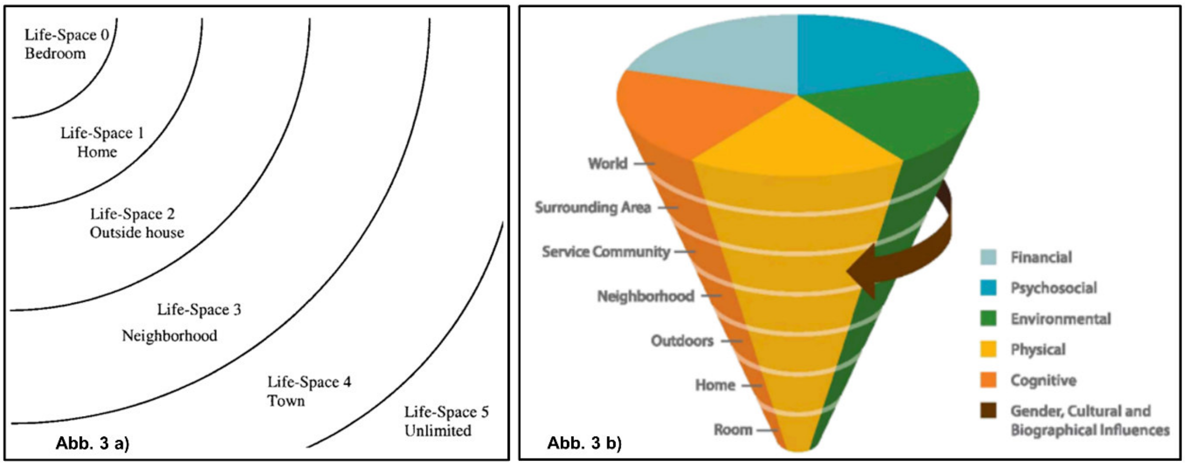

Abbildung 3: Graphische Darstellung unterschiedlicher Operationalisierungen des Life-Space Mobilitätskonzepts: Abb. 3 a) Operationalisierung nach Baker et al. (2003) und Abb. 3 b) Operationalisierung nach Webber et al. (2010).

In der vorliegenden Arbeit wird das fragebogenbasierte LSM-Assessment nach Baker et al. (2003) an die spezifischen Charakteristika von geriatrischen Patienten mit kognitiven Einschränkungen angepasst und hinsichtlich psychometrischer Testgütekriterien überprüft (→ Publikation III).

1.6 Notwendigkeit der Optimierung des Bewegungsverhaltens von multimorbiden Personen mit kognitiven Einschränkungen

Bislang können kognitive Einschränkungen und Demenzerkrankungen nicht geheilt oder ursächlich durch medikamentöse Therapien behandelt werden. Dadurch kommen nicht-pharmakologischen, symptomatischen Interventionen sowohl in Frühphasen des Krankheitsverlaufs, als auch in der Behandlung von Personen mit demenziellen Erkrankungen große Bedeutung zu (Liang et al., 2018; Tisher & Salardini, 2019). Insbesondere in der poststationären Phase nach geriatrischen Rehabilitationsmaßnahmen sind Personen mit kognitiven Einschränkungen stark von negativen Auswirkungen eines reduzierten Gesundheitsstatus bedroht, der beispielsweise durch das Auftreten von Stürzen entsteht und zu Einschränkungen der Lebensqualität oder zu einem Verlust der selbstständigen Ausführung von Alltagsaktivitäten führen kann (siehe Kapitel 1.3). Demnach besteht in der poststationären Phase ein besonders hoher Bedarf nach Optimierungen des Bewegungsverhaltens, um diesen negativen Auswirkungen effektiv entgegenwirken.

In der Literatur lassen sich verschiedene Prädiktoren finden, von denen die selbständige Ausführung von Alltagsaktivitäten bei älteren Personen abhängig ist (van Rossum & Koek, 2016). Diese Prädiktoren lassen sich nach ihrer Modifizierbarkeit differenzieren: das Alter und das Geschlecht sind nicht modifizierbar, während das körperliche Aktivitätsverhalten einen modifizierbaren Faktor darstellt (van Rossum & Koek, 2016). Aufgrund der Modifizierbarkeit kommt einer Steigerung des körperlichen Aktivitätsverhaltens eine besonders hohe Relevanz für Interventionsprogramme zu (Ley, Khaw, Duke, & Botti, 2019; Simoes et al., 2006). Aktuellen Studienergebnissen zufolge sollten Interventionen auch auf eine Optimierung von Gangparametern abzielen, da räumlich-zeitliche Gangparameter wie die Ganggeschwindigkeit wesentlichen Einfluss auf die selbstständige Ausführung von Alltagsaktivitäten haben (Perera et al., 2016; Perez-Sousa et al., 2019).

1.6.1 Heimtrainingsprogramme für Personen mit kognitiven Einschränkungen in der poststationären geriatrischen Rehabilitation

Nachdem in der Vergangenheit lange davon ausgegangen wurde, dass Personen mit kognitiven Einschränkungen nicht effektiv trainierbar sind, besteht mittlerweile Evidenz, dass ältere Personen mit kognitiven Einschränkungen durch funktionelle Trainingsprogramme vergleichbare Verbesserungen der körperlichen Leistungsfähigkeit erzielen können wie kognitiv intakte Personen (Heyn, Johnson, & Kramer, 2008). Diese Erkenntnis bezieht sich auf supervidierte Trainingsprogramme für geriatrische Patienten mit kognitiven und motorischen Einschränkungen zur Steigerung der körperlichen Leistungsfähigkeit im ambulanten Setting (Lam et al., 2018), deren Effektivität und Durchführbarkeit im Rahmen einer randomisierten, kontrollierten Studie (randomized controlled trial, kurz: RCT) auch in der Versorgungsphase nach geriatrischen Rehabilitationsmaßnahmen gezeigt wurde (Hauer et al., 2012). Die Teilnahme geriatrischer Patienten mit kognitiven und motorischen Einschränkungen an ambulanten Trainingsprogrammen wird jedoch durch ein hohes Maß an häuslicher Gebundenheit und eine reduzierte Outdoormobilität dieses Personenkreises erschwert (Gill et al., 2012; Smith et al., 2016) (siehe Kapitel 1.3). Diese Zugangsbarrieren können durch Trainingsprogramme umgangen werden, die im häuslichen Umfeld der Teilnehmer stattfinden. De Almeida et al. (2019) haben die Durchführbarkeit und Effektivität von Heimtrainingsprogrammen bei Personen mit demenzieller Erkrankung in einer Meta-Analyse untersucht und kamen zu dem Ergebnis, dass Trainingsprogramme im häuslichen Umfeld mit dieser Personengruppe möglich sind. Derartige Programme haben positive Effekte auf kognitive Funktionen, demenzspezifische, verhaltensbezogene und psychologische Symptome, selbstständige Ausführung von Alltagsaktivitäten und auf körperliche Leistungsfähigkeit (Almeida et al., 2019). Die Meta-Analyse von Almeida et al. (2019) beinhaltete allerdings weder Heimtrainingsprogramme in der poststationären Phase nach geriatrischen Rehabilitationsmaßnahmen, noch für Patienten mit kognitiven Einschränkungen ohne nachgewiesene Demenzdiagnose. Unabhängig von einer manifesten Demenzdiagnose stellen geriatrische Patienten mit kognitiven Einschränkungen unmittelbar nach Rehabilitationsmaßnahmen ein besonders vulnerables, von Pflegebedürftigkeit bedrohtes Kollektiv dar (siehe Kapitel 1.3), weshalb für diese Personengruppe unmittelbar nach Rehabilitationsmaßnahmen in besonderem Maße effektive Interventionsansätze benötigt werden. Diesem Bedarf wurde eine Pilotstudie unserer Arbeitsgruppe gerecht, die die Durchführbarkeit und erste positive Effekte auf die körperliche Leistungsfähigkeit eines Heimtrainingsprogramms bei geriatrischen Patienten mit kognitiven Einschränkungen nach geriatrischen Rehabilitationsmaßnahmen nachwies (Hauer et al., 2017). Darauf aufbauend stellt sich die Frage, ob durch ein Heimtrainingsprogramm in dieser Zielgruppe Modifikationen des Bewegungsverhaltens erreicht werden können. In diesem Zusammenhang spielt die Adhärenz eine wesentliche Rolle, die das Ausmaß widerspiegelt, in dem das tatsächliche Verhalten des Patienten mit dem Verhalten übereinstimmt, das vom Therapeuten empfohlenen wird (Sabate, 2003). Bei gebrechlichen älteren Personen hat eine hohe Adhärenz wesentlichen Einfluss auf den Erfolg einer Interventionsmaßnahme (Fairhall et al., 2012). Im Rahmen dieser Arbeit wurde die Adhärenz an die unterschiedlichen

Trainingskomponenten des HeikE-Projekts analysiert, um in unserer Zielgruppe relevante Faktoren für eine regelmäßige Durchführung des Trainings zu identifizieren (→ Publikation VI).

1.6.2 Gesundheitsökonomische Evaluation von Trainingsprogrammen

Um eine neuartige Interventionsmaßnahme in die Versorgungsrealität integrieren zu können, müssen neben der Durchführbarkeit und den potenziellen, klinischen Effekten auch gesundheitsökonomische Aspekte überprüft werden. Diese Notwendigkeit ergibt sich aus der Knappheit der finanziellen Ressourcen im Gesundheitswesen, die zu einer Diskrepanz zwischen medizinisch Durchführbarem und öffentlich Finanzierbarem führt (Marckmann, 2009). Durch gesundheitsökonomische Evaluationen werden Empfehlungen ausgesprochen, die auf eine optimale Allokation der knappen finanziellen Ressourcen abzielen (Karlsson & Johannesson, 1996; Neumann & Sanders, 2017). Vor diesem Hintergrund wird geprüft, ob die potenziell zusätzlichen Kosten, die durch eine neuartige Intervention entstehen können, durch den erreichbaren, zusätzlichen Effekt gerechtfertigt sind (Hoch, Briggs, & Willan, 2002). Im deutschen gesetzlichen Krankenversicherungssystem ergibt sich die Notwendigkeit der gesundheitsökonomischen Überprüfung neuartiger Interventionsmaßnahmen unter anderem durch das Wirtschaftlichkeitsgebot gemäß §12 SGB V, nach dem die gesetzlichen Krankenkassen Gesundheitsleistungen nur dann bewilligen dürfen, wenn diese nachweislich ausreichend, zweckmäßig und wirtschaftlich sind. Zur Beurteilung, ob ein neuartiger Interventionsansatz diesen Anforderungen genügt, kommen quantitative, gesundheitsökonomische Methoden wie Kosteneffektivitätsanalysen zum Einsatz. Führt eine neuartige Interventionsalternative einerseits zu einem verbesserten Effekt, andererseits zu höheren Gesamtkosten im Vergleich zur bisherigen Versorgungsstruktur, hängt die Beurteilung der Kosteneffektivität von der Zahlungsbereitschaft des Kostenträgers ab (Briggs, O'Brien, & Blackhouse, 2002). Aus gesundheitsökonomischer Sicht ist eine neuartige Interventionsmaßnahme hinsichtlich des untersuchten Effekts kosteneffektiv, wenn die Kosten für den zusätzlichen Effekt unterhalb der Zahlungsbereitschaft des Kostenträgers für diesen zusätzlichen Effekt liegen (Briggs et al., 2002; O'Brien & Briggs, 2002). Zur Evaluation der Kosteneffektivität wurde in den letzten Jahren der Net Monetary Benefit (NMB) als statistisch robustester Parameter empfohlen (Briggs et al., 2002; Hoch et al., 2002; Stinnett & Mullahy, 1998). NMBs werden als Differenz zwischen den direkten Gesundheitskosten (C = costs) und dem klinischen Effekt (E = effect) unter Berücksichtigung der Zahlungsbereitschaft für eine gesteigerte Einheit dieses Effekts (willingness to pay, kurz: WTP) mit der Formel $NMB = WTP \times E - C$ berechnet (Stinnett & Mullahy, 1998). Ein Vergleich der Kosteneffektivität zweier Interventionsalternativen kann bei gegebenen, theoretischen Zahlungsbereitschaften mit Hilfe der inkrementellen Net Monetary Benefits (iNMB) evaluiert werden, indem die Differenz zwischen dem NMB der neuartigen Interventionsmaßnahme (NMB_{neu}) und dem NMB der bisherigen Versorgungsstruktur (NMB_{alt}) mit der Formel $iNMB = NMB_{neu} - NMB_{alt}$ berechnet wird (Hoch et al., 2002). Ein positiver iNMB deutet darauf hin, dass die neuartige Intervention im Vergleich zur bisherigen Versorgungsstruktur kosteneffektiver ist, was aus gesundheitsökonomischer Sicht zu einer Empfehlung für die Durchführung der neuartigen Interventionsalternative führt (Hoch et al., 2002). Kosteneffektivitätsanalysen von körperlichen Interventionen mit älteren Personen wurden bislang vornehmlich im Rahmen von Sturzpräventionsprogrammen durchgeführt (Matchar et al., 2019; McLean, Day, & Dalton, 2015). Das im Rahmen des HeikE-Projekts durchgeführte Trainingsprogramm stellt eine neuartige Interventionsalternative zur bestehenden Versorgungsstruktur dar. Im Zuge der vorliegenden Arbeit wurde der gesundheitsökonomische Nutzen dieses Trainingsprogramms zur Steigerung des Bewegungsverhaltens von multimorbiden älteren Personen mit kognitiven Einschränkungen, analysiert (→ Publikation VIII).

2 Ziele und Fragestellungen

Das HeikE-Projekt verfolgte das übergeordnete Ziel, poststationäre Versorgungsstrukturen nach geriatrischen Rehabilitationsmaßnahmen von kognitiv eingeschränkten Patienten zu verbessern. Basierend auf erfolgreichen Vorarbeiten der Forschungsabteilung des AGAPLESION Bethanien Krankenhauses in Heidelberg, wurde das HeikE-Projekt und die darin eingesetzte Intervention in Form einer RCT initiiert. Publikation I stellt ein ausführliches Studienprotokoll dar, in dem im Detail das Interventionskonzept sowie die umfassende Assessmentstrategie dargestellt werden, die im Rahmen des HeikE-Projekts zum Einsatz kamen.

Die Ziele der vorliegenden Dissertation bestehen darin, die Validität sensor- und fragebogenbasierter Messmethoden zu evaluieren, mit denen unterschiedliche Konstrukte des habituellen Bewegungsverhaltens von geriatrischen Patienten mit kognitiven Einschränkungen im Alltag erfasst werden. Darauf aufbauend wird deren Bewegungsverhalten unmittelbar nach Abschluss einer geriatrischen Rehabilitationsmaßnahme im Alltag gemessen. Potenzielle Determinanten des körperlichen Aktivitätsverhaltens sollen identifiziert und hinsichtlich ihres Einflusses auf das körperliche Aktivitätsverhalten analysiert werden. Abschließend wird sowohl unter klinischen als auch unter ökonomischen Gesichtspunkten evaluiert, ob eine Durchführung der HeikE-Intervention machbar und sinnhaft ist.

Aus den skizzierten Zielen leiteten sich Fragestellungen ab, die in der vorliegenden Dissertation auf der Grundlage der im Rahmen des HeikE-Projekts generierten Daten evaluiert wurden.

**Fragestellungen des Themenbereichs 1:
„Entwicklung innovativer Messmethoden zur Erfassung
des habituellen Bewegungsverhaltens“**

- Erfüllt das ambulante uSense-Sensorsystem relevante psychometrische Testgütekriterien zur Erfassung des habituellen körperlichen Aktivitätsverhaltens und habitueller Gangmuster bei geriatrischen Patienten mit kognitiven Einschränkungen? (Publikation II)

- Erfüllt das fragebogenbasierte Life-Space Assessment LSA-CI relevante psychometrische Testgütekriterien zur Erfassung der Life-Space Mobilität bei geriatrischen Patienten mit kognitiven Einschränkungen? (Publikation III)

Fragestellungen des Themenbereichs 2:
„Charakteristika und Determinanten des habituellen Bewegungsverhaltens“

- Welches Ausmaß an körperlicher Aktivität und welche Gangcharakteristika weisen geriatrische Patienten mit kognitiven Einschränkungen unmittelbar nach geriatrischen Rehabilitationsmaßnahmen im Alltag auf? (Publikation IV)

- Welche Faktoren sind wesentliche Determinanten des habituellen Bewegungsverhaltens geriatrischen Patienten mit kognitiven Einschränkungen unmittelbar nach geriatrischen Rehabilitationsmaßnahmen identifizierbar? Welchen Anteil leisten diese Determinanten bei der Erklärung des habituellen Bewegungsverhaltens? (Publikation IV)

- Welches Ausmaß hat die Life-Space-Mobilität von geriatrischen Patienten mit kognitiven Einschränkungen unmittelbar nach geriatrischen Rehabilitations-maßnahmen? (Publikation V)

- Welche Faktoren sind wesentliche Determinanten der Life-Space-Mobilität geriatrischer Patienten mit kognitiven Einschränkungen unmittelbar nach geriatrischen Rehabilitationsmaßnahmen identifizierbar? Welchen Anteil leisten diese Determinanten bei der Erklärung der Life-Space Mobilität? (Publikation V)

Fragestellungen des Themenbereichs 3:
„Durchführbarkeit, Effekte und Kosteneffektivität eines Heimtrainingsprogramms“

- Wie gut ist ein Heimtrainingsprogramm zur Steigerung der körperlichen Aktivität und zur Verbesserung der motorischen Leistungsfähigkeit bei geriatrischen Patienten mit kognitiven Einschränkungen durchführbar und wie hoch ist die Adhärenz an die Interventionskomponenten während der Trainingsphase? (Publikation VI)

- Welchen Effekt hat ein standarisiertes Heimtrainingsprogramm zur Steigerung der körperlichen Aktivität und zur Verbesserung der motorischen Leistungsfähigkeit bei geriatrischen Patienten mit kognitiven Einschränkungen auf das Ausmaß der Life-Space Mobilität? (Publikation VII)

- Ist ein standarisiertes Heimtrainingsprogramm zur Steigerung der körperlichen Aktivität und zur Verbesserung der motorischen Leistungsfähigkeit bei geriatrischen Patienten mit kognitiven Einschränkungen kosteneffektiv? (Publikation

3 Publikationsübersichten und Zusammenfassungen

3.1 Publikation I. Development of a home-based training program for post-ward geriatric rehabilitation patients with cognitive impairment: study protocol of a randomized-controlled trial

Martin Bongartz, Rainer Kiss, Phoebe Ullrich, Tobias Eckert, Jürgen Bauer, Klaus Hauer (2017). Development of a home-based training program for post-ward geriatric rehabilitation patients with cognitive impairment: study protocol of a randomized-controlled trial. *BMC Geriatrics, 17* (214). doi: 10.1186/s12877-017-0615-0

Hintergrund und Zielsetzung

Geriatrische Patienten mit kognitiven Einschränkungen weisen im Vergleich zu älteren Personen ohne kognitive Einschränkungen einen geringeren funktionellen Status (Zekry et al., 2008), Einschränkungen in Alltagsaktivitäten (Njegovan et al., 2001), ein erhöhtes Sturzrisiko (Lach et al., 2016), höhere Sterberaten (Poynter et al., 2011) sowie schlechtere Rehabilitationsoutcomes (Seematter-Bagnoud et al., 2013) auf und stellen daher ein besonders vulnerables Kollektiv dar, das unmittelbar von Institutionalisierung bedroht ist (Poynter et al., 2011). Demnach haben diese Patienten insbesondere nach Rehabilitationsmaßnahmen einen hohen Bedarf an Interventionsmaßnahmen, durch die die körperliche Leistungsfähigkeit sowie die körperliche Aktivität gesteigert und die Wahrscheinlichkeit einer selbstständigen Lebensführung erhöht werden. Das Projekt HeikE verfolgte das Ziel, ein sicher durchführbares und problemlos in die aktuelle Versorgungslandschaft integrierbares Heimtrainingsprogramm für geriatrische Patienten mit leichten bis mittleren kognitiven Einschränkungen unmittelbar nach Entlassung aus einer geriatrischen Rehabilitationsmaßnahme zu konzipieren und unter verschiedenen Gesichtspunkten zu evaluieren. Die Interventionsziele bestanden sowohl aus einer Verbesserung der körperlichen Leistungsfähigkeit, als auch aus einer Steigerung des Bewegungsverhaltens im Sinne der körperlichen Aktivität. Auf der Basis des theoretischen Rahmenkonzepts nach Abraham & Michie (2008) wurden BCTs in das Interventionskonzept integriert, um eine gesteigerte Motivation der Teilnehmer für die Modifizierung des Bewegungsverhaltens zu erreichen.

Methoden

Das Projekt wurde gemäß der CONSORT Richtlinien nach Moher et al. (2012) in Form eines verblindeten, randomisierten kontrollierten Studiendesigns mit Intervention- und Kontrollgruppe unter Berücksichtigung der ethischen Grundsätze der Deklaration von Helsinki durchgeführt. Einschlusskriterien waren die Entlassung aus einer geriatrischen Rehabilitationsmaßnahme, ein Alter von ≥ 65 Jahren, leichte bis moderate kognitive Einschränkungen (Mini-Mental State Examination, MMSE 17 – 26), eine Gehfähigkeit von mindestens 4 m ohne Gehhilfe sowie die schriftliche Zustimmung zur Teilnahme durch den Patienten oder dessen gesetzlichen Vertreter/Betreuungsperson. Von einer Studienteilnahme ausgeschlossen wurden Patienten, die nicht ins häusliche Umfeld entlassen wurden, eine terminale Erkrankung oder ein Delir aufwiesen. Teilnehmer der Interventionsgruppe führten ein standardisiertes zwölfwöchiges Training im häuslichen Umfeld der Teilnehmer durch. Das Programm zielte darauf ab, die körperliche Leistungsfähigkeit und das körperliche Aktivitätsverhalten unter Berücksichtigung der zielgruppenspezifischen Charakteristika zu steigern. Der Trainer vermittelte das Programm in fünf Hausbesuchen und begleitete den Trainingsprozess durch wöchentliche Anrufe. Die Trainingsinhalte bestanden aus funktionellen Übungen zur Verbesserung der statischen und dynamischen posturalen Kontrolle, zur Kräftigung der unteren Extremitäten und individuellen, in Kooperation mit dem Trainer definierten Gehstrecken. Die Teilnehmer sollten zu einer selbstständigen, täglichen Ausführung der Trainingsinhalte befähigt und motiviert werden. Das Motivationskonzept bestand aus der sozialen Interaktion zwischen dem Teilnehmer und dem Trainer, Zielsetzung sowie aus dem Einsatz unterschiedlicher Trainingsmaterialen, die den Teilnehmern zur Verfügung gestellt wurden. Das Benutzung der Trainingsmaterialien (u.a. Trainingsposter, Trainingstagebuch, Schrittzähler) wurde vom Trainer vermittelt, um die Studienteilnehmer zur Eigenkontrolle („Self-Monitoring“) des persönlichen Trainingsverlaufs zu befähigen. Dadurch sollten die Teilnehmer den Trainingsprozess als wahrnehmbar und kontrollierbar erleben. Die Kontrollgruppe wurde über unspezifische Mobilitätsübungen informiert und erhielt ebenfalls fünf Hausbesuche und wöchentliche Anrufe durch den Trainer, um einen Einfluss durch die soziale Unterstützung auszuschließen. Primäre Studienendpunkte waren die körperliche Leistungsfähigkeit (Short Physical Performance Battery, kurz: SPPB) und die körperliche Aktivität, die über 48 Stunden sensorbasiert im Alltag der Teilnehmer erfasst wurde. Sekundäre Studienendpunkte waren fragebogenbasierte Erfassungen von Stürzen, Gesundheitskosten und die LSM sowie psychosoziale, motorische und funktionelle Parameter, die fragebogenbasiert und mittels motorischer Tests erhoben wurden. Verblindete Assessoren führten die Datenerhebungen zu drei Messzeitpunkten vor Beginn der Intervention, unmittelbar nach Beendigung der Interventionsphase und zwölf Wochen nach Abschluss der Interventionsphase im häuslichen Umfeld der Teilnehmer durch. Die anschließende Analyse der Daten erfolgte nach dem *intention-to-treat-Ansatz*.

Diskussion

Dies ist die erste RCT, in der die Effekte eines Heimtrainingsprogramms auf die körperliche Leistungsfähigkeit sowie das körperliche Aktivitätsverhalten bei geriatrischen Patienten mit kognitiven Einschränkungen in der Übergangsphase von der Rehabilitationsmaßnahme in das häusliche Umfeld evaluiert werden. In dieser sensiblen Versorgungsphase sind die Patienten unmittelbar und hochgradig von einem Verlust der Selbstständigkeit und damit von Pflegeheimeinweisungen bedroht, was die Notwendigkeit von gezielten Interventionsmaßnahmen zur Steigerung selbstständiger Aktivitäten verdeutlicht. Im Gegensatz zu unserer Studie inkludierten bisherige Heimtrainingsstudien, die in dieser Versorgungsphase durchgeführt wurden, lediglich Subgruppen von Patienten mit kognitiven Einschränkungen und waren auf die Untersuchung funktioneller Endpunkte fokussiert (Moseley et al., 2009; Sherrington et al., 2014; Shyu et al., 2012). Effekte auf Parameter des körperlichen Aktivitätsverhaltens wurden in diesen Studien nicht untersucht. Heimtrainingsprogramme mit kognitiv eingeschränkten Personen, in denen die körperliche Aktivität untersucht wurde, nutzten fragebogenbasierte Instrumente und fanden nicht in der Übergangsphase von einer Rehabilitationsmaßnahme in das häusliche Umfeld statt (Steinberg, Leoutsakos, Podewils, & Lyketsos, 2009; Suttanon et al., 2013; Wesson et al., 2013), wodurch sich diese Studien ebenfalls von unserer Studie unterschieden. Diese Studien waren auf die Verbesserung funktioneller Parameter und nicht auf Verhaltensmodifikationen im Sinne einer Steigerung der körperlichen Aktivität fokussiert. Keine der genannten Heimtrainingsstudien integrierte eine theoriebasierte Strategie, um die intrinsische

Motivation und die Selbstregulation hinsichtlich körperlicher Aktivität zu steigern. Die vorliegende Studie ermöglicht innovative Einblicke in die Effekte eines speziell an die Teilnehmer angepassten Heimtrainingsprogramms auf die körperliche Leistungsfähigkeit und das sensorbasiert erfasste körperliche Aktivitätsverhalten, bei unmittelbar von Institutionalisierung bedrohten, geriatrischen Patienten mit kognitiven Einschränkungen.

3.2 Publikation II. Validity, reliability, and feasibility of the uSense activity monitor to register physical activity and gait performance in habitual settings of geriatric patients

Martin Bongartz, Rainer Kiss, André Lacroix, Tobias Eckert, Phoebe Ullrich, Carl-Philipp Jansen, Manuel Feißt, Sabato Mellone, Lorenzo Chiari, Clemens Becker, Klaus Hauer (2019). Validity, reliability, and feasibility of the uSense activity monitor to register physical activity and gait performance in habitual settings of geriatric patients. *Physiological Measurement, 40* (9). doi: 10.1088/1361-6579/ab42d3

Hintergrund und Zielsetzung

Kognitive Einschränkungen sind mit motorischen Defiziten assoziiert und führen bei älteren Personen zu spezifischen, habituellen Bewegungsmustern, bei deren Messung bisherige ambulante Sensorsysteme methodische Mängel im Sinne von hohen Messungenauigkeiten aufweisen (McCullagh, Brady, Dillon, Horgan, & Timmons, 2016). Die valide und reliable Erfassung des habituellen Bewegungsverhaltens älterer Personen mit kognitiven Einschränkungen setzt demnach die Entwicklung ambulanter Sensorsysteme voraus, die speziell für die Erfassung dieser Bewegungsmuster adjustiert sind. Darüber hinaus müssen die Messgütekriterien dieser Sensorsysteme als hinreichend nachgewiesen worden sein (McCullagh et al., 2016). Bei der Evaluation der Messgütekriterien muss darüber hinaus das Messsetting berücksichtigt werden. Zahlreiche Studien haben nachgewiesen, dass Bewegungen, die unter supervidierten Laborbedingungen ausgeführt werden, in der Regel dem Optimum der Bewegungsausführung entsprechen und damit deutlich von den Bewegungen im habituellen

Setting abweichen (Brodie et al., 2016; Urbanek et al., 2018). Die Validität ambulanter Sensorsysteme zur Messung des Bewegungsverhaltens von multimorbiden, älteren Personen wurde bislang nur in vereinzelten Studien im habituellen Setting überprüft (Dijkstra, Kamsma, & Zijlstra, 2010; Hollewand et al., 2016; L. M. Taylor et al., 2014). In diesen Studien wurde die Übereinstimmung zwischen den generierten Parametern der ambulanten Sensorsysteme mit direkten Beobachtungen oder Videoaufnahmen auf zeitlich und räumlich begrenzten, definierten Gehstrecken überprüft, wodurch ein habituelles Bewegungsverhalten durch die Probanden verhindert wurde. Das Ziel von Manuskript II besteht in der Überprüfung der Validität, Reliabilität und Durchführbarkeit von Messungen des körperlichen Aktivitätsverhaltens und innovativer, quantitativer Gangparameter im habituellen Setting älterer Personen mit kognitiven und motorischen Einschränkungen durch das ambulante Sensorsystem uSense.

Methoden

Diese Validierungsstudie basierte auf Baseline-Querschnittsdaten der RCT *HeikE* (siehe Kap. 3.1). Für die Erfassung des habituellen Bewegungsverhaltens kamen die ambulanten Sensorsysteme uSense und PAMSys simultan zum Einsatz. Die Teilnehmer trugen die Sensoren über einen Zeitraum von 48 Stunden im Alltag, wobei der zu validierende uSense-Sensor am unteren Rücken und der PAMSys-Sensor am Sternum befestigt wurde. Im Gegensatz zum PAMSys-Sensorsystem erfasst der uSense-Sensor neben etablierten Parametern der körperlichen Aktivität zusätzlich Gangparameter des Geradeaus Gehens (z.B. Schrittregelmäßigkeit, Gangsymmetrie) sowie des Kurvengehens (z.B. Winkelgeschwindigkeit, Drehwinkel). Die Validität des uSense-Sensorsystems wurde mittels Übereinstimmungs- und Konstruktvalidität geprüft. Zur Beurteilung der Übereinstimmungsvalidität wurden Bland-Altman-Plots und bivariate Korrelationen zwischen den uSense-Parametern und identischen Parametern, die zeitgleich mit dem Vergleichssystem PAMSys generiert wurden, berechnet. Die Kongruenz hypothesenbasierter, theoretischer Zusammenhänge zwischen körperlichen Aktivitäts- und Gangparametern und Parametern von klinisch relevanten Konstrukten (u.a. körperliche Leistungsfähigkeit, LSM, psychosozialer Status) wurde zur Evaluation der Konstruktvalidität genutzt. Zur Überprüfung der Test-Retest Reliabilität wurde die absolute Übereinstimmung von uSense-Parametern, die an zwei aufeinander folgenden Tagen bei identischen Personen gemessen wurden, mittels

Intraklassen-Korrelationskoeffizienten ($ICC_{3,1}$: absolute Übereinstimmung) berechnet. Die Erfassung der prozentualen Anteile der fehlerfrei durchgeführten Messungen sowie der Abbruchraten aus patientenbedingten oder technischen Gründen, wurden für die Beurteilung der Durchführbarkeit genutzt.

Ergebnisse

Es wurden 110 geriatrische Patienten mit kognitiven und motorischen Einschränkungen in die Studie eingeschlossen. Die Auswertung von 16 uSense-Messungen war fehlerhaft, sodass die Analysen auf 94 vollständigen Datensätzen basierten. Die Korrelationskoeffizienten zwischen identischen Parametern, die mit den Sensorsystemen PAMSys und uSense gemessen wurden, waren hoch (r = 0,59 – 0,91). Bland-Altman-Plots deuteten jedoch auf absolute Unterschiede zwischen den Parametern beider Sensorsysteme hin. Diese Unterschiede zeigten sich in Form linearer Zusammenhänge zwischen den Mittelwerten und den Differenzen der Parameter beider Sensorsysteme. Die Konstruktvalidität der uSense-Parameter wurde bei körperlichen Aktivitätsparametern und bei quantitativen Gangparametern des Kurvengehens nahezu vollständig und bei quantitativen Gangparametern des Geradeaus Gehens in Teilen nachgewiesen. Es zeigte sich eine moderate bis exzellente Test-Retest-Reliabilität (ICC-Range: 0,68 – 0,97) und der Anteil der fehlerfreien, vollständigen Messung wies mit 85,5 % eine gute Durchführbarkeit auf.

Diskussion

Die Ergebnisse belegen eine moderate bis gute psychometrische Messqualität des uSense-Sensorsystems bei der Erfassung von körperlichem Aktivitätsverhalten und innovativen, quantitativen Gangparametern, die erstmals im habituellen Setting von älteren Personen mit kognitiven und motorischen Einschränkungen nachgewiesen werden konnte. Im Gegensatz zu den meisten bisherigen Validierungsstudien berücksichtigten wir durch die Überprüfung der Konstruktvalidität den Umstand, dass aktuell kein Messsystem existiert, das den Gold-Standard für ambulante Messungen im habituellen Setting darstellt und als Vergleichssystem herangezogen werden könnte (B. Ainsworth et al., 2015). Die absoluten Unterschiede und die systematischen Bias in Form linearer Zusammenhänge zwischen den Mittelwerten und den Differenzen, die bei der Messung identischer Parameter der körperlichen Aktivität durch die Sensorsysteme uSense und PAMSys identifiziert wurden, deuten auf eine höhere Sensitivität des uSense-Systems im Vergleich zum PAMSys-System im Sinne der Schrittdetektion hin. Eine sensitive Schrittdetektion war ein Ziel bei der Entwicklung des uSense-Sensorsystems, um die niedrige Messgenauigkeiten bei der Messung langsamer Gehgeschwindigkeiten bisheriger Sensorsysteme zu überwinden (Hollewand et al., 2016; McCullagh et al., 2016). Bei der Interpretation der Absolutwerte beider Systeme weisen die vom uSense-System erfassten Parameter (z.B. Kadenz, Metabolische Äquivalente) eine höhere Plausibilität auf, als die gleichen, vom PAMSys-System erfassten Parameter (B. E. Ainsworth et al., 1993; Tudor-Locke et al., 2018). Die im Rahmen der Konstruktvalidität überprüften Hypothesen zeigten vereinzelt Unterschiede zwischen Korrelationen, die in epidemiologischen Studien festgestellt wurden und denen in unserer Studie identifizierten Zusammenhängen mit uSense Parametern. Der überwiegende Teil der Hypothesen konnte jedoch bestätigt werden. Die Test-Retest-Reliabilität des uSense-Systems zeigte ein vergleichbar gutes Ergebnis wie eine Studie, in der das Sensorsystem Step Watch bei älteren, funktionell eingeschränkten, kognitiv intakten Personen getestet wurde (Mudge & Stott, 2009). Demnach deuten unsere Ergebnisse darauf hin, dass sensorbasierte Aktivitätsmessungen auch bei kognitiv eingeschränkten, älteren Personen reliabel durchführbar sind. Insgesamt wurde im habituellen Setting von älteren Personen mit kognitiven und motorischen Einschränkungen nachgewiesen, dass das uSense-Sensorsystem Parameter des körperlichen Aktivitätsverhaltens und quantitative Gangparameter mit moderater bis guter Konstruktvalidität, hoher Test-Retest-Reliabilität und guter Durchführbarkeit misst. Dadurch werden erstmals innovative Einblicke in das habituelle Bewegungsverhalten dieser vulnerablen Personengruppe ermöglicht.

3.3 Publikation III. Validation of a modified Life-Space Assessment in multimorbid older persons with cognitive impairment

Phoebe Ullrich, Christian Werner, **Martin Bongartz**, Rainer Kiss, Jürgen Bauer, Klaus Hauer (2019). Validation of a Modified Life-Space Assessment in Multimorbid Older Persons with Cognitive Impairment. *Gerontologist, 59* (2), e66–e75. doi:10.1093/geront/gnx214

Hintergrund und Zielsetzung

Der Life-Space umschreibt die räumliche Ausdehnung der multifaktoriellen Mobilität (Webber et al., 2010) einer Person in Zonen, die von der eigenen Wohnung bis über die Grenzen des Heimatortes hinaus gehen (May et al., 1985). Die ersten Messungen des Life-Space waren auf die Quantifizierung der räumlichen Ausdehnung der Mobilität beschränkt (May et al., 1985). Im weiteren Verlauf wurden die Instrumente zur Erfassung des Life-Space älterer Menschen weiterentwickelt. Die größte Verbreitung erfuhr das University of Alabama at Birmingham Study of Aging Life-Space Assessment (UAB-LSA), in dem neben der räumlichen Ausdehnung der Mobilität auch die Frequenz, in der die Life-Space Zonen erreicht wurden, und die dabei in Anspruch genommenen Hilfestellungen erfasst wurden (Baker et al., 2003). Dieser Fragebogen wurde speziell für ältere Personen ohne kognitive Einschränkungen entwickelt und in dieser Personengruppe validiert (Baker et al., 2003). Das UAB-LSA wurde in Studien eingesetzt, in die Subgruppen von kognitiv eingeschränkten, älteren Personen eingeschlossen wurden (Al Snih et al., 2012; Fairhall et al., 2012; Silberschmidt et al., 2017), obwohl das UAB-LSA weder an die speziellen Einschränkungen kognitiv eingeschränkter Personen adaptiert, noch in dieser Zielgruppe validiert wurde. Ungenauigkeiten von Selbstauskünften und Erinnerungsprobleme sind bei kognitiv eingeschränkten, älteren Personen üblich und erfordern adäquate Adaptionen von Fragebögen (Shephard, 2003). Das Ziel von Manuskript III bestand deshalb darin, eine zielgruppenspezifisch modifizierte Version des UAB-LSA, das Life-Space Assessment für Personen mit kognitiven Einschränkungen (Kurz: LSA-CI, „Life-Space Assessment for Persons with Cognitive Impairment“) in der Zielgruppe älterer, multimorbider Personen mit kognitiven Einschränkungen zu validieren.

Methoden

Im Vergleich zum UAB-LSA weist der LSA-CI einen verkürzten Abfragezeitraum von vier auf eine Woche und spezielle Techniken der Interviewführung zur Reduktion von Erinnerungsproblemen von kognitiv eingeschränkten Personen auf (Hauer et al., 2011). Analog zum UAB-LSA wurden beim LSA-CI neben dem Life-Space Gesamtscore, Sub-Scores zum maximal erreichte Life-Space mit und ohne Hilfsmittel/ Hilfspersonen erfasst. Diese Validierungsstudie wurde im Rahmen der RCT *HeikE* (siehe Kap. 3.1) durchgeführt. Mittels standardisierter, interviewbasierter Fragebögen wurden die Kognition, psychosoziale Parameter, Stürze und Sturzangst erfasst. Die körperliche Leistungsfähigkeit wurde anhand etablierter motorischer Tests (Short Physical Performace Battery, Timed Up and Go-Test) gemessen. Parameter des körperlichen Aktivitätsverhaltens und der räumlichen Ausdehnung von Outdoor-Aktivitäten wurden durch den Einsatz von Akzelerometer- und GPS-basierter, ambulanter Sensorsysteme in einer 48 stündigen Messung im Alltag der Teilnehmer erhoben. Zur Evaluation der Konstruktvalidität wurden Korrelationen zwischen den LSA-CI-Scores und klinisch relevanten oder inhaltlich verwandten Konstrukten (kognitiver Status, psychosoziale Parameter, Stürze, Sturzangst, körperliche Aktivität, Outdooraktivität und körperliche Leistungsfähigkeit) berechnet. Die Test-Retest-Reliabilität wurde durch $ICC_{3,1}$ zwischen zwei LSA-CI Messungen an aufeinander folgenden Tagen ermittelt. Zur Überprüfung der Veränderungssensitivität wurden durch t-tests und Standardized Response Mean (SRM) Veränderungen der LSA-CI Scores zwischen Baseline-Messungen (T1) und Post-Messungen (T2) überprüft. Die Beurteilung der Durchführbarkeit erfolgte anhand von Analysen des Anteils vollständig durchgeführter Messungen sowie Boden- und Deckeneffekten.

Ergebnisse

Es wurden 118 geriatrische Patienten mit kognitiven und motorischen Einschränkungen in die Studie eingeschlossen. Die Prüfung der Konstruktvalidität zeigte moderate bis hohe Korrelationen zwischen den LSA-CI-Scores und der körperlichen Leistungsfähigkeit (r = 0,27 – 0,56), der Sturzangst (r = $|0{,}24 – 0{,}44|$) sowie der körperlichen Aktivität (r = 0,23 – 0,63). Wiederholte Messungen an aufeinander folgenden Tagen wiesen hohe Übereinstimmungen auf, die eine gute bis exzellente Test-Retest-

Reliabilität (ICC-Range: 0,65 – 0,91) belegten. Bei allen LSA-CI-Scores zeigten sich nach der zwölfwöchigen Intervention signifikante Steigerungen im Vergleich zu den Baseline-Messungen. Ein hoher SRM wurde jedoch nur bei dem LSA-CI Gesamtscore (LSA-CI-C) festgestellt (SRM = 0,80). Sowohl ausbleibende Boden- und Deckeneffekte, als auch der hohe Anteil vollständig durchgeführter Messungen deuteten auf eine gute Durchführbarkeit des LSA-CI hin.

Diskussion

Im Vergleich zur Originalversion des Fragebogens ergaben sich ähnliche Korrelationen zwischen dem LSA-CI und klinisch relevanten Konstrukten wie der körperlichen Leistungsfähigkeit (Baker et al., 2003). Unterschiede zu Baker et al. (2003) zeigten sich bei depressionsbezogenen Parametern, die in unserer Stichprobe nicht im Zusammenhang mit der LSM standen. Unsere Ergebnisse zeigten hohe Korrelationen zwischen LSA-CI-Scores und Parametern des körperlichen Aktivitätsverhaltens und waren konsistent mit Studienergebnissen bei gesunden älteren Personen (Portegijs, Tsai, Rantanen, & Rantakokko, 2015; Tsai et al., 2015), wodurch die Konstruktvalidität insgesamt bestätigt wurde. Äquivalent zu der in unserer Studie nachgewiesenen guten Test-Retest-Reliabilität wurde für den UAB-LSA eine vergleichbare Test-Retest-Reliabilität bei kognitiv intakten älteren Personen nachgewiesen (Baker et al., 2003; Portegijs, Iwarsson, Rantakokko, Viljanen, & Rantanen, 2014). Der hohe SRM und eine signifikante Steigerung von der Baseline- zur Postmessung machen deutlich, dass der LSA-CI-C änderungssensitiv ist. Es wurde eine gute Durchführbarkeit des LSA-CI, ohne Boden- oder Deckeneffekte des Gesamtscores, festgestellt. Durch Manuskript IV konnte nachgewiesen werden, dass der LSA-CI als valides, reliables, veränderungssensitives Instrument eingesetzt werden kann, um das breite Spektrum der LSM von älteren Personen mit kognitiven Einschränkungen zu erfassen.

3.4 Publikation IV. Will we do if we can? Habitual qualitative and quantitative physical activity in multi-morbid, older persons with cognitive impairment

Bastian Abel*, **Martin Bongartz***, Tobias Eckert, Phoebe Ullrich, Rainer Beurskens, Sabato Melone, Jürgen M. Bauer, Sallie E. Lamb, Klaus Hauer. Will we do if we can? Habitual Qualitative and Quantitative Physical Activity in Multi-morbid, Older Persons with Cognitive Impairment.

Zur Publikation eingereicht bei der *Sensors*.

(*Bastian Abel und Martin Bongartz teilen Erstautorenschaft)

Hintergrund und Zielsetzung

Hohes Alter und kognitive Einschränkungen sind mit einer verringerten körperlichen Leistungsfähigkeit und einem reduzierten habituellen körperlichen Aktivitätsverhalten assoziiert (Aboutorabi, Arazpour, Bahramizadeh, Hutchins, & Fadayevatan, 2016; Sun, Norman, & While, 2013; van Alphen et al., 2016). Eine geringe körperliche Aktivität ist wiederum mit einer Vielzahl von negativen Gesundheitsfaktoren, wie beispielsweise motorischen Einschränkungen, Stürzen, psychosozialen Problemen und einem erhöhten Mortalitätsrisiko assoziiert (Kressig, Herrmann, Grandjean, Michel, & Beauchet, 2008; Trayers et al., 2014). Daher ist eine Beibehaltung oder Steigerung des habituellen körperlichen Aktivitätsverhaltens bei älteren Personen mit kognitiven Einschränkungen besonders wichtig, um den dargestellten negativen Gesundheitsfaktoren entgegen zu wirken. Kognitive Einschränkungen führen zu spezifischen Veränderungen von Gangparametern (Bahureksa et al., 2017) und zu einem verringerten habituellen körperlichen Aktivitätsverhalten (van Alphen et al., 2016). Die Determinanten des habituellen Bewegungsverhaltens von älteren Personen mit kognitiven und motorischen Einschränkungen sind bislang nur unzureichend erforscht. Das Ziel dieser Studie bestand darin, einen neuartigen Einblick in das habituelle Bewegungsverhalten von älteren Personen mit kognitiven und motorischen Einschränkungen zu generieren und zu untersuchen, inwiefern etablierte Parameter, wie die körperliche Leistungsfähigkeit und gesundheitsbezogene Variablen sowie darüber hinaus habituelle Gangparameter, potenzielle Determinanten des habituellen körperlichen Aktivitätsverhaltens darstellen.

Methoden

Die Analysen basieren auf Baseline-Daten der RCT *HeikE*. Neben der Erfassung demographischer Variablen (Alter, Geschlecht), wurden gesundheitsbezogene Variablen (Pflegegrad, Medikation, psychosoziale und sturzassoziierte Fragebögen) und Parameter der körperlichen Leistungsfähigkeit (u.a. SPPB, Timed-Up and Go-Test) erfasst. Bewegungsparameter wurden in einer 48-stündigen, sensorbasierten Messung im Alltag der Studienteilnehmer erfasst. Zu diesen gehörten quantitative Parameter des habituellen körperlichen Aktivitätsverhaltens, gemessen als Dauer, Frequenz und Intensität des Gehens sowie der körperlichen Gesamtaktivität. Darüber hinaus wurden Gangparameter als zeitliche Parameter des Geradeausgehens (Gangvariabilität, Schrittregelmäßigkeit, Gangsymmetrie) sowie des Kurvengehens (Drehgeschwindigkeit, Drehwinkel) erfasst. Hierzu kam ein ambulantes Bewegungssensorsystem zum Einsatz, dessen Validität, Test-Retest Reliabilität und Durchführbarkeit bereits im habituellen Setting von multimorbiden, älteren Personen mit kognitiven Einschränkungen nachgewiesen wurde und dadurch insbesondere Ganganalysen im habituellen Setting ermöglicht (siehe Publikation II) (Bongartz et al., 2019). Deskriptive Werte wurden in Abhängigkeit von den jeweiligen Skalenniveaus und Variablenarten als Mittelwert ± Standardabweichungen (SD), Median und Interquartil-Range (IQR) oder Prozentangaben dargestellt. Durch univariate Regressionsanalysen konnten potenzielle Determinanten der abhängigen, quantitativen Parameter des habituellen körperlichen Aktivitätsverhaltens (Dauer, Frequenz, Intensität und körperliche Gesamtaktivität) identifiziert werden. Die unabhängigen Variablen stellten zum einen etablierte Parameter der Kategorien 1) demographische Variablen, 2) gesundheitsbezogene Variablen und 3) Variablen der körperlichen Leistungsfähigkeit, zum anderen innovative, habituelle Gangparameter der Kategorien 4) Gangvariabilität, 5) Schrittregelmäßigkeit, 6) Gangsymmetrie und 7) Gangmerkmale während des Kurvengehens dar. Aus jeder dieser sieben Kategorien wurde jeweils diejenige Variable ermittelt, die nach den Ergebnissen der univariaten Regressionsanalysen den höchsten, signifikanten Regressionskoeffizienten und damit den stärksten Zusammenhang mit den abhängigen Variablen aufwies. Die jeweils ausgewählten Parameter wurden anschließend als unabhängige Variablen in multiple Regressionsmodelle eingeschlossen, um potenzielle Determinanten für jede einzelne Dimension des quantitativen habituellen körperlichen Aktivitätsverhaltens, sowie der körperlichen Gesamtaktivität zu identifizieren.

Ergebnisse

Auf der Basis von 94 sensorbasierten Messungen, die vollständig über 48 Stunden durchgeführt wurden, wiesen die Studienteilnehmer ein zu erwartendes, deutlich reduziertes, körperliches Aktivitätsniveau auf (43,0 ± 2,4 Std. [89,6 %] inaktives Verhalten vs. 5,0 ± 2,4 Std. [10,4 %] aktives Verhalten). Sowohl die Kadenz (74 ± 7 Schritte/Minute), als auch die durchschnittliche Schrittdauer (0,72 Sek., IQR 0,68 – 0,79) implizierten eine langsame habituelle Ganggeschwindigkeit. Aus den Ergebnissen der multiplen Regressionsanalysen wurde ersichtlich, dass lediglich die innovativen zeitlichen Gangparameter des Geradeaus- und des Kurvengehens in allen Regressionsmodellen als unabhängige Determinanten der unterschiedlichen Dimensionen des körperlichen Aktivitätsverhaltens identifiziert wurden. Lediglich die Dauer der körperlichen Aktivität wurde von einer etablierten Variablen der körperlichen Leistungsfähigkeit (SPPB-Gesamtscore) determiniert. In den Regressionsmodellen verblieben weder etablierte demographische, noch gesundheitsbezogene Parameter als unabhängige Determinanten der körperlichen Aktivitätsdimensionen. Die Regressionsmodelle wiesen mit adjustierten R^2 von 0,40 – 0,68 hohe Varianzaufklärungen der abhängigen Variablen auf, wobei zeitliche Parameter des Kurvengehens (durchschnittliche und maximale Winkelgeschwindigkeit) in allen Regressionsmodellen die höchsten ß-Werte (0,35 – 0,80) zeigten.

Diskussion

Die Ergebnisse zeigen, dass ältere Personen mit kognitiven Einschränkungen ein niedriges Ausmaß an körperlicher Aktivität aufweisen. Dies bestätigt die Ergebnisse von Studien, die bei älteren Personen mit demenzieller Entwicklung durchgeführt wurden (Hartman, Karssemeijer, van Diepen, Olde Rikkert, & Thijssen, 2018; van Alphen et al., 2016). Bisherige Studien haben gezeigt, dass Gangparameter beim Geradeaus- und insbesondere beim Kurvengehen bei älteren Personen einen hohen prädiktiven

Wert für die Entstehung von Stürzen haben (Leach, Mellone, Palumbo, Bandinelli, & Chiari, 2018; Mancini, Schlueter, et al., 2016; van Schooten et al., 2015; Weiss et al., 2013). Erste Studien deuten darauf hin, dass spezifischen, unter Laborbedingungen gemessenen Gangparameter mit dem körperlichen Aktivitätsverhalten von älteren Personen assoziiert sind (Ciprandi et al., 2017; Dawe et al., 2018). Unsere Analysen deuten darauf hin, dass auch habituelle Gangparameter wesentlichen Einfluss auf das körperliche Aktivitätsverhalten von älteren Personen mit motorischen und kognitiven Einschränkungen haben. Im Gegensatz zu den Ergebnissen von Dawe et al. (2018) und Ciprandi et al. (2017) machen unsere Ergebnisse deutlich, dass unter habituellen Bedingungen Gangparameter des Geradeaus-, insbesondere aber des Kurvengehens (durchschnittliche und maximale Winkelgeschwindigkeit), Hauptdeterminanten des körperlichen Aktivitätsverhaltens von älteren Personen mit motorischen und kognitiven Einschränkungen darstellen. Demographische und gesundheitsbezogene Variablen haben hingegen keinen Effekt, die körperliche Leistungsfähigkeit hat lediglich einen geringen Aufklärungswert für das habituelle körperliche Aktivitätsverhalten.

3.5 Publikation V. Life-space mobility in older persons with cognitive impairment after discharge from geriatric rehabilitation

Phoebe Ullrich, Tobias Eckert, **Martin Bongartz**, Christian Werner, Rainer Kiss, Jürgen M. Bauer, Klaus Hauer (2019). Life-space mobility in older persons with cognitive impairment after discharge from geriatric rehabilitation. *Archives of Gerontology and Geriatrics, 81*, 192–200. doi: 10.1016/j.archger.2018.12.007

Hintergrund und Zielsetzung

In einem umfassenden, theoretischen Rahmenkonzept nach Webber et al. (2010) wird dargestellt, dass die LSM sowohl von persönlichen (z.B. physische und psychische Gesundheit) als auch von umweltbezogenen (z.B. Umgebung oder Kultur) Faktoren abhängt. Personen, die einen anhaltenden Verlust der selbstständigen Mobilität erfahren haben, erlangen diese nur mit geringer Wahrscheinlichkeit wieder (Gill et al., 2012). Darüber hinaus weisen diese Personen eine erhöhte Sterblichkeitsrate auf (Gill et al., 2012). Möglichst detaillierte Kenntnisse über LSM und deren Determinanten in spezifische Personengruppen sind demnach erforderlich, um gefährdete Personen frühzeitig identifizieren und deren Risiko reduzieren zu können. Bei gesunden älteren Personen wurde festgestellt, dass vor allem Parameter der körperlichen Leistungsfähigkeit (Kraft der oberen und unteren Extremitäten) entscheidende Determinanten der LSM sind (Al Snih et al., 2012). Der Fokus bisheriger Studien zur Erfassung der LSM lag auf der Zielgruppe älterer Personen ohne gesundheitliche Einschränkungen, wohingegen ältere Personen, die durch motorische und kognitive Einschränkungen in besonderem Maße von Einschränkungen der LSM gefährdet sind, bislang nur vereinzelt in Studien eingeschlossen wurden. In diesen Studien wurde die LSM von älteren Personen mit kognitiven Einschränkungen auf der Basis von Fragebögen (Uemura et al., 2013) und sensorbasiert mittels GPS-Technik (Tung et al., 2014) untersucht, ohne detaillierte Einblicke in die Frequenz oder die Inanspruchnahme von Hilfsmitteln/ Hilfspersonen zu erfassen. Eine mögliche Ursache für die geringe Anzahl an Studien zur Evaluation der LSM bei älteren Personen mit kognitiven Einschränkungen kann darin bestehen, dass erst seit der in Kapitel 3.3 dargestellten Validierung des LSA-CI ein zielgruppenspezifisch validiertes Messinstrument zur Erfassung der LSM zur Verfügung steht. Das Ziel dieser Studie bestand deshalb darin die LSM von Patienten mit kognitiven Einschränkungen nach geriatrischer Rehabilitation zu erfassen und potenzielle Determinanten der LSM zu identifizieren.

Methoden

Diese Studie basiert auf Baseline-Daten der RCT *HeikE* (siehe Kap. 3.1). Die LSM wurde fragebogenbasiert mit dem LSA-CI erfasst. Durch den Einsatz des LSA-CI wurden neben dem LSA-CI-C (Range: 0 – 90; 0= vollständig eingeschränkte LSM (Bettlägerigkeit) bis 90= tägliches, selbstständiges Verlassen des Wohnortes/der Stadt), folgende LSA-CI-Subscores erfasst (Range Subscores: 0 – 5): maximal erreichte Life-Space Zone mit Hilfsmittel und mit Hilfsperson (maximum life-space, kurz: LSA-CI-M); maximal erreichte Life-Space Zone mit Hilfsmittel aber ohne Hilfsperson (maximum life-space with equipment, kurz: LSA-CI-E) und die maximal erreichte Life-Space Zone ohne Hilfsmittel und ohne Hilfsperson (maximum independent life-space, kurz: LSA-CI-I). Darüber hinaus wurden neuartige Parameter generiert, mit denen potentielle Erweiterungen der Life-Space-Zonen ermittelt wurden, die durch die

Unterstützungen durch Hilfspersonen und/ oder Hilfsmittels berechnet wurden. Deskriptive Daten wurden als Mittelwerte ± Standardabweichung oder prozentuale Anteile der gesamten Stichprobe ermittelt. Die Auswahl potentieller Determinanten der LSM in Form des LSA-CI-C erfolgte gemäß des theoretischen Rahmenkonzepts nach Webber et al. (2010). Die ausgewählten Parameter wurden mittels etablierter Messmethoden erfasst. Zunächst wurden bivariate Korrelationen zwischen den potenziellen Determinanten und dem LSA-CI-C berechnet. Anschließend wurden Parameter, die signifikant mit der abhängigen Variable LSA-CI-C korrelierten, als erklärende, unabhängige Variablen in multiple, lineare Regressionsmodelle eingeschlossen, um die Determinanten der LSM zu identifizieren.

Ergebnisse

Es wurden 118 geriatrische Patienten mit kognitiven und motorischen Einschränkungen in die Studie eingeschlossen. Diese wiesen einen Mittelwert des LSA-CI -C von 23,9 ± 13,2 (Range: 0 - 90) auf. Die Analyse der LSA-CI Subscores zeigte, dass 49,6 % der Probanden ein Hilfsmittel oder eine Hilfsperson benötigten, um das Bett zu verlassen. Lediglich 3,4 % waren dazu in der Lage, ohne Hilfsmittel oder Hilfsperson den Wohnort zu verlassen. Mit der Nutzung von Hilfsmitteln verließen 8,5 % der Studienteilnehmer den Wohnort, durch die Nutzung von Hilfsmitteln und zusätzlich einer Hilfsperson steigerte sich der Anteil auf 29,1 %. Die multiple, lineare Regressionsanalyse ergab eine Varianzaufklärung der LSM von 42,4 %, durch die im Modell verbliebenen, unabhängigen Variablen „körperliche Leistungsfähigkeit“, „Anzahl durchgeführter sozialer Aktivitäten“, „männliches Geschlecht“ und „körperliche Aktivität“. Die standardisierten Regressionskoeffizienten (ß-Werte) dieser unabhängigen Variablen zeigten eine Range von ß = 0,18 - 0,27 auf, wobei der Parameter „körperliche Aktivität“ den höchsten Aufklärungswert aufwies. Die Ergebnisse der variance influence factor- Berechnungen zeigten keinen Hinweis auf eine Multikollinearität der unabhängigen Variablen.

Diskussion

Unsere Ergebnisse zeigen, dass die LSM bei älteren Patienten mit kognitiven Einschränkungen nach geriatrischen Rehabilitationsmaßnahmen mit einem LSA-CI-C von 23,9 von maximal möglichen 90 Punkten deutlich eingeschränkt ist. Bei unseren Studienteilnehmern wurde im Mittel ein LSA-CI-M Score von 3,7 erfasst, was einem maximalen Life-Space Bereich entspricht, der sich in die Nachbarschaft erstreckt, wohingegen andere Studien zeigten, dass sich der maximalen Life-Space Bereich bei kognitiv intakten älteren Personen mit einem Score von 4,2 bis 4,6 über den Bereich des gesamten Heimatortes außerhalb der direkten Nachbarschaft erstreckte (Baker et al., 2003; Curcio et al., 2013). Bei älteren Personen mit kognitiven Einschränkungen verdeutlichten die LSA-CI-Subscores eine starke Abhängigkeit der LSM von Hilfspersonen und/oder Hilfsmitteln. Ohne diese Form der Unterstützung wären zahlreiche älterer Personen mit kognitiven Einschränkungen in ihrer Mobilität auf das häusliche Umfeld beschränkt, wodurch die Teilhabe an sozialen und gesellschaftlichen Aktivitäten reduziert wird (Szanton et al., 2016).

3.6 Publikation VI. Promoting physical activity in geriatric patients with cognitive impairment after discharge from ward-rehabilitation: a feasibility study.

Tobias Eckert, **Martin Bongartz**, Phoebe Ullrich, Bastian Abel, Christian Werner, Rainer Kiss, Klaus Hauer (2020). Promoting physical activity in geriatric patients with cognitive impairment after discharge from ward-rehabilitation: a feasibility study. *European Journal of Ageing, 17*, 309-320. doi: 10.1007/s10433-020-00555-w

Hintergrund und Zielsetzung

Bei der Implementierung eines Heimtrainingsprogramms zur funktionellen Verbesserung von kognitiv eingeschränkten Personen wurde eine hohe Adhärenz als eine wesentliche Voraussetzung für eine erfolgreiche Intervention identifiziert (M. E. Taylor et al., 2017). Kognitive Einschränkungen älterer Personen stellen in diesem Zusammenhang eine Hürde dar, da die Adhärenz an die Durchführung von

Trainingseinheiten in dieser Personengruppe geringer ist, als bei kognitiv intakten Personen (Moseley et al., 2009). Interventionsmaßnahmen zur Steigerung des körperlichen Aktivitätsverhaltens erfordern eine ausreichende Motivation, die durch BCTs modifiziert werden kann (Abraham & Michie, 2008). In der Folge wurden BCTs in Interventionsstudien hinsichtlich ihrer Effekte auf die Steigerung der körperlichen Aktivität bei älteren Personen mit kognitiven Einschränkungen untersucht. Diese Studien zeigten unterschiedliche Ergebnisse hinsichtlich der verschiedenen BCTs. Einerseits wurde kein Nachweis dafür gefunden, dass die BCTs *Zielsetzung* und *Eigenüberwachung* („*Self-Monitoring“)* die Effektivität der Interventionen steigern (Kerse et al., 2008; Vidoni et al., 2016), andererseits wurde die BCT *soziale Unterstützung* als wichtiger Bestandteil einer Steigung der körperlichen Aktivität hervorgehoben (Suttanon, Hill, Said, Byrne, & Dodd, 2012). Die Adhärenz an den BCTs wird in diesen Studien nicht untersucht, sodass unklar bleibt, in welchem Ausmaß die eingesetzten BCTs von den Studienteilnehmern im Verlauf der Intervention genutzt wurden. Das Ziel unserer Studie bestand darin, die Durchführbarkeit der Zielsetzung und der sozialen Unterstützung zu überprüfen. Darüber hinaus wurde die Adhärenz im Verlauf der Intervention an das Trainingsprogramm sowie an die Zielsetzung und das Self-Monitoring sowie die Akzeptanz eines Heimtrainingsprogramms aus der Sicht älterer Personen mit kognitiven Einschränkungen nach geriatrischer Rehabilitation auf der Basis quantitativer Erfassungsmethoden evaluiert.

Methoden

Diese Studie basiert auf der RCT *HeikE* (siehe Kap. 3.1), in der die Teilnehmer zu einer selbstständigen, täglichen Ausführung des Trainings befähigt und motiviert werden sollten. Es wurden ausschließlich Daten der Interventionsgruppenteilnehmer analysiert, die zu Baseline und im Verlauf sowie unmittelbar nach der Interventionsphase erfasst wurden. Die Messung der Studienoutcomes erfolgte mittels:

- Trainingstagebüchern während der Interventionsphase (Adhärenz an Goal-Setting, an das Selfmonitoring und an die selbstständige Trainingsausübung)
- modifizierter Talking-Mats Fragebögen (Murphy, Tester, Hubbard, Downs, & MacDonald, 2005) vor der Interventionsphase (Durchführbarkeit des Goal-Settings)

- standardisierter Fragebogen nach der Interventionsphase (Akzeptanz und Durchführbarkeit des Trainingsprogramms)
- standardisierter Dokumentationen durch die Trainer (Durchführbarkeit der sozialen Unterstützung in Form von Hausbesuchen und Telefonanrufen durch den Trainer).

Anhand des Anteils der Teilnehmer, die im Rahmen der modifizierten Talking-Mats Fragebogen dazu in der Lage waren, mindestens ein Trainingsziel anzugeben, wurde die Durchführbarkeit der Zielsetzung berechnet. Die Adhärenz an die selbstständige Trainingsdurchführung und an die Nutzung der Pedometer wurde durch den Anteil der Tage erfasst, an denen im Interventionszeitraum Trainingsdurchführungen und Nutzungen der Pedometer durch die Teilnehmer im Trainingstagebuch dokumentiert wurden. Eine lückenlose, täglich dokumentierte Nutzung im zwölfwöchigen Interventionszeitraum entsprach einer vollständigen Adhärenz mit einem Anteil von 100 %. Nach Abschluss der Intervention wurde durch einen standarisierten Fragebogen die Akzeptanz in Form von Effektivität („Hat Ihnen die Durchführung von … geholfen sich zu verbessern?“) und in Form der subjektiv wahrgenommenen Durchführbarkeit („Waren Sie dazu in der Lage … durchzuführen?“) der unterschiedlichen Komponenten des Trainingsprogramms inklusive der BCTs aus Sicht der Teilnehmer erfasst. Für die Beantwortung wurde eine 4-stufige Likert-Skala mit einer Range von 1 („nein“), 2 („eher nein“), 3 („eher ja“) bis 4 („ja“) genutzt. Die Effektivität und subjektiv wahrgenommene Durchführbarkeit der einzelnen Interventionskomponenten wurden anhand des prozentualen Anteils derjenigen Teilnehmer berechnet, die einen Score von ≥ 3 angaben.

Ergebnisse

Es wurden 63 multimorbide, geriatrische Patienten mit kognitiven und motorischen Einschränkungen in die Studie eingeschlossen, von denen 54 Personen die Intervention vollständig beendeten. Neun Teilnehmer nahmen lediglich an der Baseline-Messung teil, wodurch in diesen Fällen ausschließlich die Baseline-Daten in die Analyse einflossen. Das Benennen mindestens eines Ziels im Rahmen der Zielsetzung war für 62 Teilnehmer durchführbar. Ein Teilnehmer war aufgrund kognitiver Einschränkungen nicht zur Zielsetzung in der Lage. Teilnehmer, die die Studie vollständig beendeten, lag die soziale Unterstützung durch die Trainer bei fünf Hausbesuchen

(IQR = 5 - 5) und neun Telefonanrufen (IQR = 8 – 10). Die Adhärenz an die selbstständige Trainingsausübung lag im Mittel bei 63,6 % für die Durchführung funktioneller Übungen und bei 57,9 % für das Outdoor-Walking, wobei beide Komponenten im Verlauf der zwölfwöchigen Intervention eine signifikante Reduktion aufwiesen. Hinsichtlich der BCTs wies die Adhärenz an die Zielsetzung 40,1 % und an das Self-Monitoring durch den Einsatz von Pedometern 60,1 % auf, von denen die Adhärenz an das Self-Monitoring im Verlaufe der zwölfwöchigen Interventionsphase eine signifikante Reduktion zeigte. Der Anteil der Teilnehmer, die Komponenten des Interventionsprogramms als effektiv bewerteten, reichte von 63,5 % für das Self-Monitoring mittels Pedometer bis 90,6 % für die soziale Unterstützung durch Hausbesuche. Die Range vom Anteil derjenigen Teilnehmer, die Komponenten des Interventionsprogramms als durchführbar wahrnahmen, reichte von 68,2 % für das Self-Monitoring mittels Pedometer, bis 83,0 % für die Durchführung funktioneller Übungen.

Diskussion

Unsere Ergebnisse zeigen bei multimorbiden, geriatrischen Patienten mit kognitiven und motorischen Einschränkungen eine hohe Adhärenz an ein selbstständig durchgeführtes Trainingsprogramm, was in ähnlicher Ausprägung in Studien gezeigt wurde, in denen die Adhärenz an Trainingsprogramme bei kognitiv eingeschränkten Personen untersucht wurde, die mit Unterstützung ihrer Bezugspersonen trainierten (Suttanon et al., 2013; M. E. Taylor et al., 2017). Im Verlauf der zwölfwöchigen Trainingsphase wurde eine Reduktion der Adhärenz festgestellt, die auch in anderen Trainingsstudien bei kognitiv eingeschränkten Personen festgestellt wurde (M. E. Taylor et al., 2017). Der Einsatz der nonverbal durchführbaren Talking-Mats Methode (Murphy et al., 2005) ging mit einer guten Durchführbarkeit des Zielsetzens einher, was mit den Ergebnissen eines Reviews im Einklang war, in dem festgestellt wurde, dass komplexere Instrumente im Vergleich zu der Talking Mats Methode eine schlechtere Durchführbarkeit der Zielsetzung bei kognitiv eingeschränkten Personen aufwiesen (Stevens, Beurskens, Koke, & van der Weijden, 2013). Unsere Ergebnisse zeigten eine moderate Adhärenz an die gesetzten Ziele, was den Ergebnissen einer Studie entsprach, die ebenfalls mit kognitiv eingeschränkten Personen durchgeführt wurde (Kerse et al., 2008). Dies kann dadurch begründet sein, dass die Teilnehmer vor dem Hintergrund ihrer funktionellen Einschränkungen unrealistische, nicht erreichbare Ziele formulierten. Das Pedometer erwies sich als geeignetes Instrument für ein Self-Monitoring, das hohe Akzeptanz und Adhärenz aufwies. Bei älteren Personen mit kognitiven Einschränkungen treten vermehrt Schwierigkeiten mit dem Handling von Pedometern auf (Logsdon, McCurry, Pike, & Teri, 2009), weshalb die Auswahl eines besonders einfach zu bedienenden Pedometers in unserer Studie zu einer hohen Akzeptanz und Adhärenz an das Self-Monitoring geführt haben kann. Die soziale Unterstützung in Form von Hausbesuchen durch den Trainier wurde von den Studienteilnehmern als die effektivste Komponente des Trainingsprogramms wahrgenommen. Auch eine qualitative Studie, die mit dementiell erkrankten Pflegeheimbewohnern durchgeführt wurde, kam zu dem Ergebnis, dass der Trainer als entscheidender Faktor für einen Trainingserfolg wahrgenommen wird, weil er durch individuelle Adjustierung der Trainingsinhalte Über- und Unterforderungen verhindert und dadurch die Selbstwirksamkeit steigert (Olsen, Telenius, Engedal, & Bergland, 2015). Darüber hinaus zeigten auch quantitative Analysen, dass regelmäßige soziale Unterstützung durch professionelle Trainer positive Effekte auf die Steigerung der körperlichen Aktivität bei Pflegeheimbewohnern (Jansen, Classen, Wahl, & Hauer, 2015) und bei sedentären über 80-jährigen Frauen (Poulsen, Elkjaer, Vass, Hendriksen, & Avlund, 2007) haben. Unsere Ergebnisse machten zudem deutlich, dass der direkte soziale Kontakt effektiver wahrgenommen wird als ein sozialer Kontakt in Form eines Telefonanrufs.

3.7 Publikation VII. Increasing life-space mobility in community-dwelling older persons with cognitive impairment following rehabilitation: A randomized controlled trial

Phoebe Ullrich, Christian Werner, **Martin Bongartz**, Tobias Eckert, Bastian Abel, Anton Schönstein, Rainer Kiss, Klaus Hauer (2020). Increasing Life-Space Mobility in community-dwelling older persons with cognitive impairment following rehabilitation: A randomized controlled trial. *The Journals of Gerontology: Series A.* doi: 10.1093/gerona/glaa254

Hintergrund und Zielsetzung

Unmittelbar nach geriatrischen Rehabilitationsmaßnahmen akkumulieren Patienten mit kognitiven Einschränkungen Eigenschaften, die mit einem erhöhten Risiko für eine reduzierte LSM einhergehen (Ullrich et al., 2019). Zu diesen Eigenschaften gehören das hohe Alter, körperliche und kognitive Einschränkungen und ein geringer zeitlicher Abstand zu einem Krankenhausaufenthalt (Brown et al., 2009; Peel et al., 2005). Dadurch haben ältere Patienten mit kognitiven Einschränkungen nach geriatrischen Rehabilitationsmaßnahmen einen besonders hohen Bedarf an Interventionen zur Steigerung der LSM. Die Wirksamkeit von Interventionen zur Verbesserung der LSM von älteren Personen nach einer stationären Behandlung wurde bislang nur vereinzelt untersucht (Brown et al., 2016). Personen mit kognitiven Einschränkungen wurden aus dieser Studie ausgeschlossen, was mit weiteren Studien vergleichbar ist, in denen Modifikationen der LSM ebenfalls evaluiert wurden (Brown et al., 2016; Clemson et al., 2012; Collins et al., 2018).Das Ziel der vorliegenden Studie besteht darin, akute und nachhaltige Effekte eines standarisierten Heimtrainingsprogramms auf die LSM von geriatrischen Patienten mit kognitiven Einschränkungen zu evaluieren, die sich in der Übergangsphase von der Rehabilitationsmaßnahme in ihr häusliches Umfeld befinden. Darüber hinaus wird eine Analyse zur Identifikation von Prädiktoren für die Modifikation der LSM durchgeführt.

Methoden

Die Studie basiert auf Daten, die im Rahmen der in Publikation I beschriebenen RCT *HeikE* generiert wurden (Bongartz et al., 2017). Der LSM wurde auf der Basis des LSA-CI Fragebogen erfasst, der im Rahmen von Publikation III speziell für ältere Personen mit kognitiven Einschränkungen entwickelt und in dieser Zielgruppe validiert wurde (Ullrich et al., 2018). Neben dem LSA-CI-C, der sich aus den erreichten Zonen, sowie der Frequenz und den in Anspruch genommenen Hilfsmitteln berechnet, fließen auch die drei Subscores des LSA-CI in die Analyse ein, die die LSA-CI-M, LSA-CI-E und LSA-CI-I angeben. Der LSA-CI wurde zu Baseline (T1), unmittelbar nach der zwölfwöchigen Trainingsphase (T2) und nach einer 12-wöchigen Follow-Up-Phase (T3) durchgeführt. Um Unterschiede des LSA-CI-C und der LSA-CI Subscores zwischen der Interventions- und Kontrollgruppe zu evaluieren, wurden Kovarianzanalysen durchgeführt, in denen die Messwerte für die Baseline-Werte (T1) kontrolliert und die absoluten Veränderungen im Interventionszeitraum (zwischen T1 und T2), sowie im gesamten Observationszeitraum (zwischen T1 und T3) untersucht wurden. Zur Einschätzung der Effektstärke wurde das partielle Eta-Quadrat (η_p^2) berechnet und nach Cohen in folgender Weise interpretiert: kleine Effektstärke= $0{,}01 \geq \eta_p^2 \leq 0{,}06$; mittlere Effektstärke= $0{,}06 < \eta_p^2 \leq 0{,}14$; große Effektstärke= $\eta_p^2 > 0{,}14$ (Cohen, 1988). Potentielle Prädiktoren für Veränderungen der LSM (Delta des LSA-CI-C zwischen T1 und T2) wurden identifiziert, indem Variablen (LSM baseline, Adhärenzvariablen, soziodemographische Variablen, kognitiver, physischer und psychosozialer Status, Anzahl der Schritte), die signifikant mit der Veränderung des LSM korrelierten, als unabhängige Variablen in ein multiples, lineares Regressionsmodell eingefügt wurden.

Ergebnisse

In dem Interventionszeitraum von T1 zu T2 zeigten sich in der Interventionsgruppe im Vergleich zur Kontrollgruppe signifikante Steigerungen sowohl des LSA-CI-C ($p < 0{,}001$; $\eta_p^2 = 0{,}20$), als auch aller drei LSA-CI-Subscores ($p = 0{,}003 - 0{,}023$; $\eta_p^2 = 0.05 - 0.08$). Über den gesamten Observationszeitraum von T1 zu T3 zeigten sich signifikante Steigerungen des LSA-CI-C ($p = 0{,}23$; $\eta_p^2 = 0{,}06$), sowie des Subscores LSA-CI-E ($p = 0{,}27$; $\eta_p^2 = 0{,}06$). Im Vergleich zur Kontrollgruppe stieg in der Interventionsgruppe die Anzahl der Teilnehmer, die nach der Intervention ohne Hilfsperson aber mit Hilfsmitteln die Nachbarschaft verließen, sowie die Anzahl der Teilnehmer, die ohne Hilfsperson und ohne Equipment den Outdoorbereich erreichten, signifikant. Die multiple, lineare Regressionsanalyse identifizierte den Baseline-Wert des LSA-CI-C und die Adhärenz, gemessen an der Nutzungshäufigkeit eines zur Verfügung gestellten Pedometers als unabhängige Prädiktoren der Veränderung des LSM, die 21,8 % der Varianz des LSA-CI-C zwischen T1 und T2 aufklärten.

Diskussion

Die Ergebnisse zeigen, dass das standarisierte Heimtrainingsprogramm HeikE in der vulnerablen Gruppe geriatrischer Patienten mit kognitiven Einschränkungen in der kritischen Übergangsphase nach der Entlassung aus der geriatrischen Rehabilitation in das häusliche Umfeld zu einer Steigerung der LSM führt. Der gesteigerte LSA-CI-C deutet darauf hin, dass die Interventionsgruppe eine gesteigerte räumliche Ausdehnung der Mobilität, eine gesteigerte Frequenz der Mobilität und eine reduzierte Inanspruchnahme von Hilfspersonen aufweist. Dieser Effekt zeigt sich sowohl akut, d.h. unmittelbar nach der zwölfwöchigen Interventionsphase, als auch nachhaltig, d.h. nach der zwölfwöchigen Follow-Up Phase. Akute Steigerungen der LSM durch Interventionsmaßnahmen konnten bislang in vereinzelten Studien gezeigt werden, in denen im Gegensatz zu unserer Studie Personen mit kognitiven Einschränkungen ausschlossen wurden (Brown et al., 2016; Fairhall et al., 2012) oder auf Pflegeheimsettings beschränkt waren (Crotty et al., 2019). Bislang konnten keine nachhaltige Effekte von Interventionen auf die LSM älterer Personen in 3 – 11-monatigen Follow-Up Phasen gezeigt werden (Clemson et al., 2012; Collins et al., 2018; Crotty et al., 2019). Die erstmals in unserem Heimtrainingsprogramm gezeigte Nachhaltigkeit des Effekts auf die LSM von älteren Personen mit kognitiven Einschränkungen könnte auf die in das Heimtrainingsprogramm integrierte Motivationsstrategie zurückzuführen sein, die im Vergleich zu den genannten Studien (Clemson et al., 2012; Collins et al., 2018; Crotty et al., 2019) ein Alleinstellungsmerkmal darstellt. Bei Personen im mittleren Lebensalter zeigte eine Studie, dass die Nutzung eines Pedometers eine wirksame Motivationstechnik zur Mobilitätssteigerung (Bravata et al., 2007). Unsere Untersuchung bestätigt dieses Ergebnis für ältere Personen mit kognitiven Einschränkungen, da die Nutzungshäufigkeit des Pedometers als ein unabhängiger Prädiktor für die Verbesserung der LSM identifiziert wurde. Darüber hinaus zeigen unsere Ergebnisse, dass eine niedrige initiale LSM ein weiterer unabhängiger Prädiktor für Steigerungen der LSM von älteren Personen mit kognitiven Einschränkungen ist. Dies ist im Einklang mit der Erkenntnis, dass Personen mit niedrigen Baselinewerten ein höheres Verbesserungspotenzial und eine höhere Wahrscheinlichkeit für einen positiven Interventionseffekt aufweisen, als Personen mit hohen Baselinewerten (Quisenberry, Snider, & Bickel, 2016).

3.8 Publikation VIII. Cost-effectiveness and cost-utility of a home-based exercise program in geriatric patients with cognitive impairment

Tobias Eckert, Pamela Wronski, **Martin Bongartz**, Phoebe Ullrich, Bastian Abel, Rainer Kiss, Michel Wensing, Jan Koetsenruijter, Klaus Hauer. Cost-effectiveness and cost-utility of a home-based exercise program in geriatric patients with cognitive impairment. Accepted in *Gerontology*

Hintergrund und Zielsetzung

Die Knappheit der finanziellen Ressourcen im Gesundheitssystem erfordert eine effektive Allokation der zur Verfügung stehenden Finanzmittel (Marckmann, 2009). Daher müssen umfassende Evaluationen von Interventionsprogrammen neben der klinischen auch die ökonomische Effektivität eines Therapieansatzes überprüfen (Auais, Eilayyan, & Mayo, 2012). Zur Überprüfung effektiver Allkationen kommen gesundheitsökonomische Evaluationen zum Einsatz (Karlsson & Johannesson, 1996). Bislang wurden vornehmlich Kostenevaluationen von körperlichen Trainingsprogrammen für kognitiv intakte, ältere Personen durchgeführt (Davis et al., 2010; Matchar et al., 2019; McLean et al., 2015), wohingegen die ökonomische Überprüfung von körperlichen Trainingsprogrammen für ältere Personen mit kognitiven Einschränkungen nur selten durchgeführt wurde, für die Zukunft jedoch vermehrt empfohlen wird (Apostolo et al., 2018; Nickel, Barth, & Kolominsky-Rabas, 2018). Studien, in denen Kostenanalysen von körperlichen Trainingsprogrammen für ältere Personen mit kognitiven Einschränkungen durchgeführt wurden, weichen hinsichtlich der eingesetzten gesundheitsökonomischen Methoden und hinsichtlich der Trainingsprotokolle und -ziele von unserer Studie ab (Khan et al., 2019; Pitkälä et al., 2013). Das Ziel der vorliegenden Studie bestand darin, ein Heimtrainingsprogramm für geriatrische Personen mit kognitiven und motorischen Einschränkungen unmittelbar nach Rehabilitationsmaßnahmen, hinsichtlich der Kosteneffektivität in Bezug auf Verbesserungen der körperlichen Leistungsfähigkeit, sowie einer Kosten-Nutzen-Analyse in Bezug auf qualitätsbereinigte Lebensjahre (QALYs = Quality Adjusted Life Years) zu evaluieren.

Methoden

Die ökonomische Evaluation wurde im Rahmen der RCT *HeikE* (siehe Publikation I) durchgeführt. Für die Kosten-Effektivitäts-Analyse wurde die Veränderung der körperlichen Leistungsfähigkeit (SPPB-Gesamtscore), für die Kosten-Nutzen-Analyse der QALYs zwischen Interventions- und Kontrollgruppe herangezogen. Die gesundheitsökonomischen Analysen wurden auf der Basis einer gesellschaftlichen Perspektive durchgeführt, wodurch neben den direkten Kosten der in Anspruch genommenen Gesundheitsleistungen auch die Kosten für informelle Pflegeleistungen durch Angehörige einbezogen wurden. NMBs wurden für jeden Probanden (i) nach den Formeln $NMB_i = SPPB_{T3\text{-}T1} \times WTP - C_i$ für die Kosten-Effektivitäts-Analyse und $NMB_i = QALY_i \times WTP - C_i$ für die Kosten-Nutzen-Analyse berechnet. Dabei stellt WTP die Zahlungsbereitschaft des Kostenträgers für einen Punkt des SPPB-Gesamtscore oder ein QALY und C_i (aus dem Englischen Costs) die gesamten Gesundheitskosten (Summe aus direkten Gesundheitskosten, informellen Gesundheitskosten und ggfs. Interventionskosten) eines Probanden dar (Briggs et al., 2002; Hoch et al., 2002). Inkrementelle NMBs (iNMBs) wurden als Differenz zwischen den NMB-Werten der Interventions- und der Kontrollgruppe berechnet und mittels Regressionsanalysen überprüft, ob positive iNMBs eine Kosteneffektivität der Interventionsgruppe nachweisen (Hoch et al., 2002). Zusätzlich wurden Kosten-Effektivitäts-Akzeptanzkurven berechnet und dargestellt, um die Wahrscheinlichkeiten einer potenziell vorliegende Kosteneffektivität auf den unterschiedlichen WTP-Schwellen zu ermitteln (Briggs et al., 2002; Hoch et al., 2002).

Ergebnisse

Die Interventionsgruppe wies im Vergleich zur Kontrollgruppe einen signifikant höheren SPPB-Gesamtscore und einen marginal höheren, aber nicht signifikanten QALY-Wert auf. Die durchschnittlichen Kosten zur Durchführung der Intervention lagen bei 284 Euro pro Person, die durchschnittlichen gesamten Gesundheitskosten während der Studienteilnahme über 24 Wochen wiesen mit 7942 Euro in der Interventionsgruppe und 9475 Euro in der Kontrollgruppe eine durchschnittliche, nicht signifikante Differenz von 1533 Euro auf. Die inkrementelle Kosten-Effektivitäts-Analyse wies hinsichtlich der Effekte auf den SPPB-Gesamtscore bei jedem angenommen WTP-

Grenzwert von 0 bis 5000 Euro positive iNMBs auf. Die lineare Regressionsanalyse zeigte signifikante Unterschiede der iNMBs bei WTP-Schwellen ≥ 2000 Euro und wies nach, dass die Wahrscheinlichkeit für eine Kosteneffektivität des Interventionsprogramms im Zusammenhang mit einer Steigerung des SPPB-Gesamtscores um einen SPPB-Punkt ab einer WTP von 2000 Euro bei 99 % liegt. Die Kosten-Nutzen-Analyse wies hinsichtlich der Effekte auf die QALYs bei jedem angenommen WTP-Grenzwert positive iNMBs auf, die Unterschiede zwischen den NMBs der Interventions- und der Kontrollgruppe waren jedoch nicht signifikant.

Diskussion

Im Rahmen dieser Studie wurde erstmals ein körperliches Heimtrainingsprogramm, das in der vulnerablen Gruppe kognitiv eingeschränkter Patienten nach geriatrischer Rehabilitation durchgeführt wurde, ökonomisch evaluiert. Die Ergebnisse unserer Kosten-Nutzen-Analyse weisen keinen ökonomischen Nutzen hinsichtlich einer Steigerung der QALYs nach. Dies ist in Einklang mit den meisten Kosten-Nutzen-Analysen bisheriger Trainingsstudien bei älteren Personen (Fairhall et al., 2015; Khan et al., 2019; Taraldsen et al., 2019). Ein Grund hierfür kann in der geringen Veränderungssensitivität von QALYs im Zusammenhang mit körperlichen Trainingsprogrammen bestehen, weshalb die Überprüfung der Kosteneffektivität von körperlichen Trainingsprogrammen auf die Modifikation spezifischer klinischer Parameter sinnvoll erscheint. Die Ergebnisse unserer Kosten-Effektivitätsanalyse zeigen, dass ein 12-wöchiges Heimtrainingsprogramm bei älteren, kognitiv eingeschränkten Personen hinsichtlich der Verbesserung des SPPB-Gesamtscores als Maß der körperlichen Leistungsfähigkeit im Vergleich zur Kontrollgruppe ab einer Zahlungsbereitschaft von 2000 Euro mit einer Wahrscheinlichkeit von 99 % kosteneffektiv ist. Zu vergleichbaren Ergebnissen kamen Studien, in denen die Kosteneffektivität von körperlichen Trainingsprogrammen ebenfalls hinsichtlich der Verbesserung spezifischer klinischer Parameter wie der körperlichen Leistungsfähigkeit und dem Status der Gebrechlichkeit bei älteren Personen ohne kognitive Einschränkungen (Fairhall et al., 2015; Farag et al., 2015) und der Verbesserung demenzspezifischer Verhaltensweisen bei älteren Personen mit kognitiven Einschränkungen nachgewiesen wurde (D'Amico et al., 2016).

4 Einordnung der Studienergebnisse in den Forschungszusammenhang

Die vorliegende Arbeit leistet einen wesentlichen Beitrag zum Verständnis des habituellen Bewegungsverhaltens von Patienten mit kognitiven Einschränkungen, die sich in der Phase des Übergangs von einer geriatrischen Rehabilitationsmaßnahme zurück in ihr häusliches Umfeld befinden. Zuvor bestehende Forschungslücken der in Abbildung 1 dargestellten Themenbereiche „1. Validierung innovativer Messmethoden des habituellen Bewegungsverhaltens“, „2. Charakteristika und Determinanten des habituellen Bewegungsverhaltens“ und „3. Durchführbarkeit, Effekte und Kosteneffektivität eines Heimtrainingsprogramms“ wurden geschlossen.

Themenbereich 1:

In einer aktuellen State-of-the-art-Darstellung der geriatrischen Rehabilitation fordern Achterberg et al. (2019) neue Rehabilitationskonzepte, die den geriatrischen Patienten aktiv in die Gestaltung des therapeutischen Prozesses einbinden und verstärkt an die individuellen Fähigkeiten des Patienten angepasst werden. Die Evaluation des individuellen Bewegungsverhaltens ist in diesem Zusammenhang von entscheidender Bedeutung. Ein Feedback des Bewegungsverhaltens liefert sowohl dem Patienten, als auch den behandelnden Therapeuten und Ärzten klinisch relevante Informationen zum Gesundheitsstatus. Darüber hinaus dient es der Festlegung individueller, messbarer Rehabilitationsziele (Achterberg et al., 2019).

Verfahren zur Messung des individuellen Bewegungsverhaltens sind bislang unzureichend auf geriatrische Patienten mit kognitiven Einschränkungen abgestimmt. Sensorsysteme zur Erfassung körperlicher Aktivitätsparameter wurden bislang vornehmlich unter Laborbedingungen validiert und nur vereinzelt in habituellen Settings durchgeführt (Chigateri, Kerse, Wheeler, MacDonald, & Klenk, 2018; Dijkstra et al., 2010; Najafi et al., 2003; L. M. Taylor et al., 2014). Die Datenerfassung von Validierungsstudien in habituellen Settings fand in kurzen Zeitfenstern unter direkter Beobachtung oder nach standardisierten Bewegungsaufgaben statt, wodurch ein realistisches, habituelles Bewegungsverhalten der Studienteilnehmer weder entstehen noch erfasst werden konnte. Das Gangverhalten im Labor unterscheidet sich signifikant von dem Gangverhalten im Alltag (Brodie et al., 2016; Urbanek et al., 2018). Daher stellt die Erfassung des habituellen Bewegungsverhaltens durch ambulante Sensorsysteme, deren Validität lediglich unter Laborbedingungen nachgewiesen wurde, eine methodische Limitation dar. Darüber hinaus weisen bisherige ambulante Sensorsysteme hohe Messfehler bei der Erfassung körperlicher Aktivitätsparameter von älteren Personen auf, bei denen bedingt durch gesundheitliche Einschränkungen, spezielle Bewegungscharakteristika auftreten (McCullagh et al., 2016). Während bisherige Sensorsysteme für die Messung des Bewegungsverhaltens von älteren Personen ohne gesundheitliche Einschränkungen entwickelt wurden, setzt die Erfassung des Bewegungsverhaltens von älteren Personen mit gesundheitlichen Einschränkungen neuartige, speziell für den zielgruppenspezifischen Einsatz konzipierte Sensorsysteme voraus. Diese methodischen Limitationen bisheriger Validierungsstudien wurden in Publikation II berücksichtigt. Der uSense-Bewegungssensor wies bei der Messung körperlicher Aktivitätsparameter (Dauer, Frequenz, Intensität des Gehens) und Gangparameter des Kurvengehens (z.B. Drehgeschwindigkeit, Drehwinkel) eine hohe Konstruktvalidität auf. Bei der Messung zeitlicher Gangparameter des Geradeausgehens (z.B. Gangvariabilität, Schrittregelmäßigkeit, Gangsymmetrie) konnte eine moderate Konstruktvalidität nachgewiesen werden. In den Vergleichsstudien, die zur Evaluation der Konstruktvalidität der Gangparameter des Geradeausgehens genutzt wurden, bildeten die Studienteilnehmer ein vergleichbares Altersspektrum wie unsere Population ab (Hausdorff, Rios, & Edelberg, 2001). Im Vergleich zu unseren Teilnehmern wiesen sie allerdings geringere gesundheitliche Einschränkungen auf (Hausdorff et al., 2001), wodurch sich die Unterschiede zu unseren Ergebnissen erklären lassen. Ungeachtet dessen konnten die meisten unserer Hypothesen mit hoher Übereinstimmung zu den Vergleichsstudien bestätigt werden. Dadurch konnte gezeigt werden, dass mit dem uSense-Bewegungssensor ambulante Erfassungen von etablierten Parametern der körperlichen Aktivität und darüber hinaus von Gang- und Drehparametern im Alltag von älteren Personen mit kognitiven Einschränkungen valide möglich sind. Trotz einer großen Anzahl an existierenden Sensorsystemen, ist in bisherigen Studien insbesondere die Validität von Gangparametern, die im Alltag von älteren Personen mit gesundheitlichen Einschränkungen erfasst wurden, in Frage gestellt worden (Vienne et al., 2017).

Eine vergleichbare Situation zeigt sich bei der Erfassung der LSM. Bislang existierende Methoden wurden ebenfalls nicht für die hier vorliegende, in ihrem häuslichen Umfeld lebende Zielgruppe konzipiert. Generell stehen technik- und fragebogenbasierte Methoden zur Verfügung (De Silva, Gregory, Venkateshan, Verschoor, & Kuspinar, 2019). Technikbasierte Methoden können den Life-Space in hoher räumlich-zeitlicher Auflösung erfassen (Tung et al., 2014). Im Vergleich dazu geben fragebogenbasierte Methoden zusätzlich Auskunft darüber, ob der Life-Space selbstständig, mit Hilfsmitteln, aktiv oder passiv erreicht wurde. Darüber hinaus haben fragebogenbasierte Methoden den Vorteil kostengünstiger durchführbar zu sein. Fragebogenbasierte Methoden, wie das etablierte UAB-LSA, ermöglichten die valide Erfassung der LSM von kognitiv intakten älteren Personen (Baker et al., 2003). Der Einsatz des UAB-LSA ist hingegen bei Personen mit kognitiven Einschränkungen unter anderem durch den langen Erfassungszeitraum von vier Wochen nicht geeignet. Für die Erfassung der LSM unserer Studienpopulation wurde demnach ein speziell an die Charakteristika dieser Zielgruppe angepasstes Instrument benötigt. Durch die Entwicklung und Validierung des LSA-CI im Rahmen von Publikation III steht nun ein fragebogenbasiertes Instrument zur Verfügung, bei dem gezeigt wurde, dass erstmals valide Erfassungen der LSM auch bei älteren Personen mit moderaten bis leichten kognitiven Einschränkungen möglich sind. Es ist zu beachten, dass die Anwendung dieser fragenbogenbasierten Methode in dem untersuchten Bereich kognitiver Einschränkungen (MMSE: 17 – 26) valide möglich ist. Für Personen mit höhergradigen kognitiven Einschränkungen ist die Validität dieser Messmethode bislang nicht nachgewiesen worden.

Themenbereich 2:

Durch die Validierung dieser beiden Erhebungsmethoden besteht nun die Möglichkeit, Einblicke in das habituelle Bewegungsverhalten der vorliegenden Zielgruppe zu gewinnen, die über das bisherige Maß hinausgehen. Für diese Personengruppe kann ein gesundheitsförderliches Bewegungsverhalten insbesondere nach geriatrischen Rehabilitationsmaßnahmen ein entscheidender Faktor für den Erhalt der selbstständigen Lebensführung sein. Ob und in welchem Ausmaß multimorbide Patienten mit kognitiven Einschränkungen nach einer geriatrischen Rehabilitationsmaßnahme in ihrem häuslichen Umfeld das aktive, gesundheitsförderliche Bewegungsverhalten fortführen ist bislang nicht untersucht worden.

In Publikationen IV wird erstmals das habituelle Aktivitäts- und Gangverhalten der Zielgruppe unmittelbar nach geriatrischen Rehabilitationsmaßnahmen untersucht. Unsere Ergebnisse zeigen, dass die körperliche Aktivität stärker eingeschränkt ist, als bei kognitiv intakten, älteren Personen ohne vorherige Rehabilitationsmaßname (Klenk et al., 2016; Sun et al., 2013). Das körperliche Aktivitätslevel des hier untersuchten Patientenkollektivs liegt unterhalb der Mindestempfehlungen der WHO zur Durchführung von körperlicher Aktivität bei Personen über 65 Jahren (WHO, 2010). Unsere Zielgruppe weist eine durchschnittliche Gangdauer von 60 Minuten in etwa 315 Gangepisoden pro Tag auf. Es ist davon auszugehen, dass die einzelnen Gangphasen die von der WHO empfohlene Mindestdauer von 10 Minuten pro Aktivitätsepisode in der Regel unterschreiten. Diese Annahme wird durch ein Ergebnis in Publikation V gestützt, aus dem hervorgeht, dass lediglich 43 % unserer Studienteilnehmer ohne eine Hilfsperson das häusliche Umfeld verlassen. Gangepisoden finden demnach vorwiegend im räumlich begrenzten häuslichen Umfeld statt, in der Gangphasen mit einer Dauer von mehr als 10 Minuten unwahrscheinlich sind. Die Untersuchung des habituellen Gangverhaltens zeigt, eine hohe Variabilität der Schrittdauer und eine niedrige Gangsymmetrie beim Geradeausgehen sowie lange Drehdauern, kleine Drehwinkel und niedrige Winkelgeschwindigkeiten beim Kurvengehen. Insgesamt macht diese Analyse ein defizitäres Gangbild der Zielgruppe im Vergleich zu älteren Personen ohne kognitive Einschränkungen deutlich. Diese Veränderungen des Gangbildes können Kompensationsstrategien infolge verschlechterter koordinativer Fähigkeiten von älteren Personen mit kognitiven Einschränkungen darstellen. Unsere Ergebnisse erweitern die bisherigen Kenntnisse über die multifaktorielle Entstehung des körperlichen Aktivitätsverhaltens von geriatrischen Patienten im Behandlungsverlauf. Bisher wurde gezeigt, dass das körperliche Aktivitätsverhalten eines geriatrischen Patienten in der frühen Behandlungsphase im Akutkrankenhaus zunächst wesentlich von der körperlichen Leistungsfähigkeit determiniert wird (Evensen, Sletvold, Lydersen, & Taraldsen, 2017). Unsere Ergebnisse deuten hingegen darauf hin, dass in der Übergangsphase von der geriatrischen Rehabilitation in die häusliche Umgebung zusätzlich Gang- und Drehparameter bei der Entstehung von körperlicher Aktivität eine zentrale Rolle spielen.

Demnach sollten Interventionsprogramme zur Steigerung der körperlichen Aktivität neben der körperlichen Leistungsfähigkeit auch auf eine Verbesserung des habituellen Gangverhaltens abzielen.

Analog zum körperlichen Aktivitätsverhalten kann auch der Life-Space sensor- und fragebogenbasiert gemessen werden. Bei kognitiv eingeschränkten Personen wurde der Life-Space bereits auf der Basis von GPS-Sensoren erfasst (Tung et al., 2014). Fragebogenbasierte Erfassungen der LSM von älteren Personen, die in ihrem häuslichen Umfeld leben, kamen bislang ausschließlich bei kognitiv intakten, älteren Personen ohne vorherige Rehabilitationsmaßname zum Einsatz (Baker et al., 2003; Fristedt, Kammerlind, Bravell, & Fransson, 2016; Tsai et al., 2015). Ein Vergleich dieser Studienergebnisse mit unseren Ergebnissen in Publikation V macht deutlich, dass kognitiv eingeschränkte Patienten nach geriatrischen Rehabilitationsmaßnahmen im Vergleich zu kognitiv intakten Personen geringere maximale Life-Space-Zonen erreichen und wesentlich stärker von Hilfsmitteln oder Hilfspersonen abhängig sind. Physische, psychosoziale, kognitive und umweltbedingte Faktoren stellen die wesentlichen Determinanten der LSM älterer Personen ohne spezifische Einschränkungen dar (Umstattd Meyer, Janke, & Beaujean, 2014). In Publikation V wird ersichtlich, dass die Entstehung der LSM bei älteren, multimorbiden Patienten mit kognitiven Einschränkungen unmittelbar nach geriatrischen Rehabilitationsmaßnahmen ebenfalls multifaktoriell ist und wesentlich durch das Geschlecht, die körperliche Leistungsfähigkeit sowie das Ausmaß körperlicher und sozialer Aktivitäten determiniert wird. Im Vergleich zu unserer Studie, untersuchten Umstattd Meyer et al. (2014) kognitiv intakte Probanden mit einem niedrigeren Durchschnittalter (74,7 ± 7,1 Jahre), wodurch Unterschiede in den Ergebnissen zustande kommen können. Dies deutet darauf hin, dass die LSM unserer Zielgruppe stärker von Faktoren der körperlichen Leistungsfähigkeit sowie vom habituellen Bewegungsverhalten abhängt als bei älteren Personen ohne spezifische Einschränkungen. Zukünftige Interventionsstudien müssen im Längsschnitt analysieren, ob Verbesserungen der körperlichen Leistungsfähigkeit sowie Modifikationen der körperlichen und sozialen Aktivitäten zu Steigerungen der LSM führen.

Themenbereich 3:

Neben diesen Querschnittsanalysen zur Untersuchung des habituellen Bewegungsverhaltens wurden im Rahmen der vorliegenden Arbeit die Durchführbarkeit und Effektivität des Heimtrainingsprogramms nach geriatrischen Rehabilitationsmaßnahmen anhand der HeikE-Stichprobe im Hinblick auf die LSM sowie die Kosteneffektivität evaluiert. Unsere Ergebnisse in Publikation VI zeigen, dass das vorrangig selbstständig durchgeführte HeikE-Trainingsprogramm bei Personen mit kognitiven Einschränkungen nach geriatrischen Rehabilitationsmaßnahmen sicher durchführbar ist. Dies ist sowohl in Einklang mit dem Ergebnis einer zuvor von unserer Arbeitsgruppe durchgeführten Pilotstudie (Hauer et al., 2017), als auch mit einer Metaanalyse, in der eine hohe Evidenz für die sichere Durchführbarkeit von Heimtrainingsprogrammen bei demenziell erkrankten Personen ohne vorherige Rehabilitationsmaßnahme gezeigt wurde (Almeida et al., 2019). In bisherigen Heimtrainingsstudien mit kognitiv eingeschränkten, älteren Personen wurden pflegende Angehörige oder Trainer strukturiert in die Durchführung und Supervision der regelmäßigen Trainingsdurchführung eingebunden (Dawson, Judge, & Gerhart, 2019; Holthoff et al., 2015; Padala et al., 2017; Pitkälä et al., 2013; Suttanon et al., 2013; Wesson et al., 2013). Das hier eingesetzte Heimtrainingsprogramm ist demgegenüber durch eine vorrangig selbstständige Trainingsdurchführung und den Einsatz einer individualisierten Motivationsstrategie (siehe Publikation I) gekennzeichnet. In der zweiten Woche des Trainingsprogramms führten die Teilnehmer 76,8 % aller geplanten Trainingseinheiten durch, was eine hohe initiale Adhärenz an die körperlichen Trainingsinhalte darstellt. Dieses Ergebnis ist vergleichbar mit einer Studie, in der Personen mit demenziellen Erkrankungen durch pflegende Angehörige bei der Durchführung körperlicher Trainingseinheiten unterstützt wurden (Prick, de Lange, Scherder, Twisk, & Pot, 2016). Im Laufe der Intervention ging mit einer verringerten Anzahl der Hausbesuche durch die Trainer eine Reduktion der Adhärenz an das Training auf 51,5 % einher. Dies deutet darauf hin, dass die soziale Unterstützung durch den Trainer auch bei Heimtrainingsprogrammen mit vorrangig selbstständiger Durchführung durch die Teilnehmer für ein Aufrechterhalten der Adhärenz von hoher Relevanz ist.

Im Rahmen der vorliegenden Arbeit wurde neben der Durchführbarkeit und der Adhärenz des Heimtrainingsprogramms auch die Effektivität dieses Interventionsansatzes auf die LSM von geriatrischen Patienten mit kognitiven Einschränkungen nach Rehabilitationsmaßnahmen evaluiert. Obwohl geriatrische Personen mit kognitiven Einschränkungen in besonderem Maße auch von Einschränkungen der LSM gefährdet sind, wurde diese Zielgruppe bislang nicht in Interventionsstudien zur Modifikation der LSM eingeschlossen (Fairhall et al., 2012; Turunen et al., 2020). Dies könnte darin begründet sein, dass vor der Entwicklung und Validierung des LSA-CI (siehe Publikation IV) kein valides Instrument zur Erfassung der LSM bei älteren, im häuslichen Umfeld lebende Personen mit kognitiven Einschränkungen zur Verfügung stand. Unsere Ergebnisse aus Publikation VII zeigen, dass ein auf die spezifischen Charakteristika von geriatrischen Patienten mit kognitiven Einschränkungen angepasstes Heimtrainingsprogramm in der Übergangsphase von der Rehabilitationsmaßnahme in das häusliche Umfeld zu einer Steigerung der selbstständig erreichten, maximalen Life-Space Bereiche führt. Gleichzeitig wurde eine Verringerung der Inanspruchnahme von Hilfsmitteln und Hilfspersonen festgestellt, was insgesamt eine Steigerung der LSM widerspiegelt. Dieses positive Ergebnis könnte dadurch erklärt werden, dass das HeikE-Trainingsprogramm auf eine Verbesserung der körperlichen Leistungsfähigkeit und auf eine Steigerung der körperlichen Aktivität abzielte. Damit war die Intervention auf Faktoren fokussiert, die in der Zielgruppe wesentliche Determinanten der LSM darstellen (siehe Publikation V). Heimtrainingsprogramme bei kognitiv intakten Personen zeigten widersprüchliche Effekte auf die LSM (Fairhall et al., 2012; Turunen et al., 2020). Unsere Ergebnisse sollten ebenfalls durch weitere Studien bei älteren Personen mit kognitiven Einschränkungen verifiziert werden, die auch den Einfluss sozialer Aktivitäten auf die LSM überprüfen sollten, da dieser Faktor nach Publikation V ebenfalls eine Determinante der LSM darstellt. Zukünftige Studien sollten berücksichtigen, dass Steigerungen der körperlichen Aktivität bei älteren Personen zu einer erhöhten Exposition sturzgefährdender Situationen führen (Del Din et al., 2020). Daher sollte die Interpretation einer gesteigerten körperlichen Aktivität in Relation zum Auftreten von Stürzen erfolgen (Del Din et al., 2020). Analog dazu sollte auch eine Steigerung der LSM in Relation zu der Anzahl auftretender Stürzer bewertet werden.

Neben der Untersuchung klinischer Effekte wurde die Kosteneffektivität des dieser Arbeit zugrunde liegenden Heimtrainingsprogramms HeikE evaluiert. Vergleichbar mit anderen Trainingsstudien, in denen ältere, demenziell erkrankte Personen initial supervidierte Gruppentrainingsprogramme (Khan et al., 2019) oder kognitiv intakte ältere Personen nach Hüftfraktur supervidierte Heimtrainingsprogramme (Taraldsen et al., 2019) durchführten, zeigen unsere Ergebnisse keinen ökonomischen Nutzen hinsichtlich einer Steigerung der qualitätskorrigierten Lebensjahre. Darüber hinaus wurde in unserer Studie die Kosteneffektivität in Bezug auf eine Modifikation spezifischer, klinischer Parameter wie dem SPPB-Gesamtscore überprüft. Das Ergebnis dieser Analyse zeigte, dass HeikE bei älteren, kognitiv eingeschränkten Personen hinsichtlich der Verbesserung des spezifischen klinischen Parameters der körperlichen Leistungsfähigkeit im Vergleich zur Regelversorgung ab einer Zahlungsbereitschaft von 2000 € für eine Steigerung des SPPB-Gesamtscores um einen Punkt kosteneffektiv ist. Aus gesundheitsökonomischer Sicht ist die Durchführung des HeikE-Trainingsprogramms zur Steigerung der körperlichen Leistungsfähigkeit bei älteren Patienten mit kognitiven Einschränkungen in der poststationären geriatrischen Rehabilitation demnach zu empfehlen.

5 Fazit und Ausblick

In der vorliegenden Arbeit wurden zwei verschiedene Methoden zur Erfassung unterschiedlicher Aspekte des habituellen Bewegungsverhaltens von multimorbiden Personen mit motorischen und kognitiven Einschränkungen entwickelt, validiert und erstmals im häuslichen Umfeld der Studienteilnehmer angewendet. Bisherige Messinstrumente waren weder an die spezifischen Bewegungscharakteristika dieser Zielgruppe angepasst, noch im häuslichen Umfeld validiert. Insgesamt leistet diese Arbeit einen relevanten Beitrag zur Erweiterung valider Assessmentverfahren zur Quantifizierung des habituellen Bewegungsverhaltens und dessen erstmaliger Erfassung. Darüber hinaus werden die Durchführbarkeit, Effekte auf die LSM und Kosteneffektivität eines Heimtrainingsprogramms evaluiert. Das Heimtrainingsprogramm erwies sich als durchführbar, wirksam in Bezug auf die Verbesserung der LSM und kosteneffektiv. Mit diesem Programm könnte es gelingen, die Versorgungssituation von Patienten mit kognitiven und motorischen Einschränkungen, die nach geriatrischen Rehabilitationsmaßnahmen in ihr häusliches Umfeld zurückkehren und unmittelbar von einem Verlust der selbstständigen Lebensführung und von Pflegeheimeinweisungen bedroht sind, zu optimieren.

Aufgrund der im Rahmen dieser Arbeit nachgewiesenen Validität der beiden eingesetzten Messmethoden können diese zur Erhebung unterschiedlicher Dimensionen des körperlichen Aktivitätsverhaltens multimorbider, geriatrischer Patienten mit kognitiven Einschränkungen genutzt werden. Das in dieser Arbeit validierte Bewegungssensorsystem ermöglicht eine verlässliche Erfassung körperlicher Aktivität und zeitlicher Gang- und Drehparameter speziell im häuslichen Umfeld der hier untersuchten Zielgruppe. In Querschnittsanalysen wurde gezeigt, dass neben einer hohen körperlichen Leistungsfähigkeit vor allem die Gangsymmetrie und Drehgeschwindigkeit beim Kurvengehen wesentliche Determinanten der körperlichen Aktivität darstellen. Die zusätzliche Integration von Maßnahmen zur gezielten Gangschulung in Interventionsmaßnahmen zur Steigerung des körperlichen Aktivitätsverhaltens kann demnach zielführend sein. Diese Hypothese gilt es mittels Längsschnittanalysen im Rahmen von Interventionsstudien zu verifizieren.

Das in dieser Arbeit validierte uSense-System sollte hinsichtlich seiner Größe und des Energieverbrauchs optimiert werden. Analog zu ausschließlich akzelerometerbasierten Sensorsystemen (wie z.B. ActivePAL) könnte dadurch das habituelle Bewegungsverhalten, insbesondere Gang- und Drehparameter, über längere Zeiträume im Alltag erfasst werden. Derartige Sensoren sollten in zukünftigen Längsschnittstudien zur Evaluierung von spezifischen, habituellen Bewegungs- und Gangmustern herangezogen werden, um potenziell auftretende Prädiktoren für gesundheitsgefährdende Ereignisse, wie beispielsweise das Auftreten eines Sturzes zu identifizieren. Der Nachweis über differenzierte Prädiktoren für Stürze im habituellen Setting würde eine direkte Verbesserung der Versorgungssituation darstellen: Sturzgefährdete Personen könnten frühzeitig identifiziert und in Präventionsprogramme eingesteuert werden. In diesen Programmen könnte die Messung von sturzbegünstigenden Bewegungsmustern wiederum zur Quantifizierung von Trainingseffekten genutzt werden.

Zukünftige Weiterentwicklungen ambulanter Sensorsysteme sollten neben zeitlichen Gangparametern auch eine zusätzliche Erfassung von räumlich-zeitlichen Parametern im habituellen Setting anstreben. Das größte Entwicklungspotenzial für eine Optimierung der Messungen weisen neben der Art der eingesetzten Sensorik insbesondere die der Datengenerierung zugrunde liegenden Algorithmen auf (Caldas et al., 2017). Nach Caldas et al. (2020) können Algorithmen zukünftig durch die Nutzung künstlicher Intelligenz um adaptive und prädiktive Fähigkeiten erweitert werden. Durch die Analyse vorheriger individueller Bewegungsmuster können zukünftige zu erwartende Bewegungen vorhergesagt, verifiziert und dadurch mit erhöhter Genauigkeit gemessen werden (Caldas, Fadel, Buarque, & Markert, 2020).

Die Entwicklung und Validierung des fragebogenbasierten LSA-CI ermöglicht die valide Erfassung der LSM von älteren Personen mit kognitiven Einschränkungen. Ergebnisse der im Rahmen dieser Arbeit durchgeführten Querschnittsanalysen zeigen, dass ältere Personen mit kognitiven Einschränkungen im Vergleich zu älteren, kognitiv intakten Personen, eine geringere LSM aufweisen und darüber hinaus in besonders hohem Maße auf die Nutzung von Hilfsmitteln oder die Unterstützung durch Hilfspersonen angewiesen sind. Die LSM der hier untersuchten Zielgruppe wurde zu 42 % durch die Parameter „körperliche Aktivität“, „körperliche Leistungsfähigkeit“,

„Teilnahme an sozialen Aktivitäten“ und „männliches Geschlecht“ erklärt. Mit Ausnahme des Geschlechts sind diese Faktoren modifizierbar. Interventionen, die auf die Verbesserung der modifizierbaren Determinanten abzielen, haben demnach ein hohes Potenzial die LSM in dieser Zielgruppe zu verbessern. Darüber hinaus sollten weitere Studien untersuchen, welche Faktoren den nicht aufgeklärten Anteil der LSM determinieren. Anschließend muss durch Längsschnittanalysen im Rahmen von Interventionsstudien verifiziert werden, ob gezielte Verbesserungen der Determinanten zu Verbesserungen der LSM führen.

Abschließend legt die vorliegende Arbeit wesentliche Grundsteine, um das Heimtrainingsprogramm in die Gesundheitsversorgung von geriatrischen Patienten mit kognitiven Einschränkungen zu implementieren. Die Ergebnisse zeigen, dass das spezifisch auf die Charakteristika der Zielgruppe zugeschnittene Heimtrainingsprogramm bei überwiegend selbstständigem Training eine gute Durchführbarkeit aufweist. Sowohl in Bezug auf das Trainingsprogramm, als auch die eingesetzten BCTs weist dieses vulnerable Kollektiv eine hohe initiale Adhärenz auf, die im Laufe der Intervention abnimmt. Die soziale Unterstützung durch die Trainer wurde von den Studienteilnehmern als effektivste Programmkomponente wahrgenommen. Weitere Studien sollten daher überprüfen, ob eine engmaschigere Supervision durch die Trainer zu einer höheren Adhärenz über die Trainingsdauer führt.

Darüber hinaus wurde durch das Heimtrainingsprogramm eine erhöhte LSM der Teilnehmer im Vergleich zur Kontrollgruppe erreicht. Diese Steigerung der LSM bietet multimorbiden Patienten mit kognitiven Einschränkungen ein hohes Potenzial zu erhöhter gesellschaftlicher Teilhabe. Dies stellt im Sinne der ICF, die im Jahr 2001 von der WHO veröffentlicht wurde, unabhängig von potenziellen vorhandenen körperlichen oder geistigen Einschränkungen eine Verbesserung des Gesundheitsstatus dar (Escorpizo et al., 2013). Dies bestärkt auch bei geriatrischen Patienten mit kognitiven Einschränkungen die Notwendigkeit eines Paradigmenwechsels von einer rein defizitorientierten, hin zu einer verstärkt ressourcenorientierten Therapie. In zukünftigen Längsschnittanalysen ist zu prüfen, ob das Heimtrainingsprogramm ebenfalls positive Auswirkungen auf weitere Dimensionen des körperlichen Aktivitäts- und Gangverhaltens sowie auf die körperliche Leistungsfähigkeit von geriatrischen Patienten mit kognitiven Einschränkungen hat. Neben dem Nachweis des klinischen Effektes in

Form einer gesteigerten LSM konnte gezeigt werden, dass das Heimtrainingsprogramm hinsichtlich der Steigerung der körperlichen Leistungsfähigkeit im Vergleich zur Regelversorgung kosteneffektiv ist. Daher ist eine Implementierung und Finanzierung des dargestellten Heimtrainingsprogramms unmittelbar nach geriatrischen Rehabilitationsmaßnahmen bei Patienten mit kognitiven Einschränkungen nach den ersten Ergebnissen sowohl aus klinischer, als auch aus gesundheitsökonomischer Sicht zu empfehlen. Weitere Studien sind erforderlich, um zu evaluieren inwiefern das Heimtrainingsprogramm ebenfalls hinsichtlich einer Modifikation der habituellen körperlichen Aktivität in der untersuchten Zielgruppe kosteneffektiv ist. Sollten die Ergebnisse dieser Analysen ebenfalls in einer Empfehlung zur Durchführung und Finanzierung des Heimtrainingsprogramms münden, wäre eine flächendeckende Integration des Programms in die Versorgungsrealität davon abhängig, ob aus politischer Sicht eine Verortung derartiger Interventionsarten im Sozialgesetzbuch (SGB) gewollt ist und erreicht werden kann. Analog zu koronaren Herzsportgruppen oder zum orthopädischen Rehabilitationssport könnte ein nächster Schritt darin bestehen, das Heimtrainingsprogramm nach §64 Abs. 1 Nr. 3 SGB IX als *ergänzende Leistung zur Rehabilitation* in die Versorgungsrealität von multimorbiden Personen mit kognitiven Einschränkungen nach geriatrischen Rehabilitationsmaßnahmen zu integrieren. Somit wäre die gesetzliche Grundlage für eine Finanzierung durch die gesetzlichen Krankenkassen geschaffen. Dadurch könnte das Heimtrainingsprogramm flächendeckend für diese zukünftig immer größer werdende Zielgruppe zugänglich gemacht werden.

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Abbildungs- und Tabellenverzeichnis

Abbildungen

Tabellen

Abkürzungsverzeichnis

BCT	Behavior Change Technique
CI	Cognitive Impairment
GPS	Global Positioning System
HeikE	Heimtraining bei kognitiver Einschränkung
ICC	Intraklassen-Korrelationskoeffizient
ICF	International Classification of Functioning, Disability and Health
IMU	Inertial Measurement Unit
IQR	Interquartile Range
LSA-CI	Life-Space Assessment for persons with Cognitive Impairment
LSA-CI-C	LSA-CI Gesamtscore
LSA-CI-E	maximal erreichte Life-Space Zone mit Hilfsmittel aber ohne Hilfsperson
LSA-CI-I	maximal erreichte Life-Space Zone ohne Hilfsperson und ohne Hilfsmittel
LSA-CI-M	maximal erreichte Life-Space Zone mit Hilfsmittel und mit Hilfsperson
LSM	Life-Space Mobilität
MCI	Mild Cognitive Impairment
MMSE	Mini-Mental State Examination
NMB	Net Monetary Benefit
QALY	Quality Adjusted Life Year
RCT	Randomized controlled trial
SGB	Sozialgesetzbuch
SPPB	Short Physical Performance Battery
SRM	Standardized Response Mean
UAB-LSA	University of Alabama at Birmingham Study of Aging Life-Space Assessment
WHO	World Health Organisation
WTP	Willingness To Pay

Weitere dissertationsassoziierte Publikationen und Kongressbeiträge

Weitere dissertationsassoziierte Publikationen

Phoebe Ullrich, Christian Werner, Tobias Eckert, **Martin Bongartz**, Rainer Kiss, Manuel Feisst, Kim Delbaere, Jürgen Bauer, Klaus Hauer (2018). Cut-off for the Life-Space Assessment in persons with cognitive impairment. Aging Clin Exp Res. doi:10.1007/s40520-018-1062-2

Weitere dissertationsassoziierte Publikationen in Vorbereitung

Phoebe Ullrich, Tobias Eckert, **Martin Bongartz**, Rainer Kiss, Christian Werner, Jürgen M. Bauer, Klaus Hauer. Review on existing life space assessments including biometrical quality and sample specifics.

Klaus Hauer, Phoebe Ullrich, Tobias Eckert, **Martin Bongartz**, Rainer Kiss, Christian Werner, Jürgen M. Bauer. Effects of a home based training program in frail older persons with CI following ward based rehabilitation.

Phoebe Ullrich, Tobias Eckert, **Martin Bongartz**, Rainer Kiss, Christian Werner, Jürgen M. Bauer, Klaus Hauer. Effects of a home training program on outdoor activity assessed by GPS monitoring.

Dissertationsassoziierte Kongressbeiträge – Poster

Martin Bongartz, Rainer Beurskens, Phoebe Ullrich, Tobias Eckert, Klaus Hauer. Studienprotokoll eines Heimtrainingsprogramms bei Patienten mit kognitiver Einschränkung (HeikE).
Veranstaltung: Gemeinsamer Jahreskongress der DGG und DGGG vom 07.09. bis zum 10.09.2016 in Stuttgart.

Martin Bongartz, Phoebe Ullrich, Tobias Eckert, Christian Werner, Rainer Kiss, Bastian Abel, Jürgen M. Bauer, Klaus Hauer. Zusammenhänge zwischen motorischer Leistungsfähigkeit und körperlicher Alltagsaktivität bei älteren Personen mit kognitiver Einschränkung nach geriatrischer Rehabilitation.
Veranstaltung: Gemeinsamer Jahreskongress der DGG und DGGG vom 06.09. bis zum 09.09.2016 in Köln.
Abstract publication: Z Gerontol Geriat 2018 · 51 (Suppl 1):S1–S162.

Martin Bongartz, Phoebe Ullrich, Tobias Eckert, Christian Werner, Rainer Kiss, Bastian Abel, Sabato Mellone, Jürgen M. Bauer, Klaus Hauer Associations Of Motor Performance And Qualitative/ Quantitative Physical Activity Behavior In Older Persons With Cognitive Impairment After Discharge From Geriatric Rehabilitation.
Event: 14th EuGMS Congress from 10 to 12 October 2018 in Berlin, Germany.
Abstract publication: Eur Geriatr Med (2018) 9 (Suppl 1):S1–S367.

Klaus Hauer, **Martin Bongartz**, Rainer Kiss, Andre Lacroix, Phoebe Ullrich, Tobias Eckert, Carl-Philipp Jansen, Sabato Mellone. Validity of sensor-based habitual physical activity and gait analysis in multimorbid older persons. Innovation in Aging, 2018, Vol. 2, No. S1; DOI: 10.1093/geroni/igy023.2703.
Event: GSA Annual Scientific Meeting from 14th to 18th November 2018 in Boston, USA.

Dissertationsassoziierte Kongressbeiträge – Vorträge

Martin Bongartz, Rainer Kiss, Andre Lacroix, Phoebe Ullrich, Tobias Eckert, Carl-Philipp Jansen, Jürgen M. Bauer, Klaus Hauer. Validierung eines Aktivitätssensors zur Erfassung körperlicher Aktivitätsparameter und innovativer Gangparameter im Alltag von multimorbiden, geriatrischen Patienten mit kognitiven Einschränkungen nach Rehabilitation.
Veranstaltung: Gemeinsamer Jahreskongress der DGG und DGGG vom 06.09. bis zum 08.09.2018 in Köln.
Abstract publication: Z Gerontol Geriat 2018 · 51 (Suppl 1): S1–S162.

Martin Bongartz, Rainer Kiss, André Lacroix, Phoebe Ullrich, Tobias Eckert, Sabato Mellone, Jürgen M. Bauer, Klaus Hauer. Validity Of Sensor-based, Habitual Physical Activity And Gait Analysis In Older Persons With Cognitive Impairment After Discharge From Geriatric Rehabilitation.
Event: 14th EuGMS Congress from 10 to 12 October 2018 in Berlin, Germany.
Abstract publication: Eur Geriatr Med (2018) 9 (Suppl 1): S1–S367.

Martin Bongartz, Tobias Eckert, Rainer Kiss, Phoebe Ullrich, Christian Werner, Jürgen M. Bauer, Klaus Hauer. Ein poststationäres Heimtrainingsprogramm bei älteren Personen mit kognitiver Einschränkung – Erste Ergebnisse zur körperlichen Leistungsfähigkeit und zum Aktivitätsverhalten.
Veranstaltung: Jahrestagung der dvs-Kommission Gesundheit vom 04. Bis 06. April 2019 in Hamburg.

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FAKULTÄT FÜR VERHALTENS-
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Doctoral Committee of the Faculty of Behavioural and Cultural Studies of Heidelberg University

Erklärung gemäß § 8 (1) c) der Promotionsordnung der Universität Heidelberg für die Fakultät für Verhaltens- und Empirische Kulturwissenschaften
Declaration in accordance to § 8 (1) c) of the doctoral degree regulation of Heidelberg University, Faculty of Behavioural and Cultural Studies

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Anhang A: Autorenbeiträge zu den Publikationen

Tabelle 1: Beiträge der einzelnen Autoren zu den Publikationen I bis VIII.

Publika-tion	Studien-design	Daten-erfassung	Daten-anayse	Inter-pretation Ergebnisse	Erstellung Manuskript
I	KH, RK, PU	Studienproto-koll	Studienpro-tokoll	Studienproto-koll	**MB**, RK, PU, TE, JB, KH
II	**MB**, KH, RK	**MB**, RK	**MB**, MF, AL	**MB**, AL, TE, SM	**MB**, RK, AL, TE, PU, CJ, MF, SM, LC, CB, KH
III	PU, RK, KH	**MB**, RK	PU, CW	PU, CW, **MB**, RK, KH	PU, CW, **MB**, RK, JB, KH
IV	BA*, **MB***, KH	**MB**, RK	BA, **MB**, TE	BA, **MB**, TE, SM, KH	BA, **MB**, TE, PU, RK, SM, KH
V	PU, KH	**MB**, RK	PU, TE	PU, TE, **MB**, CW, KH	PU, TE, **MB**, CW, RK, JB, KH
VI	TE, KH	**MB**, RK	TE	TE, **MB**, CW, KH	TE, **MB**, PU, BA, CW, RK, KH
VII	PU, KH	**MB**, RK	PU, CW	PU, CW, **MB**, TE, KH	PU, CW, **MB**, TE, BA, RK, KH
VIII	TE, PW, KH	**MB**, RK	TE, PW, JK	TE, PW, **MB**, JK, KH	TE, PW, **MB**, JK, PU, BA, RK, JB, MW, KH

Hinweise: Dargestellt sind die Namenskürzel der einzelnen Autoren gemäß ihrer Beiträge; das Namenskürzel des Verfassers dieser Dissertation ist jeweils fett hervorgehoben.
* Autoren teilen Erstautorenschaft.

Anhang B: Publikationen zur publikationsbasierten Dissertation

Publikation I

Martin Bongartz, Rainer Kiss, Phoebe Ullrich, Tobias Eckert, Jürgen Bauer, Klaus Hauer (2017). Development of a home-based training program for post-ward geriatric rehabilitation patients with cognitive impairment: study protocol of a randomized-controlled trial. *BMC Geriatrics, 17* (214). doi: 10.1186/s12877-017-0615-0

Bongartz et al. BMC Geriatrics (2017) 17:214
DOI 10.1186/s12877-017-0615-0

BMC Geriatrics

STUDY PROTOCOL Open Access

Development of a home-based training program for post-ward geriatric rehabilitation patients with cognitive impairment: study protocol of a randomized-controlled trail

Martin Bongartz[1*], Rainer Kiss[1], Phoebe Ullrich[1], Tobias Eckert[1], Jürgen Bauer[1,2] and Klaus Hauer[1]

Abstract

Background: Geriatric patients with cognitive impairment (CI) show an increased risk for a negative rehabilitation outcome and reduced functional recovery following inpatient rehabilitation. Despite this obvious demand, evidence-based training programs at the transition from rehabilitation to the home environments are lacking. The aim of this study is to evaluate the efficacy of a feasible and cost-effective home-based training program to improve motor performance and to promote physical activity, specifically-tailored for post-ward geriatric patients with CI.

Methods: A sample of 101 geriatric patients with mild to moderate stage CI following ward-based rehabilitation will be recruited for a blinded, randomized controlled trial with two arms. The intervention group will conduct a 12 week home-based training, consisting of (1) Exercises to improve strength/power, and postural control; (2) Individual walking trails to enhance physical activity; (3) Implementation of patient-specific motivational strategies to promote behavioral changes. The control group will conduct 12 weeks of unspecific flexibility exercise. Both groups will complete a baseline measurement before starting the program, at the end of the intervention, and after 24 weeks for follow-up. Sensor-based as well as questionnaire-based measures will be applied to comprehensively assess intervention effects. Primary outcomes document motor performance, assessed by the Short Physical Performance Battery, and level of physical activity (PA), as assessed by duration of active episodes (i.e., sum of standing and walking). Secondary outcomes include various medical, psycho-social, various PA and motor outcomes, including sensor-based assessment as well as cost effectiveness.

Discussion: Our study is among the first to provide home-based training in geriatric patients with CI at the transition from a rehabilitation unit to the home environment. The program offers several unique approaches, e.g., a comprehensive and innovative assessment strategy and the integration of individually-tailored motivational strategies. We expect the program to be safe and feasible in geriatric patients with CI with the potential to enhance the sustainability of geriatric rehabilitation programs in patients with CI.

Trial registration: International Standard Randomized Controlled Trial (#ISRCTN82378327). Registered: August 10, 2015.

Keywords: Home-based training, Post-ward (patients) geriatric rehabilitation, Cognitive impairment, Physical activity promotion, Motor performance

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Background

The prevalence of cognitive impairment (CI) in patients admitted to geriatric rehabilitation units ranges from 30% to 80%, depending on sample characteristics and cut-off criteria [1, 2]. CI is accompanied with high demands for the health care systems, as decreased cognitive functioning is associated with increased care costs in this vulnerable population [3]. Compared to cognitively-intact patients, patient with CI show an increased number of risk factors affecting their health status, i.e., multi-morbidity [4], lower functional status [5], an increased risk of falling [6], and higher institutionalization and mortality rates [2]. Particularly, CI is often associated with specific motor-related symptoms, such as impaired functioning (i.e., deficits in balance and gait performance) [7–9], reduced participation in activities of daily living (ADL; i.e., shopping, dressing, or eating) [9] and reduced outdoor activities [10]. Further, a higher probability of neuropsychiatric symptoms is typical in patients with CI (i.e., apathy, anxiety, depression, irritability and agitation) [11–13], resulting in a loss of motivation to become physically active [14]. Patients with CI show an increased risk for negative rehabilitation outcome, leading to limited functional recovery during inpatient rehabilitation [15] and a lower functional status at hospital discharge [5]. Also, their access to medical services is limited, including post-ward rehabilitation (e.g., traveling too far to participate in rehabilitation programs is considered a typical barrier) [16]. These findings indicate the need for appropriate rehabilitation concepts for geriatric patients with CI at the transition from inpatient rehabilitation to their home environments and innovative, individually-tailored training concepts with low entry barriers are required. Effective post-ward rehabilitation programs may increase the ability to perform ADL, representing one of the most important predictor of societal costs of care of community-dwelling patients and improve functional performances and mobility (i.e., allowing proper preservation of autonomy).

Home-based training programs represent suitable exercise regimens that have been shown feasible and save in community-dwelling older adults with CI [17–21]. However, results of these home-based training programs are inconsistent. Some studies indicated improvements in motor performance [17, 18], while others only showed decelerated deterioration of physical function and mobility [22] or did not find any effects on performance [20, 21]. Further, studies showed methodological inconsistencies, e.g., not providing sufficient information on registered motor performance measures [20], not measuring key motor features (i.e., gait, balance, strength) as primary endpoints [19, 20], or using rather small sample sizes [18, 21].

Publications on home-based training programs in the vulnerable group of post-ward patients with CI are still scarce or inconclusive, despite overwhelming evidence based on supervised ward-based and post-ward programs are effective in improving motor function and physical activity (PA) in these specific population [23, 24]. Interventions at the transition from geriatric inpatient rehabilitation to the home environments have only been evaluated in heterogeneous patient populations [25–29]. Most programs included cognitively intact patients [25, 26] and only few studies integrated sub-groups of cognitively-impaired patients [27–29]. Some studies reported beneficial effects of home-based training on motor performance and mobility [25, 29], while others did not find training-related performance improvements [26, 27]. Furthermore, Moseley and colleagues indicated that patients with CI showed worse adherence rates compared to cognitive-intact persons during a home-based training program [27]. Hence, motivational strategies should be integrated into physical exercise programs to promote adherence and increase participation. The importance of motivational strategies is further emphasized by Heyn and colleagues [30], who explicitly state that previous interventions did not integrate appropriate motivational concepts to foster participation and enhance motivation in older adults with CI.

Surprisingly, behavioral aspects, such as PA have hardly been investigated in home-based training programs, although such behavioral changes are crucial for the sustainability of rehabilitation programs. Primary aim of most programs was to improve motor performance and only a few studies documented PA using questionnaires [17, 18, 21]. None found training-related improvements and none objectively registered PA using sensor-based assessment strategies. The latter is astonishing since, due to recall and response bias, questionnaire-based assessments are less valid and reliable in cognitively-impaired older adults [31]. Thus, assessment strategies including objective sensor-based as well as subjective questionnaire-based measurements are advised to comprehensively register changes in activity behavior following training interventions.

The current study protocol addresses the situation of multi-morbid and frail geriatric patients with mild to moderate CI following inpatient rehabilitation. Primary aim of the study is the development and evaluation of a safe and feasible home-based exercise program to improve motor performance and to promote PA (i.e., initiate sustained behavioral changes) in the vulnerable group of multi-morbid, geriatric patients with CI, suitable to be implemented in existing health care plans.

Methods/Design

Study design

The presented study is a blinded randomized-controlled trial (RCT) with two arms (i.e., an intervention group [INTV] and a control group [CTRL]; Fig. 1) and will be

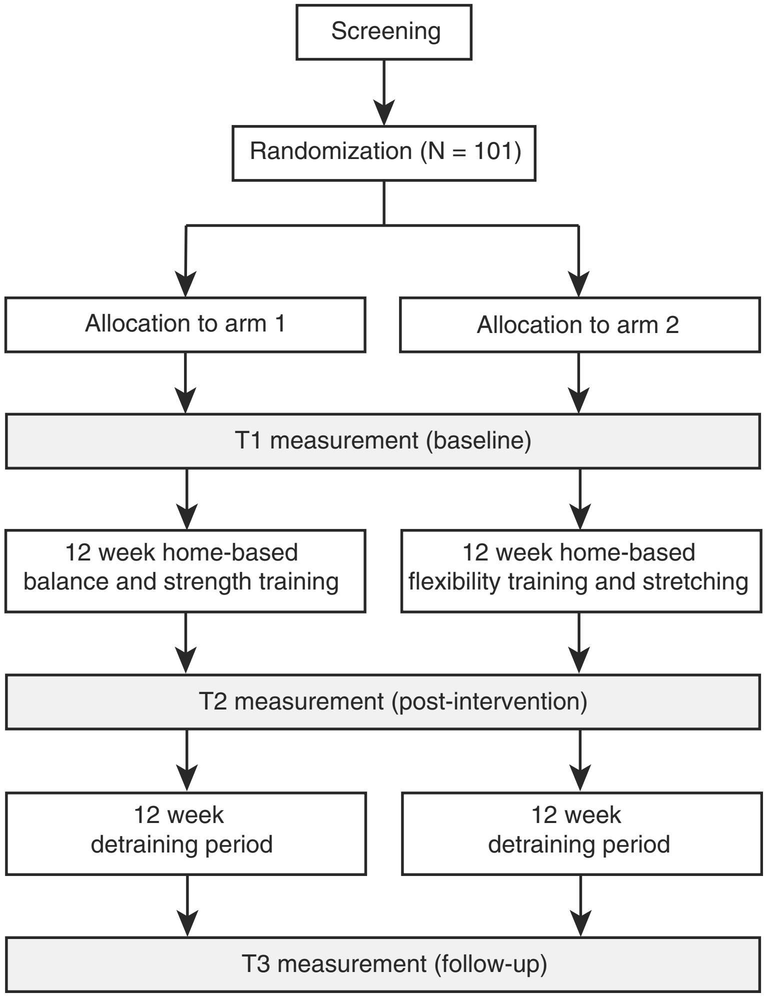

Fig. 1 Schematic illustration of the study design

implemented according to CONSORT guidelines [32]. Ethical approval according to the ethical standards of the Helsinki declaration was obtained from the internal review board at the Medical Faculty of the University of Heidelberg, Germany (reference#: S-252/2015). The study protocol has been registered with the "International Standard Randomized Controlled Trial Number" (ISRCTN) trial register (http://www.isrctn.com/ISRCTN82378327).

Sample characteristics

Inclusion criteria are (1) patients admitted to ward-based rehabilitation in a geriatric hospital in Heidelberg, Germany; (2) age ≥ 65 years; (3) mild to moderate CI (Mini-Mental-State-Examination [MMSE]: 17–26); (4) ability to walk 4 m without support; (5) residency within 30 km of the study center; (6) discharge from rehabilitation unit to home environment; (7) no terminal disease/ no delirium; (8) German-speaking; and (9) written informed consent from participant or care giver. All patients admitted to the geriatric inpatient rehabilitation at the AGAPLESION Bethanien Hospital are consecutively screened for inclusion.

Measures

After inclusion of the participants, primary and secondary outcome parameters are registered at baseline (T1), following the training intervention (T2), and 12 weeks after the training is completed (T3). At baseline, additional descriptive parameters (i.e., age, gender, height, weight, Barthel Index) are registered. Blinded assessors will conduct the measurements at the patients' home.

Motor performance

Key motor performances will be assessed using the Short-Physical-Performance-Battery (SPPB) including sub-tests of static balance, walking performance and sit-to-stand performance [33]. Outcome parameters are the total SPPB score (i.e. 0–12 scores) calculated as the summation of each sub-test score and the scores in each of the sub-tests (i.e. 0–4 scores) [33]. The “Timed Up and Go-test” (TuG) is performed to assess basic functional mobility [34]. Outcome parameter is the time in seconds needed to perform the task.

Additionally, objective performance measures are registered for SPPB using advanced body-fixed motion sensors (DynaPort MT, McRoberts B.V., The Hague, Netherlands). The sensor is attached to subject’s lower back at the height of the second lumbar vertebra. The measurement system (106.6 × 58 × 11.5 mm, 55 g) contains three pre-calibrated seismic accelerometers (sensor range: ± 2 g, resolution: 1 mg) and three gyroscopes (range: ± 100 deg./s, resolution: 0.0069 deg./s). Data is recorded at a sampling rate of 100 Hz. Outcome parameters are defined as body sway in terms of Center of Pressure (CoP) displacements in mm and CoP velocity in mm/s to evaluate static balance performance. During the 5-times-chair-rise test, sit-to-stand and stand-to-sit durations in seconds and maximum angular velocities in deg./s are calculated.

Physical activity

PA will be registered using a small-scaled (51 × 30 × 16 mm, 24 g) activity monitor (PAMSys, BioSensics, Cambridge, MA, USA), attached on subjects’ chest using adhesive bands. The activity monitor includes a tri-axial accelerometer sensor registering accelerations in three perpendicular directions (accelerations in the frontal, vertical, and lateral directions) at a sampling frequency of 40 Hz. Additionally, a second activity monitor (uSense) will be used for validation purpose. The uSense sensor is a non-commercial prototype, developed by the EU-funded “FARSEEING” project allowing detailed quantitative as well as qualitative data analysis. The sensor (42 × 10 × 68 mm, 36 g) includes a 9-axis inertial platform (accelerometer, gyroscope, magnetometer) registering acceleration and orientation in X, Y and Z direction at a sampling frequency of 100 Hz and is attached to subjects’ lower back using adhesive bands.

Raw data from both activity monitors is transferred to a stationary computer for offline analysis using established algorithms [35]. Outcome parameters are number and duration (registered in minutes) of postural episodes (lying, sitting, standing, and walking), cadence defined as steps per minute, number of steps (i.e., total number of steps, number of steps per gait episode) and sit-to-stand/stand-to-sit transitions (number of sit-to-stand/stand-to-sit transitions). The uSense sensor additionally registers qualitative gait parameters (e.g., mean step duration [s], step regularity [%], turning velocity [deg/s]) during each walking episode. Participants are asked to wear the monitor continuously for 48 h.

Life-space

The University of Alabama at Birmingham Study of Aging Life-Space Assessment has been used to document the mobility of community-dwelling older people [36]. Life-space zones range from a person’s bedroom (level 0) to beyond the person’s home town (level 5). For each life-space zone, subjects report how often they travel to that area per week and whether they need assistance. Higher scores indicate high life-space mobility from 0 (“totally bed-bound”) to 120 points (“traveled out of town every day without assistance”) [36]. We developed a modified version of the University of Alabama at Birmingham Study of Aging Life-Space Assessment to assess participants’ life-space (LSA). The LSA is adjusted to specific limitations of patients with CI to eliminate recall bias and has been successfully validated in geriatric patients with CI (paper submitted).

Additionally, participants’ outdoor life-space will be objectively measured using a Global Position System (GPS) tracker. Participants are asked to wear the mobile GPS tracker (QStarz BT1000X, Qstarz International Co., Ltd., Taipei, Taiwan) for 48 consecutive hours. Using a sampling rate of 0.2 Hz, the GPS tracker records participants’ outdoor location (i.e., longitude and latitude coordinates) with an accuracy of ±5 m. Outcome measures for a patient’s life-space are total LSA score, the maximum distance in meters from the participant home and the mean distance of outdoor walking episodes in meters assessed by GPS using location data [37].

Psycho-social parameters

Health-related quality of life – EuroQol - 5 Dimensions (EQ-5D):

The EQ-5D, including five health-related domains (mobility, self-care, pain/discomfort, usual activities and anxiety/depression) will be used to measure health-related quality of life [38]. Outcome parameters are the EQ-5D total score (5–15 points) and participants’ self-rated perceived health status (0–100 points).

Geriatric Depression Scale – Short Form (GDS-SF):

The 15-item GDS-SF will be used to register depressive symptoms [39] by assessing their presence/absence in frail older people (e.g. “Are you basically satisfied with your life?” or “Do you feel happy most of the time?”) [40]. A total score of 0–15 points can be achieved with higher scores representing a higher probability of depression (i.e., total score > 5 points indicates mild depressive symptoms, a total score ≥ 10 points indicates moderate to severe depression) [39].

Apathy Evaluation Scale-Clinical version (AES-C):

The 18 item AES-C will be used to evaluate participants’ for apathy [41]. The AES-C defines apathy as a psychological dimension based on deficits in behavioral, cognitive, and emotional circumstances of goal-directed behavior. Using the AES-C, the evaluation of apathy is based on clinical observations and subjects' self-reports during a semi-structured interview. A total score of 0 to 54 points can be achieved with higher scores representing a higher probability of apathy.

Fall-related parameters

Fall history:

Falls are defined as an unexpected event where a person comes to rest on the ground, floor or lower level [42]. We will assess the number of falls prospectively during the intervention period using diaries administered by the participants and weekly phone calls conducted by the trainer [43]. Fall history of patients is registered retrospectively at T1, T2 and T3 by asking the participants how often he/she fell during the preceding 4 weeks and 12 months. At T3, participants are additionally asked how often he/she fell during the preceding 12 weeks between T2 and T3.

Short - Falls Efficacy Scale – International (Short-FES-I):

Fall-related self-efficacy will be registered using the 7-item Short-FES-I [44], measuring the level of concern about falling during indoor/outdoor social and physical activities. A total score of 7 (no concern about falling) to 28 (severe concern about falling) can be achieved.

Fear of Falling Avoidance Behavior Questionnaire (FFABQ):

The FFABQ is used to assess activity avoidance behavior due to fear of falling [45]. The FFABQ total score ranges from 0 to 56 points. Higher score indicate greater activity limitations and participation restrictions as a consequence of fear of the falling.

Cognitive Performance

The Digit-Span sub-test of the Wechsler Adult Intelligence Scale (WAIS) [46] is registered to assess participants' short-term working memory. The number of correct repetitions is used for further analyses.

Cost effectiveness

To evaluate cost effectiveness, incremental cost-effectiveness ratios (ICERs) will be calculated [47]. ICERs are calculated by dividing the difference in costs (between the INTV and the CTRL) by the group difference in the outcomes and can be interpreted as the cost to obtain an extra unit of effectiveness, quantifying the trade-offs between patient outcomes gained and resources spend [47]. In our analysis, ICERs will be calculated for primary outcomes (e.g., *motor performance; SPPB total score*) and secondary outcomes (e.g., *health-related quality of life; EQ-5D questionnaire*). Therefore, average costs of the exercise interventions (e.g., training material, visits by trainer, phone calls) as well as overall health care costs (e.g., general practitioner consultations, inpatient and outpatient care, days in hospital, hours of nursing care, hours of professional domestic help or help by family members/friends) will be collected for INTV and CTRL [48]. Overall health care costs will be assessed retrospectively, covering a period of 12 weeks before T1, T2 and T3, using an established questionnaire (FIMA) [49].

Primary outcomes

- *motor performance:* SPPB total score (0–12 points)
- *physical activity:* duration of active episodes (i.e., sum of standing and walking)

Secondary outcomes

- *motor performance:* SPPB sub-test scores (0–4 points each), TuG total time, sensor-based parameters during SPPB sub-tests (e.g. CoP displacements, CoP velocity, sit-to-stand and stand-to-sit duration, maximum angular velocities), and qualitative gait parameters (e.g., mean step duration, step regularity, turning velocity)
- *physical inactivity:* duration of inactive episodes (i.e., sum of lying and sitting), quantitative gait parameters (i.e., cadence as steps per minute, total number of steps, and number of steps per gait episode)
- *life-space:* LSA total score (0–90 points), maximum distance from home and mean walking distances (GPS-based measurements)
- *quality of life:* EQ-5D total score (5–15 points), VAS score (0–100 points)
- *psychosocial status:* GDS-SF total score (0–15 points), AES-C total score (0–54 points), FES-I total score (7–28 points), FFABQ score (0–56 points)
- *falls*: fall history, number of falls during the intervention period
- *short-term working memory:* WAIS-IV test performance (0–9 points)
- *cost evaluation:* ICER for operational as well as health care costs

Intervention

Participants in INTV take part in a standardized 12-week home-based training program. The program is specifically-tailored for geriatric patients with CI after post-ward rehabilitation to improve motor performance and enhance PA. The training intervention was derived from an exercise program developed by our research group, which was feasible and effective to increase strength and functional performances in patients with

CI [24]. Based on results of a successfully conducted home-based exercise pilot RCT, our program includes six exercises to improve static and dynamic postural control (i.e., standing and walking) and strength (i.e., tiptoe stance, stair climbing, sit-to-stand transfers). Exercises are explained and regularly reviewed by a professional trainer and illustrated at the patient's home using a large poster (84.1 × 59.4 cm; Fig. 2). A brief description of key elements for each exercise is provided using a printed manual. Training progress and adherence is supervised by weekly phone calls and regular home visits of the trainer (5 visits in 12 weeks).

One major aim of the intervention is to motivate participants to induce behavioral changes in terms of enhanced PA by incorporating walking trails into their everyday life. Therefore, an individual outdoor walking course is defined next to the patients' homes (i.e., in the respective neighborhoods). Motivational strategies will be used to encourage behavioral changes. Participants are asked to regularly set individual goals, e.g., to extend the individually-defined walking distance. Barriers hampering regular walking sessions and solutions to overcome these barriers are identified in cooperation with the trainer and benefits of regular training/walking sessions are discussed. Variations of the walking trails and physical exercises program are developed to adjust the training protocol to meet the participants' needs (e.g., number of repetitions, handrail support, eyes open/closed, etc.). During the home visits and weekly phone calls, the trainer encourages the participant to conduct the training exercises and the walking trails independently. Furthermore, training descriptions (i.e., training manual; poster), training logs and pedometers are provided to foster participation, to enable self-monitoring of performance, and to define individual goals (e.g., increase number of daily steps). Participation in a local sports club is offered to each participant as an incentive for social participation.

The training program will include a motivational concept that is based on the Theory of Planned Behavior (TPB [50]), Social-Cognitive Theory (SCogT [51]), and Control Theory (CT [52]). The concept will use behavioral change techniques introduced by Abraham & Michie (cf. [53] for a detailed description of the theoretical framework) and integrated into our intervention as followed:

(1) Information about benefits/consequences of regular training and walking sessions are provided (based on TPB);
(2) Encouragement to change daily routines (i.e., integrate training, walk regularly, join a local sport club) (based on TPB);
(3) Barrier identification that hamper training and development of solutions to overcome barriers (based on SCogT);
(4) Set graded tasks (i.e., variations of exercises and walking trails are developed) (based on SCogT);
(5) Provide specific instructions (during home visits using poster and manuals) (based on SCogT);

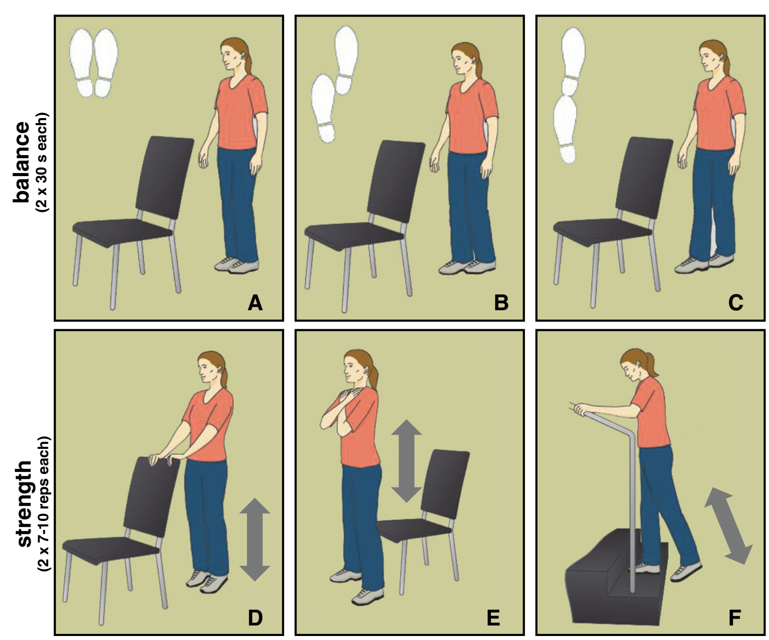

Fig. 2 Illustration of the exercise provided on a poster and used in the intervention. The upper row displays balance exercise (**a**-**c**), the lower row represents strength exercises (**d**-**f**)

(6) Definition of training goals (i.e., frequency, intensity and duration of exercises and walking trails) (based on CT);
(7) Review of behavioral goals (home visits, regular phone calls, pedometer) (based on CT);
(8) Self-monitoring of behavior (training logs, pedometer) (based on CT);
(9) Provide feedback to reinforce behavioral change (home visits, phone calls, pedometer) (based on CT/positive).

These behavioral change techniques are used to encourage patients to translate their intentions into behavioral change. Participants are expected to develop intrinsic motivation and volition to adapt their behavior.

Participants in CTRL receive newsletter-based information about unspecific flexibility and strength training, nutrition and relaxation over a period of 12 weeks. Similar to INTV, participants are called weekly and receive the same amount of home visits as the INTV group to exclude bias effects based on social support. After finishing the project, participants in CTRL will have the opportunity to perform the same exercise program than INTV and also join the local sports club.

Statistical analysis and sample size

An intention to treat analysis will be conducted. We performed an a priori power analysis to determine the sample size necessary to obtain significant effects in PA. Power analysis for PA is difficult to calculate since studies using identical sensor-based physical activity assessments in cognitively-impaired geriatric patients have not been available. Thus, the effect size is based on a study conducting a functional strength training program in 137 institutionalized patients [54]. PA, as assessed by the MTI Actigraph, showed an average increase of PA by 43% in the strength training group compared to a control group (effect size: $eta^2 = 0.18$). A priori power analysis was performed using GPower 3.1 software [55]. A repeated measure analysis of co-variance (ANCOVA) design including two groups and two repeated measurements yielded a total sample size of $N = 101$ ($\alpha = 0.05$; critical $F = 2.69$). Estimating a drop out of 15%, we will recruit a total of 116 participants. For motor performance, as assessed by the SPPB total score, a pilot study conducted by our research group showed that performance improvements can be achieved using relatively small sample sizes ($N = 34$; large effect size: $eta^2 = 0.22$ [56]). Repeated measures ANCOVA will be used to determine effects of the home-based training program on primary and secondary outcomes for effects of intervention (T1-T2) and sustainability of effects (T1-T3). Effect sizes are determined by calculating eta^2 [57]. All data will be analyzed using SPSS 23.0 (SPSS Inc., Chicago, Ill., USA).

Discussion

Our study is among the first RCTs to investigate a specifically-tailored home-based training program with low entry barriers in geriatric patients with CI at the transition from a rehabilitation unit to their home environment. The proposed training program may represent a feasible and effective tool to improve motor performance and increase PA in patients with CI, thus fostering a sustained change in patients' activity behavior. The program requires relatively low supervision and material costs and has the potential to be implemented into existing health care plans. If the program will prove to be effective, it may lower the barrier for post-ward geriatric patients to take up training and exercising. The program may enhance the sustainability of rehabilitation programs by improving medical care of multi-morbid geriatric patients with CI using an innovative therapeutic concept at this vulnerable stage of health care.

Previous home-based training studies showed methodological limitations, e.g., only included sub-groups of patients with CI [27–29] or did not measure key-motor performances as primary endpoints [25, 28] and behavioral aspects in terms of PA have not been investigated in geriatric patients with CI. Only a few studies investigated PA in community-dwelling older adults with CI using questionnaires [17, 18, 21]. Hence, there is a lack of studies in post-ward geriatric patients comprehensively evaluating motor performance and PA. The investigation of training-related effects on motor performance and behavioral changes in terms of enhanced PA requires innovative assessment strategies, including sensor-based as well as questionnaire-based measures. In the presented study we will assess primary outcome measures using well-established, validated tests and complement this approach by additionally registering objective and detailed, sensor-based motor data, a range of psycho-social parameters, such as fear of falling, depression and apathy as well as participants mobility status (life-space), quality of life and cognitive functioning. Applying this comprehensive assessment strategy, we will be able to identify training-related modifications of PA and motor performance based on state-of-the-art sensors and examine their relationship with potentially influencing factors, among others, cognitive status or fear of falling. We regard our assessment as a unique and comprehensive combination of quantitative, qualitative, questionnaire and sensor-based data that - to our knowledge - is not available so far.

One aim of our study is to modify behavior in terms of enhanced PA. Participants need to develop intrinsic motivation and volition to adapt their behavior and to become physically active. So far, only one home-based training study for older adults with CI implemented motivational strategies to increase adherence to physical training, by integrating a goal-oriented and individually-tailored training according to the individual's needs [22]. However, authors did not describe the specific motivational strategy used and did not show data on the feasibility of the motivational support. Our study is going to address this limitation by integrating a specific motivational strategy for patients with CI. Based on various theoretical frameworks (i.e., TPB, SCogT, and CT) [50–52], we will integrate several behavioral change techniques (i.e., information on consequences, barrier identification, proper instructions, goal setting, review of behavioral goals, self-monitoring, and performance-based feedback [53]) into our intervention to ramp up adherence and to increase PA. To the authors knowledge, such a comprehensive interventional approach aiming at behavioral modifications by using individually-tailored motivational instruments not been implemented and evaluated in a home-based training program for patients with CI at the transition from rehabilitation to their home environment before.

In addition, CI represents a high financial burden for the health care systems in western societies [3]. Limited resources in health care require effective interventions that provide high benefits relative to the costs [58]. The presented home-based training program aims to counteract typical health-related limitations in patients with CI and represents a low budget approach. In line with this, our program may encourage the participants to conduct the training sessions independently at their home environments (i.e., no professional monitoring) to minimize costs for supervision by professional trainers. To our knowledge, our study will be the first to also assess economical aspects of a home-based training program for geriatric patients with CI using established instruments (i.e., FIMA [49]) and analyses (i.e. ICER [47, 48]) to objectively yield potential cost effectiveness of the intervention.

In summary, this trial will provide insight into the effect of a specifically-tailored home-based exercise program in patients with CI on motor performance and behavioral change. The program offers several approaches, e.g., a comprehensive and innovative assessment strategy and the integration of individually-tailored motivational strategies to stimulate behavioral change and increase motor performance, may have the potential to enhance the sustainability of geriatric rehabilitation programs in patients with CI.

Abbreviations

ADL: Activities of daily living; AES-C: Apathy evaluation scale-clinical version; CI: Cognitive impairment; CoP: Center of pressure; CT: Control theory; CTRL: Control group; deg.: Degrees; EQ-5D: EuroQol - 5 Dimensions; FFABQ: Fear of falling avoidance behavior questionnaire; GDS-SF: Geriatric Depression Scale – Short Form; GPS: Global position system; ICERs: Incremental cost effectiveness ratios; INTV: Intervention group; LSA: Life-space assessment; MMSE: Mini-Mental-State-Examination; PA: Physical activity; RCT: Randomized-controlled trial; SCogT: Social-cognitive theory; Short-FES-I: Short - Falls Efficacy Scale – International; SPPB: Short-Physical-Performance-Battery; TPB: Theory of planned behavior; TuG: Timed up and go; WAIS: Wechsler adult intelligence scale

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Availability of data and materials

Not applicable.

Authors' contributions

All authors have read and concur with the content in the final manuscript. All authors have made substantial contributions to the manuscript as followed: (1) the conception and design of the study (KH, RK, PU), (2) drafting the article (MB) and/or revising it critically for important intellectual content (MB, RK, PU, TE, JB, KH), (3) final approval of the version to be submitted (MB, RK, PU, TE, JB, KH).

Ethics approval and consent to participate

Ethics approval for the study was received from the internal review board at the Medical Faculty of the University of Heidelberg, Germany (ref: S-252/2015; 26/06/2015). Written informed consent will be requested from subjects and/or their legal representatives (in case those were nominated for persons with severe cognitive impairment) before the onset of the study.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Publisher's Note

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Publikation II

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Validity, reliability, and feasibility of the uSense activity monitor to register physical activity and gait performance in habitual settings of geriatric patients

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Abstract

Objective: The aim of the study was to investigate the psychometrical quality of a newly developed activity monitor (uSense) to document established physical activity parameters as well as innovative qualitative and quantitative gait characteristics in geriatric patients.

Approach: Construct and concurrent validity, test-retest reliability, and feasibility of established as well as innovative characteristics for qualitative gait analysis, have been analyzed in multi-morbid, geriatric patients with cognitive impairment (n=110), recently discharged from geriatric rehabilitation.

Main results: Spearman correlations of established and innovative uSense parameters reflecting active behavior with clinically relevant construct parameters were on average moderate to high for motor performance and life-space and low to moderate for other parameters, while correlations with uSense parameters reflecting inactive behavior were predominantly low. Concurrent validity of established physical activity parameters showed consistently high correlations between the uSense and an established comparator system (PAMSys^{TM}), but the absolute agreement between both sensor systems was low. On average excellent test-retest reliability for all uSense parameters and good feasibility could be documented.

Significance: The uSense monitor allows the assessment of established and -for the first time- a semi-qualitative gait assessment of habitual activity behavior in older persons most affected by motor and cognitive impairment and activity restrictions. On average moderate to good construct validity, high test-retest reliability, and good feasibility indicated a sound psychometrical quality of most measures, while the results of concurrent validity as measured by a comparable system indicated high correlation but low absolute agreement based on different algorithms used.

Trial registration number: ISRCTN82378327.

Key words: physical activity, cognitive impairment, sensor-based activity monitoring, gait analysis, validation, everyday-life assessment

Introduction

Restrictions of physical activity (PA) and gait deficits are common in old age (Aboutorabi, Arazpour, Bahramizadeh, Hutchins, & Fadayevatan, 2016; Sun, Norman, & While, 2013) and associated with a variety of negative health outcomes, including cardiovascular diseases, loss of function, and mortality (Lee et al., 2012; Middleton, Fritz, & Lusardi, 2015). These associations are particularly important for older persons with cognitive impairment (CI), as results from previous studies indicate that CI is associated with decreased PA (Gagliardi, Papa, Postacchini, & Giuli, 2016) and increased prevalence of gait deficits (Bahureksa et al., 2017; J. A. Cohen, Verghese, & Zwerling, 2016). Observational studies identified the amount of walking (Schwenk et al., 2014) and the quality of gait as measured in laboratory and habitual settings (Kressig, Herrmann, Grandjean, Michel, & Beauchet, 2008; van Schooten et al., 2015; Weiss et al., 2013) as significant predictors for future falls. The comprehensive assessment of PA and gait behavior may therefore be considered a key aspect in geriatric healthcare. Specific activity patterns of older persons with motor and cognitive deficits such as slow or shuffling gait (Montero-Odasso et al., 2014; Peel, Alapatt, Jones, & Hubbard, 2018; van Iersel, Hoefsloot, Munneke, Bloem, & Olde Rikkert, 2004) pose major challenges for ambulatory sensor systems, substantially limiting the accuracy of activity measurements (McCullagh, Brady, Dillon, Horgan, & Timmons, 2016). Due to such limitations, devices specifically developed to classify and document activity patterns in persons with motor deficits and CI are mandatory to ensure valid and reliable measurements in populations with particularly slow walking speeds (McCullagh et al., 2016). Further, the assessment settings need to be considered in the validation of ambulatory sensor systems, as gait performance as measured in a laboratory significantly differs from habitual gait behavior in everyday life (Bock & Beurskens, 2010; Brodie et al., 2016; Urbanek et al., 2018). Qualitative gait assessment in habitual settings might open up new insights in a highly relevant lifestyle domain (Storm, Buckley, & Mazza, 2016), but appropriate ambulatory sensor systems adjusted for and validated in habitual settings of frail, older persons are lacking (Van Remoortel et al., 2012).

Relevant behavioral activity characteristics are represented by established PA parameters, reflecting the quantity of different PA dimensions, namely volume (number of active counts and steps), duration (duration of lying and walking), frequency (number of lying and walking episodes), and intensity (mean METs per min) of PA (B. Ainsworth, Cahalin, Buman, & Ross, 2015). Such established measures have been extended by innovative gait parameters allowing a qualitative interpretation of gait patterns in terms of temporal parameters, variability, regularity and symmetry of gait measured during straight walking (cadence, step duration, step duration coefficient of variance, step regularity, phase coordination index, harmonic ratio) (Weiss et al., 2013), and by parameters representing turn characteristics during walking (turning angle, turning duration, turning velocity and number of turns) (Mancini et al., 2016).

Previous validation studies yielded heterogeneous results depending on the specific sample, the setting, the psychometrical domain, and the type of outcome (established PA parameter vs. innovative gait parameters). In strictly supervised laboratory conditions (Dijkstra, Kamsma, & Zijlstra, 2010; Fokkenrood et al., 2014; Fulk et al., 2012; Langer et al., 2009; White, Wagenaar, & Ellis, 2006) as well as in habitual conditions (Chigateri, Kerse, Wheeler, MacDonald, & Klenk, 2018; Dijkstra et al., 2010; Hollewand et al., 2016; Najafi et al., 2003; Taylor et al., 2014) validation studies showed heterogeneous results from low to high concurrent validity of ambulatory PA sensor systems measuring established PA parameters in frail older adults, in older persons with chronic diseases and in neurological patients. High concurrent validity of the uSense system has been demonstrated in frail older people (Chigateri et al., 2018), but the established PA parameters were limited to simple distinctions between periods of walking and periods of non-walking. Further, the aforementioned studies attempted to validate PA behavior under habitual conditions by using subjective (direct observations) or stationary (video observations) reference methods partly during standardized short-term measurements, which may not comprehensively document realistic habitual PA behavior. A new generation of ambulatory inertial measurement units (IMUs) holds the potential to assess qualitative gait characteristics beyond established PA parameters (Vienne, Barrois, Buffat, Ricard, & Vidal, 2017). Under laboratory conditions, such IMUs revealed high concurrent validity in measuring innovative gait parameters during straight walking (e.g., cadence, stride time, gait symmetry) by comparing equivalent parameters simultaneously captured by stationary gold standard methods (e.g., GAITRite system, optical tracking system) among healthy older adults (Donath et al., 2016; Godfrey, Del Din, Barry, Mathers, & Rochester, 2014; Hartmann, Luzi, Murer, de Bie, & de Bruin, 2009; Washabaugh, Kalyanaraman, Adamczyk, Claflin, & Krishnan, 2017), and in measuring turning behavior in older persons with motor impairment (El-Gohary et al., 2014).

Only few studies have validated IMUs for measuring gait characteristics under habitual conditions (Vienne et al., 2017). One of those studies found high concurrent validity for an ambulatory sensor system measuring qualitative gait characteristics in a small sample of young, healthy adults during short-term measurements (2–15 min) in everyday-life situations (Storm et al., 2016). However, studies evaluating the concurrent validity of ambulatory, unobtrusive, long-term measurements of quality of gait under habitual conditions including functionally restricted older persons in appropriate sample sizes are missing.

Previous epidemiological studies with older adults identified various associations between established PA parameters under habitual conditions, innovative gait parameters under laboratory conditions and clinically relevant constructs including motor performance (Callisaya et al., 2009; Chale-Rush et al., 2010; DePew, Karpman, Novotny, & Benzo, 2013; Hausdorff, Rios, & Edelberg, 2001; Martinikorena et al., 2016; Mudge & Stott, 2009; Osuka et al., 2015; Pettersson et al., 2017), life-space (Tsai et al., 2015), and psychosocial parameters (Brandler, Wang, Oh-Park, Holtzer, & Verghese, 2012; Kempen, van Haastregt, McKee, Delbaere, & Zijlstra, 2009; Salguero, Martinez-Garcia, Molinero, & Marquez, 2011). Surprisingly, these findings have hardly been used in studies evaluating construct validity of ambulatory PA sensor systems in older adults.

Previous studies that evaluated construct validity of established PA parameters measured by ambulatory PA sensor systems merely focused on basic outcome measures such as active counts. These studies documented good construct validity under laboratory conditions in healthy young adults (Hendrick et al., 2010), as well as under habitual conditions in community-dwelling, high functioning older adults (Harris et al., 2009), and middle-aged patients with chronic pain (Verbunt et al., 2001). Studies evaluating construct validity of innovative gait parameters were restricted, as they focused on singular innovative gait characteristics only (step length) (de Bruin et al., 2012) and were limited to laboratory settings including young and old adults with health restrictions (de Bruin et al., 2012; Maanum et al., 2012). The construct validity of ambulatory measured innovative gait parameters has not been validated under habitual conditions in older people with health restrictions, so far.

A recent systematic "review of reviews" revealed heterogeneous test-retest reliability of established PA parameters (duration of postures and walking) measured by ambulatory PA sensor systems during habitual conditions, with poor to excellent test-retest reliability in healthy young adults and in high functioning older adults (Dowd et al., 2018). In older adults with and without motor limitations, ambulatory PA sensor systems showed good test-retest reliability in measuring established PA parameters in terms of active counts and derived parameters under habitual conditions (Almeida, Irrgang, Fitzgerald, Jakicic, & Piva, 2016; de la Camara, Higueras-Fresnillo, Martinez-Gomez, & Veiga, 2018). Test-retest reliability as measured in healthy young and healthy older adults under strictly standardized laboratory conditions was moderate to good for cadence, stride time and stride length (Donath et al., 2016; Hamacher,

Hamacher, Taylor, Singh, & Schega, 2014; Kluge et al., 2017; Orlowski et al., 2017; Washabaugh et al., 2017) and for turn characteristics (number of steps per turn, turn duration, and peak turn velocity) in patients with vestibular disorders (Sankarpandi, Baldwin, Ray, & Mazza, 2017). The assessment of test-retest reliability for innovative gait characteristics as measured by ambulatory IMUs for habitual activity behavior is lacking.

Feasibility of wearing ambulatory PA sensor systems was heterogeneous in previous studies with completion rates ranging from 70% in middle aged adults with mental illness (Chapman, Fraser, Brown, & Burton, 2015) to 87% in older adults (Zainol Abidin, Brown, Clark, Muhamed, & Singh, 2016) and 75-95% in hospitalized and community-dwelling older adults with CI (van Loevezijn, Cameron, Kurrle, & van Bodegom, 2014), with the location and type of body fixed sensors and the sample characteristics as relevant influencing factors. To our best knowledge a comprehensive validation of ambulatory sensor systems measuring established PA parameters as well as innovative gait parameters have so far not been performed under habitual conditions in vulnerable populations with activity clusters which are hard to detect and to quantify.

The aim of the present study therefore was to comprehensively investigate the psychometrical quality (concurrent/construct validity, test-retest reliability, feasibility) of a newly developed activity monitor system including established PA parameters as well as innovative gait parameters under habitual conditions in multi-morbid, geriatric patients with CI.

Methods

Study design

The present validation study is based on cross-sectional baseline data from a double-blinded randomized placebo-controlled trial (RCT) to increase PA and motor performance in patients with CI following geriatric rehabilitation (Bongartz et al., 2017). The study was approved by the ethics committee of the Medical Faculty at Heidelberg University, Germany (ref: S-252/2015) and registered at the ISRCTN-trial register (http://www.isrctn.com/ISRCTN82378327).

Study sample

Participants were consecutively recruited at rehabilitation wards of a geriatric hospital. Inclusion criteria were (1) age ≥65 years; (2) mild to moderate CI with Mini-Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975) scores of 17-26; (3) able to walk 4 m without support; (4) discharge to the home environment; (5) no terminal disease and no delirium; (6) adequate language level; and (7) written informed consent. Descriptive characteristics of the study sample are shown in table 1.

Descriptive measures

Based on medical reports and standardized interviews, we registered characteristics of participants, including age, gender, and number of medication. Psychological status was assessed using the Geriatric Depression Scale (GDS) (Greenberg, 2007) and the short-version of the Falls Efficacy Scale-International (FES-I) (Hauer et al., 2011). Life-space was measured using the Life-Space Assessment for people with CI (LSA-CI) (Ullrich et al., 2018), and motor performance by the Short Physical Performance Battery (SPPB) (Guralnik et al., 1994) and by the Timed-up-and-Go test (TUG) (Podsiadlo & Richardson, 1991).

Assessment of physical activity and gait behavior

PA was assessed for 48 hours with the newly developed uSense activity monitor, a non-commercial activity monitor developed in a recent, large EU project (FARSEEING, FP7/2007–2013, grant agreement n. 288940) suitable for ambulatory, uninterrupted long-term motion measurement. The small-scaled sensor (42 x 10 x 68 mm, 36 grams) has been attached to participants' lower back by trained staff using adhesive bands. Raw data was sampled at a frequency of 100 Hz, stored on internal storage and subsequently analyzed offline using MATLAB (R2016a, The MathWorks Inc.,Natick, MA). Analyzed raw data provided comprehensive information on established PA parameters (number of active counts, number of steps, duration of lying, duration of gait, number of lying episodes, number of gait episodes, mean METs, and mean METs per walking episode) as well as gait analysis including innovative parameters of habitual gait behavior during straight walking and during turns (cadence, step duration, step regularity, gait coordination, harmonic ratio, turning angle, turning duration, turning velocity, number of turns).

To generate this variety of parameters, the uSense includes a 9-axis inertial platform with three different types of motion sensors: (1) an accelerometer, as an inertial sensor able to measure acceleration along the sensitive anterior-posterior, medio-lateral, and vertical axis, (2) a gyroscope, able to measure the angular velocity and related parameters in anterior-posterior, medio-lateral, and vertical directions, and (3) a magnetometer, able to estimate the relative position and orientation of the sensor with respect to the magnetic source, to minimize the inherent drift of inertial sensors and gyroscopes to improve the stability and accuracy of the estimation of different types of movements (Schepers, Roetenberg, & Veltink, 2010; Tao, Liu, Zheng, & Feng, 2012). The uSense activity monitor had proved to be feasible and unobtrusive in hospitalized persons with dementia (Fleiner, Haussermann, Mellone, & Zijlstra, 2016).

<u>Data processing</u>

For the uSense activity monitor, postural events/activity levels were identified based on established algorithms including activity counts to calculate metabolic equivalent of tasks (METs) (Sasaki, John, & Freedson, 2011), which had been validated for the detection of walking in frail older adults in the setting of retirement homes (Chigateri et al., 2018). Intervals in which METs are below or equal to 1.5 are labelled as “sedentary” while intervals above 1.5 are labelled as “active” (Mansoubi et al., 2015). During “sedentary” periods intervals are labelled as “lying”, if the angle between the vertical axis and the medio-lateral or the anterior-posterior direction of the trunk is below 30°. Steps and gait are detected during “active” periods based on acceleration data calculated by an adaptive algorithm (UkJae et al., 2013). For step detection the adaptive algorithm uses continuously updated amplitude thresholds to achieve high accuracy even at slow walking speeds. A step is detected if the acceleration values E(t) [$E(t) = \sqrt{|x(t)|^2 + |y(t)|^2 + |z(t)|^2}$ with x, y, z representing the acceleration values of each axis] reach defined peak thresholds (E(t) = 1.100 to 1.175) (UkJae et al., 2013). When a peak is detected as a possible step, the algorithm verifies the peak value, the amplitude, and the stepping frequency as the time between consecutive peaks. For each bout starting value for amplitude is 0.2 g, the value is updated and adapted on the basis of the values of the last 5 steps within the bout. The start of a gait episode is identified from the forward acceleration of the lower trunk in agreement with Zijlstra (2004). Intervals are labeled as “gait episode” if more than 3 consecutive steps are registered. For the registration of number of steps each step is taken into account. Each posture and gait interval is then characterized by its duration and intensity, represented by mean MET values (e.g., mean METs per gait episode). Subsequently, the algorithm automatically detects turns during gait episodes and segments each gait interval into straight-path walking and turning (El-Gohary et al., 2013). For each single straight-path walking episode, if the duration is above 5 s, a set of advanced gait features is extracted, allowing an innovative qualitative observation of habitual gait behavior. Turning is detected if a maximum angular velocity of 15 deg/s is reached about the vertical axis. Start and end of a turn is set to the point where the angular velocity drops below 5 deg/s. To avoid redundancies in related gait parameters, the authors decided to report not all but specific and representative outcome parameters for every predefined outcome category of PA (i.e., total amount, duration, frequency, intensity) and innovative gait parameters (i.e., temporal, variability, regularity, symmetry, turning parameters). Supplement 1 provides an overview of all included gait parameters.

Assessment of measurement properties

Concurrent validity: To analyze concurrent validity, correlations and absolute agreements between similar PA parameters (duration of walking and lying, number of walking episodes, number of steps, average METs) simultaneously recorded by two different activity monitors (uSense and PAMSys™, BioSensics, Cambridge, MA, USA), were calculated. The PAMSys™ is a small-scaled (51 x 30 x 16 mm, 24 grams) activity monitor attached to a subject's chest by using adhesive bands. The activity monitor includes a tri-axial accelerometer registering accelerations in three perpendicular directions (frontal, vertical, and lateral directions) at a sampling frequency of 40 Hz. Participants were instructed to wear both activity monitors continuously for 48 hours. Raw data were stored on internal storage volumes and analyzed offline afterwards by using appropriate computer software. We used the PAMSys™ sensor as a valid and reliable comparator system with high sensitivity and specificity to identify body postures of respectively, 90.2% and 93.4% in sitting, 92.2% and 92.1% in standing and walking, and 98.4% and 99.7% in lying (Najafi et al., 2003; Najafi, Armstrong, & Mohler, 2013). The PAMSys™ has been shown to be feasible in a wide range of older adults, namely stroke survivors (Taylor-Piliae, Mohler, Najafi, & Coull, 2016), community-dwelling older adults without CI (Parvaneh, Mohler, Toosizadeh, Grewal, & Najafi, 2017) and older people with CI (Schwenk et al., 2014).

Construct validity: Correlations between established PA parameters as well as innovative gait parameters and clinically relevant constructs including motor performance (SPPB score, usual gait speed based on SPPB, TUG), life-space (LSA-CI), psychological status (GDS, FES-I), age, cognitive status (MMSE), and number of medications were calculated for construct validity.

Test-Retest-Reliability: To examine test-retest reliability, uSense measurements were repeated on two consecutive weekdays with the same uSense-monitor.

Feasibility: Completion rates, technical failures, and premature removing of the uSense monitor were documented for feasibility.

Statistical analysis

Descriptive data were presented as means and standard deviation (SD) and median and interquartile range (IQR) if appropriate. Validity of the uSense monitor was evaluated by determining construct and concurrent validity. Concurrent validity was assessed by Spearman rank correlation coefficients (rhos) between comparable parameters as assessed by the uSense and the comparator system PAMSys^{TM}. Differences (bias) between the methods (PAMSys^{TM} – uSense) and 95% limits of agreement (LoA) ($mean_{bias}$ ± 1.96 x SD_{bias}) were calculated by using the Bland Altman method (Bland & Altman, 1986). Construct validity was assessed by Spearman rank correlation coefficients (rhos) between established PA parameters as measured by uSense and clinically relevant external construct variables. Correlations were rated as low (rho <0.2), moderate (0.2≤ rho ≤0.5), or high (rho >0.5) (J. Cohen, 1988). To evaluate test-retest reliability, intra-class correlation coefficients (ICC 3.1: two-way mixed effects, absolute agreement, multiple measurements) (Koo & Li, 2016) and 95% confidence intervals were calculated for two consecutive registration days. ICCs were interpreted as poor (ICC <0.40), moderate (ICC = 0.40-0.75), or excellent (ICC >0.75) (Shrout & Fleiss, 1979). Feasibility was documented by the percentage of completed measurements, technical malfunction and individual errors caused by sensors being removed by the participants prematurely. All statistical analyses were conducted using Statistical Package for Social Sciences (SPSS) version 23.0 (IBM Corp., New York, USA) and significance level was set at α = 5%.

Results

Participant characteristics: The study sample consisted of 110 multi-morbid, older persons with advanced motor and moderate cognitive impairment. The interpretation of 16 uSense measurements failed, resulting in 94 valid uSense data sets. Participant characteristics are described in Table 1.

Table 1: Participant characteristics

Characteristics (n=110)	Mean (SD)
Age [years]	82.3 (5.9)
Medications [number]	9.6 (3.5)
SPPB [total score]	5.2 (2.3)
Gait speed (habitual) [m/s][a, b]	0.46 (0.19)
TUG [s][c]	24.4 (14.1)
LSA-CI [total score]	24.1 (13.4)
FES-I [score]	12.3 (4.3)
GDS [score]	5.3 (3.0)
MMSE [score]	23.3 (2.4)

Note: SD=Standard Deviation, SPPB=Short Physical Performance Battery, m/s=meter per second, TUG=Timed Up and Go test, s=second, LSA-CI=Life-Space Assessment for Persons with Cognitive Impairment, FES-I=Falls Efficacy Scale-International, GDS=Geriatric Depression Scale, MMSE=Mini-Mental State Examination;
[a] based on the SPPB gait speed without walking aids
[b] based on data n=107 as three participants were unable to walk without walking aid
[c] based on data n=108 as one participant refused the TUG and one participant was unable to stand up from a chair without help

Concurrent validity: Established PA parameters such as number of steps, duration of walking, and number of walking episodes, duration of lying and average METs measured with the uSense monitor showed high correlations with equivalent parameters measured by the PAMSys^{TM} monitor (rho = 0.59-0.91) representing a strong association between both methods (Table 2). The medians measured by the uSense system were higher for the parameters: “number of walking episodes”, “number of steps”, “average METs” and lower for the variable “duration of lying” in comparison to the medians generated by the comparator system PAMSys^{TM}, while comparable medians have been found for “duration of walking” (Table 2). The biases and LoA calculated by the Bland-Altman method confirmed these absolute differences (Tab. 2). The Bland-Altman plots revealed a systematic bias in terms of linear relationships between the means of and the differences between both systems for the parameters “duration of lying", "number of walking episodes", "number of steps" and "average METs" (Supplement 2).

Table 2: Concurrent validity

Established physical activity parameters (n = 94)	PAMSys^{TM} Median (IQR)	uSense Median (IQR)	Correlation -coefficient	Bias (SD)	95% LoA
Duration of walking [min]	106.1 (111.3)	110.8 (132.4)	0.88**	-8.8 (53.0)	-112.5 to 95.0
Duration of lying [min]	1421.4 (604.5)	1182.6 (315.1)	0.63**	244.4 (298.8)	-341.3 to 830.1
Walking episodes [total number]	282.1 (294.5)	543.2 (674.3)	0.82**	-319.0 (291.4)	-890.0 to 252.1
Steps [total number]	5325.0 (5767.1)	9372.1 (10463.0)	0.91**	-4274.0 (4225.3)	-12555.6 to 4007.6
Average MET [score]	1.1 (0.1)	1.6 (0.2)	0.59**	-0.53 (0.09)	-0.71 to -0.35

Note: Correlation coefficients are presented as Spearman rank correlation coefficients (rhos): <0.20=low, 0.20 – 0.50=moderate, >0.50=high, h=hours, mean differences are presented as bias± SD, IQR=Inter Quartile Range, SD=Standard Deviation, LoA=Limits of Agreement, min=minutes, MET=Metabolic Equivalent of Task, p-value: *p<0.05; **p<0.01.

Construct validity of established physical activity parameters: Objectively measured, established PA parameters addressing physically active behavior showed moderate to high correlations with the motor performance parameters (rho = │0.36-0.55│) and with the LSA-CI score (rho = 0.45-0.59). Mean METs (total), representing the average intensity of PA, showed consistently high correlations with the motor performance tests (rho = │0.54-0.62│) and with the LSA-CI score (rho = 0.50). Total PA, represented by total amount of activity counts, showed moderate correlations with two of three motor performance parameters (rho = 0.21-0.23) and with the LSA-CI score (rho = 0.35). Except for a moderate correlation between number of lying episodes and gait speed (rho = 0.21), correlations between PA variables addressing duration and frequency of sedentary behavior and motor performance and LSA-CI score were low (Table 3).

Psychosocial parameters showed consistently low correlations with PA parameters. Age revealed moderate correlations with the frequency of sedentary behavior and with the PA intensity (rho= │0.22-0.30│). Moderate correlations were also found between the cognitive status and number of steps, duration of gait and the PA intensity (rho = 0.21-0.25) and between the number of medication and number of steps and duration of gait (rho = -0.24 and rho = -0.23) (Table 3).

Table 3: Construct validity of established physical activity parameters

Parameters (n = 94)	total PA		PA duration		PA frequency		PA intensity	
	number of active counts	number of steps	duration of lying	duration of gait	number of lying episodes	number of gait episodes	Mean METs (total)	Mean METs (per gait episode)
Construct: motor performance								
SPPB total (score)	0.23*	0.51**	-0.06	0.51**	0.11	0.47**	0.54**	0.36**
Gait speed (habitual)[a] [m/s]	0.21*	0.55**	0.06	0.55**	0.21*	0.52**	0.60**	0.42**
TUG time[b] [s]	-0.19	-0.54**	-0.04	-0.54**	-0.09	-0.53**	-0.62**	-0.47**
Construct: life-space								
LSA-CI [score]	0.35**	0.59**	0.01	0.59**	0.12	0.49**	0.50**	0.45**
Construct: psychosocial/ medical/ demographic								
FES-I [score]	-0.01	-0.13	0.01	-0.14	0.01	-0.15	-0.10	-0.02
GDS [score]	-0.14	-0.07	0.07	-0.08	0.14	-0.05	0.01	0.04
Age [years]	-0.01	-0.16	0.08	-0.16	0.30**	-0.13	-0.22*	-0.25*
MMSE [score]	0.02	0.22*	-0.05	0.21*	-0.08	0.19	0.22*	0.25*
Medication [number]	-0.10	-0.24*	-0.08	-0.23*	-0.03	-0.20	-0.17	-0.12

Note: Presented are Spearman rank correlation coefficients (rho). Correlation coefficients (rho): <0.20=low, 0.20–0.50=moderate, >0.50=high, p-value: *p<0.05; **p<0.01. PA=Physical Activity, Mean METs (total) =Average Metabolic Equivalent of Tasks of all posture and walking periods over the whole measuring period of 48hours, Mean METs (per gait episode) =Average Metabolic Equivalent of Tasks value of all gait episodes over the whole measuring period of 48hours, SPPB=Short Physical Performance Battery, m/s= meter per second, s=seconds, TUG=Timed Up and Go test, LSA-CI=Life-Space Assessment for older persons with Cognitive Impairment, FES-I=Falls Efficacy Scale-International, GDS=Geriatric Depression Scale, MMSE=Mini-Mental State Examination.

[a] based on data n=91 as three participants were unable to walk without walking aid

[b] based on data n=92 as one participants refused "TUG" test and one participant was unable to complete the “TUG” test due to physical limitations

Construct validity of innovative gait characteristics (during straight walking): Temporal gait parameters showed consistently moderate correlations (rho = |0.27-0.34|) with motor performance. Parameters representing gait variability [Coefficient of Variation (CV) of step duration] and symmetry of gait [Phase Coordination Index (PCI) and harmonic ratio (HR) in the planes AP and V)] (rho = |0.23-0.37|) and parameters illustrating regularity of gait (step regularity) indicated moderate correlations (rho = |0.27-0.30|) with motor performance only in the vertical plane. Life-space correlated moderately (rho = |0.22-0.39|) with innovative gait parameters during straight walking, except for step regularity in the planes AP and ML. Psychosocial parameters, age, cognitive status, and number of medications only showed low correlations with most innovative gait characteristics (Table 4).

Table 4: Construct validity of innovative gait characteristics (during straight walking)

Parameter (n = 94)	temporal characteristics		variability	regularity			symmetry			
	Cadence [steps/s]	Step Duration [s]	Step Duration CV [%]	Step Regularity AP [%]	Step Regularity ML [%]	Step Regularity V [%]	PCI [%]	HR (AP)	HR (ML)	HR (V)
Construct: motor performance										
SPPB total [score]	0.30**	-0.27**	-0.24*	0.03	0.12	0.29**	-0.24*	0.29**	0.23*	0.34**
Gait speed (habitual)[a] [m/s]	0.33**	-0.27**	-0.26*	0.03	0.02	0.27*	-0.25*	0.31**	0.19	0.32**
TUG time[b] [s]	0.33**	0.34**	0.27*	-0.04	-0.15	-0.30**	0.23*	-0.36**	-0.30**	-0.37**
Construct: life-space										
LSA-CI [score]	0.23*	-0.22*	-0.36**	-0.04	0.19	0.24*	-0.32**	0.39**	0.30**	0.39**
Construct: psychosocial/ medical/ demographic										
FES-I [score]	-0.07	0.13	0.04	0.07	0.03	-0.02	0.02	-0.04	-0.04	-0.11
GDS [score]	0.05	-0.06	-0.02	-0.10	0.05	-0.07	-0.01	-0.01	0.02	-0.10
Age [years]	-0.15	-0.07	0.08	0.03	-0.07	-0.09	0.10	0.06	-0.04	-0.09
MMSE [score]	0.14	0.16	0.11	-0.08	0.11	0.02	0.10	-0.02	0.01	-0.02
Medication [number]	-0.14	-0.04	0.20	-0.06	-0.17	-0.11	0.17	-0.21*	-0.08	-0.21*

Note: Presented are Spearman rank correlation coefficients (rho). Correlation coefficients (rho): <0.20=low, 0.20–0.50=moderate, >0.50=high, p-value: *p<0.05; **p<0.01. m/s= meter per second, s=seconds, CV=Coefficient of Variation, AP=Anterior-Posterior, ML=Medio-Lateral, V=Vertical, PCI=Phase Coordination Index, HR=Harmonic Ratio, SPPB=Short physical performance battery, TUG=Timed Up and Go test, LSA-CI=Life-Space Assessment for older persons with Cognitive Impairment, FES-I=Falls Efficacy Scale International, GDS=Geriatric Depression Scale, MMSE=Mini-Mental State Examination.

[a] based on data n=91 as three participants were unable to walk without walking aid

[b] based on data n=92 as one participants refused "TUG" test and one participant was unable to complete the TUG due to physical limitations

Construct validity of innovative gait parameters (during turns): The highest correlations in the context of the construct validation of innovative gait parameters were found between turning characteristics, motor performance tests and life-space. All turning parameters showed moderate to high correlations (rho = │0.30-0.63│) with all motor performance parameters and consistently moderate correlations (rho = │0.33-0.47│) with the LSA-CI score, indicating high construct validity. Only few significant correlations were found between psychological status and number of medication and the turning parameters with age standing for moderate correlations (Table 5).

Table 5: Construct validity of innovative gait parameters (during turns)

Parameter (n = 94)	Turning Angle [deg]	Turning Duration [s]	Mean Turning Velocity [deg/s]	Peak Turning Velocity [deg/s]	Number of turns per walking episode
Construct: motor performance					
SPPB total [score]	0.51**	-0.30**	0.50**	0.33**	0.51**
Gait speed (habitual)[a] [m/s]	0.59**	-0.44**	0.62**	0.41**	0.51**
TUG time[b] [s]	-0.63**	0.38**	-0.60**	-0.36**	-0.58**
Construct: life-space					
LSA-CI [score]	0.33**	-0.36**	0.47**	0.36**	0.47**
Construct: psychosocial/ medical/ demgraphic					
FES-I [score]	-0.16	0.09	-0.14	-0.12	-0.13
GDS [score]	-0.01	-0.04	0.04	0.01	0.03
Age [years]	-0.26*	0.09	-0.20	-0.25*	-0.29**
MMSE [score]	0.07	-0.15	0.12	0.13	0.24*
Medication [number]	-0.07	0.11	-0.08	0.02	-0.14

Note: Presented are Spearman rank correlation coefficients (rho). Correlation coefficients (rho): <0.20=low, 0.20–0.50=moderate, >0.50=high, p-value: *p<0.05. **p<0.01. deg=degrees, s=seconds, deg/s=degrees per second, SPPB=Short Physical Performance Battery, m/s= meter per second, TUG=Timed Up and Go test, LSA-CI=Life-Space Assessment for older persons with Cognitive Impairment, FES-I=Falls Efficacy Scale-International, GDS=Geriatric Depression Scale, MMSE=Mini-Mental State Examination.

[a] based on data n=91 as three participants were unable to walk without walking aid

[b] based on data n=92 as one participants refused "TUG" test and one participant was unable to stand-up from a chair without help

Test-retest reliability: ICCs ranging from 0.68 to 0.97 for 2x 24 hour uSense measurements conducted at consecutive days indicated excellent test-retest reliability for most established PA parameters and innovative gait characteristics. A plausibility check of the parameter turning duration (ICC 0.18) revealed that the measurement of one patient was an extreme outlier. Exclusion of this single measurement yielded an ICC (95% CI) of 0.76 (0.65-0.83) comparable to the other presented ICCs (Table 6).

Table 6: Test-retest reliability

Parameters (n=94)	ICC 3.1 (95% CI)
Established physical activity parameters	
active counts [total number]	0.84 (0.76-0.89)
total steps [total number]	0.93 (0.90-0.95)
duration of lying [min]	0.68 (0.55-0.78)
duration of gait [min]	0.93 (0.90-0.96)
lying episodes [total number]	0.77 (0.67-0.84)
gait episodes [total number]	0.94 (0.91-0.96)
mean METs (total) [-]	0.96 (0.94-0.97)
mean METs (per gait episodes) [-]	0.97 (0.95-0.98)
Innovative gait characteristics	
cadence [steps/min]	0.90 (0.86-0.94)
step duration [s]	0.92 (0.89-0.95)
CV step duration [%]	0.83 (0.76-0.89)
step regularity AP [%]	0.87 (0.81-0.91)
step regularity ML [%]	0.92 (0.88-0.95)
step regularity V [%]	0.90 (0.85-0.93)
PCI gait coordination [%]	0.74 (0.63-0.82)
harmonic ratio AP [-]	0.83 (0.76-0.89)
harmonic ratio ML [-]	0.86 (0.80-0.91)
harmonic ratio V [-]	0.82 (0.74-0.88)
Innovative turning characteristics	
turning angle [deg]	0.68 (0.56-0.78)
turning duration [s]	0.18 (-0.02-0.37)[a]
mean turning velocity [deg/s]	0.96 (0.93-0.97)
peak turning velocity [deg/s]	0.97 (0.95-0.98)
Mean turns per walking episode [total number]	0.83 (0.74-0.89)

Note: ICC 3.1=Intraclass Correlation Coefficient model 3.1 (<0.40 = poor ICC, 0.40 ≤ ICC ≤ 0.75 = moderate ICC, > 0.75 = excellent ICC). min=minutes, Mean METs (total) =Average Metabolic Equivalent of Tasks value of all posture and walking periods over the whole measuring period of 48hours, Mean METs (per gait episode) =Average Metabolic Equivalent of Tasks value of all gait episodes over the whole measuring period of 48hours, s=seconds, CV=Coefficient of Variation, AP=Anterior-Posterior, ML=Medio-Lateral, V=Vertical, PCI=Phase Coordination Index, deg=degrees, deg/s=degrees per second. [a] including one extreme outlier in the data.

Feasibility: Out of n=110 designated uSense monitor measurements, n=94 measurements were completed successfully (85.5%). One measurement (0.9%) was invalid due to technical failure, 12 subjects removed their sensor (10.9%), and three subjects refused to wear the sensor (2.7%). No significant differences were found between characteristics of the 94 patients with successful uSense measurements and those of the 16 patients with failed uSense measurements (t-tests all $p > 0.05$, data not shown).

Discussion

The present study documented on average moderate to good psychometrical quality of habitual activity behavior as assessed by the ambulatory uSense system, including established PA as well as innovative gait parameters in older persons affected with motor and cognitive impairment and activity restrictions.

Concurrent validity: Due to a missing gold standard for the measurement of PA in habitual settings, the evaluation of the concurrent validity of the uSense system required a validation method based on a comparable technical system. Our results indicate a strong relationship between established PA parameters measured by the PAMSys™ and uSense systems, showing that both systems correspond in distinguishing relative values of physical activity levels. However, Bland Altman method revealed low absolute agreement between both systems of all parameters.

Absolute differences found in our results might be caused by deviating analytical algorithms used in the different monitoring systems. The detailed analysis of the Bland Altman plots revealed a systematic bias in terms of linear associations between the mean of both systems and the difference between both systems of the parameters “duration of lying”, “number of walking episodes”, “number of steps” and “average METs”. These linear associations of the biases might be based on the higher sensitivity of the adaptive step detection as used by the uSense, compared to the PAMSys™ system. Sensitive step detection was an objective in the development of the the uSense system to overcome methodological problems of current sensor systems. Other systems indicate low accuracy in measuring activity behavior in older people with shuffling gait or gait speeds below 1.0 to 0.8 m/s (McCullagh et al., 2016), which is considerably faster than the gait speed documented in the present study population (0.5 m/s). A previous study affirm the challenge of measuring activity behavior at slow walking speeds, documenting an invalid assessment of physical activity in frail older adults (Hollewand et al., 2016).

When comparing absolute values, the uSense showed higher values for the parameters “number of walking episodes”, “number of steps”, “average METs” and lower absolute values for the variable “duration of lying” as compared to the PAMSys™ system. This is in contrast to recently published findings that showed high agreement between the uSense sensor system and direct observation in frail older people, but in contrast to our study these findings were exclusively focused on the distinction between walking and non-walking (Chigateri et al., 2018). The absolute values of “number of steps” and “average METs” suggested higher plausibility measured by the uSense compared to the PAMSys™. Considering the value for the “number of steps” (9370 steps) and the walking time (110 min) measured by the uSense in 48 hours, a cadence of 9370 steps/ 110min = 85 steps/min derived which is coherent with populations of slow walkers (Tudor-Locke et al., 2018), while the PAMSys™ measurement derived a cadence of 50 steps/min, being very low even in slow walking populations.

The central value of 1.6 METs measured by the uSense is slightly above the sedentary behavior threshold of 1.5 METs which is coherent with a person mostly performing sedentary or light/very light activities (B. E. Ainsworth et al., 1993). In comparison the average value of 1.1 METs measured by the PAMSys™ is very low even considering a sedentary population with about 12 hours of lying per day. Even if for the rest of the day the person would be seated watching the TV (about 1.3 METs) the central value should still be above 1.1 METs without any other activity (e.g. walking, eating, washing).

Construct validity of established physical activity parameters: The on average good construct validity of established PA parameters as documented in the present study confirmed results of previous validation studies related to basic PA outcome parameters (active counts) assessed under standardized, laboratory conditions in healthy young adults (Hendrick et al., 2010), under habitual conditions in high functioning older persons (Harris et al., 2009), and in middle-aged adults (Verbunt et al., 2001) with other comparable systems. However these studies excluded multi-morbid, older people with CI, and did not evaluate associations between more detailed PA parameters and clinically relevant parameters such as motor performance, exacerbating the comparability of results.

To overcome the missing comparative construct validation studies, we matched our results with those found in epidemiological studies, confirming moderate associations between PA behavior and measures of motor performance for participants with and without CI (Pettersson et al., 2017). We found particularly high correlations between measures of PA intensity (i.e., total METs) and motor performance compared to other studies [e.g. (DePew et al., 2013)] confirming previous results for this associations to be most apparent in older adults (≥ 75 years) with health restrictions (Osuka et al., 2015).

Parameters documenting sedentary behavior (lying episodes) stand out with non-significant associations to motor performance/life-space, probably related to sleeping behavior. Extreme short as well as long sleeping periods, and consequently both low and high durations of lying, were previously found to be associated with lower motor performance (Reyes, Algarin, Bunout, & Peirano, 2013; Stenholm et al., 2010) while sleep disorders are most prominent in persons with CI (Guarnieri & Sorbi, 2015), as in the present study.

Construct validity of innovative gait parameters (during straight walking): The present study showed heterogeneous associations of innovative gait parameters during straight walking with motor performance and life-space. These correlations are partly in line with previous studies, proving on average moderate construct validity. In the present study, gait variability was inversely and moderately correlated with motor performance and life-space. Such inverse, but higher correlations between variability of gait and motor performance have been shown in studies with high functioning older persons (Hausdorff et al., 2001; Martinikorena et al., 2016).

Our findings revealed low to moderate correlations between regularity and symmetry of gait and motor performance and are comparable to another study conducted in a laboratory setting with people at lower age and lower health restriction, also showing low correlations between these constructs (Shin, Valentine, Evans, & Sosnoff, 2012).

In the present study within gait symmetry variables the harmonic ratio in the V and AP directions showed the highest association with motor performance and life-space, confirming the results of recently published prospective cohort studies, reporting the harmonic ratio in V and AP direction to be predictive for falls in persons with and without CI (van Schooten et al., 2016; van Schooten et al., 2015). Among innovative gait parameters symmetry-related variables are clinically most relevant as persons with slower habitual gait speeds tend to a more unsymmetrical gait, leading to more balance-threatening acceleration and deceleration phases compared to more symmetrical gait patterns.

Construct validity of innovative gait parameters during turns: In the present study moderate to high correlations were found for all observed innovative parameters representing the quality of turns with motor performance and life-space mobility. Associations between turning parameters and motor performance might be explained by the inherent properties of turning while walking, which is a complex (Hase & Stein, 1999), recurrent (Glaister, Bernatz, Klute,

& Orendurff, 2007), and challenging (Cumming & Klineberg, 1994; Cummings & Nevitt, 1994) daily task that reflects the clinical relevance of the motor performance tests applied in our study. In a previous longitudinal study, turning parameters showed a high validity to differentiate between recurrent fallers and non-fallers (Mancini et al., 2016), illustrating the innovative potential of turning characteristics as an objective gait measure in real-life environments.

Currently sensor systems measuring turning parameters have not been validated in habitual settings of older persons with health restrictions, benchmarking of present results is therefore limited. Results of cross-sectional studies, however, confirm the high association between turning variables and results of established motor assessments measured under supervised laboratory conditions in older persons with stroke (Kobayashi, Takahashi, Sato, & Usuda, 2015), or showed medium to high correlations between habitually measured turning parameters and standardized balance tests in older adults (Mancini et al., 2016).

In contrast to results of a previous study conducted under laboratory and under habitual conditions (Haertner et al., 2018), present results indicated low associations between fear of falling and turning parameters. This was probably based on the low to moderate incidence of fear of falling found in our study sample, compared to higher concerns of falling shown in the population of Haertner et al. 2018.

Lower associations for medical, psychological or demographic variables with all established PA as well as innovative gait parameters may indicate a major influence of motor impairment on PA and quality of gait in the present sample of frail older persons, overruling other potential factors which may have a higher impact especially in samples more affected with psychiatric symptoms. The fact that all persons had cognitive impairment and a high incidence of multi-morbidity with a comparably narrow range and low heterogeneity in both domains may also have resulted in a limited association to cognitive status.

The selection of construct variables for validation purpose was evidence-based with different hypotheses for levels of association to PA and quality of gait outcomes. Such expected differences relate to real differences of associations between domains, with no direct translation into the methodological evaluation of construct validity.

In conclusion, the results of the present study showed moderate to high construct validity of the uSense system in measuring established PA- and innovative gait parameters allowing valid assessment in real-life settings of older persons with motor and cognitive impairment.

Test-retest reliability: The uSense sensor demonstrated moderate to excellent test-retest reliability for almost all examined established PA and innovative gait parameters. These findings are comparable to previous test-retest reliability studies using established activity monitors (activPAL, StepWatch) in healthy younger adults (Dahlgren, Carlsson, Moorhead, Hager-Ross, & McDonough, 2010), older adults (Resnick, Nahm, Orwig, Zimmerman, & Magaziner, 2001), and older adults with mobility limitations (Mudge & Stott, 2009) (ICCs = 0.69-0.99). Considering that the assessment of cognitively impaired older adults is aggravated due to sample-specific limitations, such as severe motor impairments, attention deficits, inability to follow instructions, impaired executive function (Hauer & Oster, 2008), results seem remarkable, indicating a reliable activity assessment even in very vulnerable samples.

Feasibility: The study results showed that the use of the uSense is feasible in persons with motor and cognitive impairment. The completion rate found in our study exceeded the completion rate in younger adults (Chapman et al., 2015), but was comparable to results in older adults with and without CI (van Loevezijn et al., 2014; Zainol Abidin et al., 2016), or nursing home residents with dementia also using the uSense system (Fleiner et al., 2016). The good acceptance rate is noteworthy since patients with CI often remove body-worn devices during registration periods (Camargos, Louzada, & Nobrega, 2013), a phenomenon that was not prominent in our study sample. The unobtrusive design with its small size and the localization at subjects' lower back seem to have supported the high feasibility of the uSense system.

Limitation and strength: Study results document the successful validation of an innovative physical activity assessment in older, persons with multiple impairments allowing a new quantitative as well as qualitative insight in habitual behavior hard to detect and classify. The interpretation of concurrent validity showed methodological limitations due to the missing gold standard in measuring physical activity under habitual conditions.

Conclusions: Study results successfully document construct validity, test-retest reliability, and feasibility of the uSense activity monitor including established as well as innovative gait parameters in multi-morbid older adults with cognitive and motor impairment. In combination with its small size, low mass, and ease of use, the uSense represents a convenient and unobtrusive instrument to objectively measure habitual activity behavior for the first time in this vulnerable population.

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Measurement Article

Validation of a Modified Life-Space Assessment in Multimorbid Older Persons With Cognitive Impairment

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Abstract

Background and Objectives: To investigate the validity, reliability, sensitivity to change, and feasibility of a modified University of Alabama at Birmingham Study of Aging Life-Space Assessment (UAB-LSA) in older persons with cognitive impairment (CI).
Research Design and Methods: The UAB-LSA was modified for use in persons with CI Life-Space Assessment for Persons with Cognitive Impairment (LSA-CI). Measurement properties of the LSA-CI were investigated using data of 118 multimorbid older participants with CI [mean age (*SD*): 82.3 (6.0) years, mean Mini-Mental State Examination score: 23.3 (2.4) points] from a randomized controlled trial (RCT) to improve motor performance and physical activity. Construct validity was asessed by Spearman's rank (r_s) and point-biseral correlations (r_{pb}) with age, gender, motor, and cognitive status, psychosocial factors, and sensor-derived (outdoor) physical activity variables. Test–retest reliability was analyzed using intra-class correlation coefficients (ICCs). Sensitivity to change was determined by standardized response means (SRMs) calculated for the RCT intervention group.
Results: The LSA-CI demonstrated moderate to high construct validity, with significant correlations of the LSA-CI scores with (outdoor) physical activity (r_s = .23–.63), motor status (r_s = .27–.56), fear of falling-related psychosocial variables (r_s = |.24–.44|), and demographic characteristics (r_{pb} = |.27–.32|). Test–retest reliability was good to excellent (ICC = .65–.91). Sensitivity to change was excellent for the LSA-CI composite score (SRM = .80) and small to moderate for the LSA-CI subscores (SRM = .35–.60). A completion rate of 100% and a mean completion time of 4.1 min) documented good feasibility.
Discussion and Implications: The LSA-CI represents a valid, reliable, sensitive, and feasible interview-based life-space assessment tool in multimorbid older persons with CI.

Keywords: Assessment of Conditions/People, Clinical Trial Methods, Quantitative research methods, Measurement, Exercise/Physical Activity, Cognitive Impairment, Validation

Introduction

Community mobility has been conceptualized and measured in terms of life-space (Webber, Porter, & Menec, 2010), a concept which encompasses a concentric pattern of mobility zones from own bedroom to regions beyond city limits.

Life-space measures quantify activity and location of mobility influenced by interaction between functional, cognitive, and psychosocial ability with social, economic and cultural aspects (Parker, Baker, & Allman, 2002). Restricted life-space mobility is associated with higher mortality

(Kennedy et al., 2017), institutionalization (Sheppard, Sawyer, Ritchie, Allman, & Brown, 2013), lower quality of life (Bentley et al., 2013), and social engagement (Rosso, Taylor, Tabb, & Michael, 2013). Moreover, it has been identified as a predictor of cognitive decline (Crowe et al., 2008; Silberschmidt et al., 2017).

Cognitive impairment (CI) in older persons increases the risk for mobility limitations (Pedersen et al., 2014), and is associated with loss of functional independence (Wadley et al., 2007) and reduced time spent out-of-home (Wettstein et al., 2015).

The assessment of life space via questionnaires has been introduced in 1985 (May, Nayak, & Isaacs, 1985). Since then several questionnaires have been developed with the University of Alabama at Birmingham Study of Aging Life-Space Assessment (UAB-LSA) representing one of the most frequently used life-space mobility assessment tools in older adults (Chung, Demiris, & Thompson, 2015). The UAB-LSA was initially developed and validated for use in older community-dwelling persons without CI (Baker, Bodner, & Allman, 2003; Peel et al., 2005). In this population, the UAB-LSA was translated and validated in several languages (Auger et al., 2009; Curcio et al., 2013; Fristedt, Kammerlind, Bravell, & Fransson, 2016; Harada et al., 2010; Ji, Zhou, Liao, & Feng, 2015), proved for good to excellent test–retest reliability (Auger et al., 2009; Baker et al., 2003; Curcio et al., 2013; Ji et al., 2015; Kammerlind, Fristedt, Ernsth Bravell, & Fransson, 2014; Portegijs, Iwarsson, Rantakokko, Viljanen, & Rantanen, 2014), and demonstrated to be feasible (Auger et al., 2009; Peel et al., 2005; Portegijs et al., 2014). Sensitivity to change of the UAB-LSA has so far only been documented over time by natural course without statistical analysis (Baker et al., 2003).

The UAB-LSA has already been used to assess life-space mobility in mixed populations including some persons with CI (Al Snih et al., 2012; Crowe et al., 2008; Fairhall et al., 2012; Silberschmidt et al., 2017; Tsutsumimoto et al., 2014); however, it has not yet been validated in, nor has it been adjusted to this population, which have shown recall bias and inaccuracy in retrospective self-reports (Shephard, 2003) as well as difficulties in self-reporting physical activity (PA) (Bhandari & Wagner, 2006; Sallis & Saelens, 2000). In addition, previous UAB-LSA validation studies have not yet conducted in multimorbid older persons with acute motor impairment, although this population represents a high-risk group for life-space restrictions (Baker et al., 2003; Brown et al., 2009; Crowe et al., 2008; Portegijs, Rantakokko, Viljanen, Sipila, & Rantanen, 2016). The aim of this study was therefore to validate a modified version of the UAB-LSA (Life-Space Assessment in Persons with Cognitive Impairment, LSA-CI) specifically developed for use in multimorbid persons with CI.

Methods

Study Design

The present validation study was part of a double-blinded, randomized, placebo-controlled intervention trial (RCT) to improve motor performance and PA in older persons with mild to moderate CI recently discharged from geriatric rehabilitation (ISRCTN82378327). The RCT was performed according to the Helsinki declaration and was approved by the ethics committee of the Medical Department of the University of Heidelberg.

Study Sample

Participants were consequently recruited from rehabilitation wards of a German geriatric hospital. Individuals with Mini-Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975) scores of 17–26 indicating mild to moderate CI were included in the study (Monsch et al., 1995; O'Bryant et al., 2008; Thalmann et al., 2002). Further inclusion criteria were: age ≥65 years; ability to walk at least 4 m without a walking aid; residence within 30 kilometers of the study center; discharge to the patients' home (i.e., no nursing home residents); no terminal disease; no delirium; German-speaking, and written informed consent.

Descriptive Measures

Demographic and clinical characteristics including age, gender, and comorbidity (number of diagnoses, medications) were documented at baseline from patient charts. A trained interviewer assessed falls in the previous year, cognitive status (MMSE) (Folstein et al., 1975), professional education (school education only vs. additional vocational training or academic studies), and psychosocial status for depression (Geriatric Depression Scale, 15-item version, GDS, Yesavage et al., 1982) and fear of falling (Falls Efficacy Scale-International, 7-item version, FES-I, Kempen et al., 2008; Fear of Falling Avoidance Behavior Questionnaire, FFABQ, Landers, Durand, Powell, Dibble, & Young, 2011). Motor status was assessed by the Short Physical Performance Battery (SPPB, Guralnik et al., 1994) and the Timed "Up & Go" (TUG, Podsiadlo & Richardson, 1991).

Life-space Assessment

University of Alabama at Birmingham Study of Aging Life-Space Assessment

The UAB-LSA is an instrument to assess life-space mobility of the previous 4 weeks by the frequency of movements and assistance needed to travel via face-to-face or telephone interview. The activity area is classified into six hierarchically structured, concentric zones ranging from activity locations including a person's bedroom (level 0), to a person`s home (level 1), area outside the house (level 2), the neighborhood (level 3), the home town (level 4), and beyond the person's home town (level 5). A composite score of life-space mobility (LSA-C) is calculated by multiplying the levels reached (levels 0–5), with the frequency of activity within a level (1 = "less than 1 time per week", 2 = "1–3 times per week", 3 = "4–6 times per week", 4 = "daily") and the assistance needed to travel to the level (1 = "help of another person", 1.5 = "use of assistive device only", 2 = "no assistance"). The lowest LSA-C score of 0 indicates total immobility (bed-bound) and the maximum LSA-C score of 120 indicates daily independent out-of-town mobility. In addition, three LSA subscores can be calculated for (a) the maximum life-space level reached allowing equipment or personal assistance (LSA-M; range 0–5), (b) the maximum life-space level reached with equipment if needed but without personal assistance (LSA-E; range 0–5), and (c) the maximum life-space level reached independently without any assistance (LSA-I; range 0–5) (Baker et al., 2003).

Modifications for Life-Space Assessment in Persons with Cognitive Impairment

The assessment period covered by the UAB-LSA was reduced from 4 weeks to 1 week to prevent recall bias in persons with CI, thus the LSA-CI has a different scoring range for frequency (1 point: 1–3 times per week, 2 points: 4–6 times per week, and 3 points: daily), and consequently the composite score ranges from 0 ("totally bed-bound") to 90 points ("traveled out of town every day without assistance"). The LSA-CI constitutes an interview-based and strictly standardized questionnaire, which was conducted face-to-face without participation of proxies or caregivers. A dementia-specific interview technique, originally developed for the assessment of PA in patients with CI, was implemented to prevent recall problems (Hauer et al., 2011). The strategy included an informal conversational approach to prevent fear of failure in comprehension and recall and to improve the completeness of reports, fostering memory by precise questions and response options, structuring the observation period by referring to daily routines and highlighting landmark events such as meals, daily/weekly habits, special events as visits, celebration, and summarizing the information (Bhandari & Wagner, 2006; Shephard, 2003) (the LSA-CI questionnaire form and a manual for assessment instruction and rationale are provided as supplementary material).

Translation Process

The translation from English into German language was performed according to a structured proceeding suggested by Beaton, Bombardier, Guillemin, and Ferraz (2000) (stages I–IV), including forward- and backward-translation by bilingual translators and tests in the target population in terms of comprehensibility.

Assessment of Measurement Properties

Construct Validity

To analyze construct validity, correlations between the LSA-CI scores at baseline (LSA-CI-C, -M, -E, and -I) with demographic variables (age, gender), motor status (SPPB, gait speed from the SPPB, TUG), cognitive status (MMSE), and psychological status (GDS, FES-I, FFABQ) were calculated. These correlates were selected according to previous validation studies of the UAB-LSA, demonstrating construct validity by associations with age and gender (Harada et al., 2010; Peel et al., 2005), physical performance (Baker et al., 2003; Curcio et al., 2013; Fristedt et al., 2016; Ji et al., 2015; Peel et al., 2005), cognitive status (Curcio et al., 2013; Ji et al., 2015) and multiple psychosocial factors (Baker et al., 2003; Curcio et al., 2013; Ji et al., 2015; Peel et al., 2005). As previous observational studies in community-dwelling people reported that life-space mobility is associated with objectively measured PA (Portegijs, Tsai, Rantanen, & Rantakokko, 2015; Tsai et al., 2015), we additionally used sensor-derived PA and outdoor PA data (OPA) captured for 48 hours during the baseline assessment for validity testing.

PA was measured by a small (5.1 × 3 × 1.6 cm), light (24 g), body-fixed motion sensor (PAMSys™, BioSensics, Cambridge, MA) attached to the participant's sternum. The PAMSys™ is able to identify posture durations (i.e., minutes of lying, sitting, standing, and walking) and locomotion outcomes (i.e., number of walking steps and walking episodes) based on established and validated algorithms (Najafi et al., 2003).

OPA variables were calculated based on PA data and data derived from a mobile Global Positioning System (GPS). In our study, we used a QStarz GPS-tracker (QStarz BT1000X, Qstarz International Co., Ltd., Taipei, Taiwan), an established device to assess spatial location of physical activity (Wu et al., 2010). The Software Personal Activity Location Measurement System (PALMS; available from: http://ucsd-palms-project.wikispaces.com/.) was used to merge the GPS and PA data. PALMS is valid for processing GPS data to objectively measured PA data (Carlson et al., 2015). OPA variables included being active outdoors (yes or no), mean outdoor walking duration and distance, number of outdoor walking episodes, and maximum distance from home.

Test–retest Reliability

To test for test–retest reliability, the LSA-CI assessment was conducted twice within two days for all participants at post-intervention by the same trained interviewer to exclude interrater variability.

Sensitivity to Change

Sensitivity to change was examined for the participants randomly assigned to the intervention group of a 12-week home-based interventional trial to improve motor performance and physical activity in geriatric patients with CI following rehabilitation. The intervention included exercises to promote functional balance and strength performance as well as various motivational strategies to promote physical activity (Bongartz et al., 2017).

Feasibility

Completion rate and completion time to fill out the questionnaire were documented at baseline to determine feasibility. In case of unrealistic self-reports and implausible participant statements data was not analyzed. In addition, LSA-CI scores at baseline were checked for floor and ceiling effects, which were considered present when more than 15% of the individuals achieve the highest or lowest score (McHorney & Tarlov, 1995).

Statistical Analysis

Descriptive data were presented as frequencies and percentages for categorical variables, and means and standard deviations or medians and ranges for continuous variables as appropriate. Spearman and point-biserial correlation coefficients were calculated to assess construct validity. Correlation coefficients (*r*) were interpreted as low ($r < 0.2$), moderate ($r = 0.2–0.5$), or high ($r > 0.5$) (Cohen, 1988). Intra-class correlation coefficients (ICC3,1 for absolute agreement) with 95% confidence intervals for the LSA-CI composite score and each subscore were used to analyze test–retest reliability. ICCs were interpreted as poor (<0.4), fair to good (≥ 0.4 ≤ 0.75), and excellent (>0.75) (Fleiss, 1986). Sensitivity to change was assessed using paired t-tests to test for significant within-group differences between baseline and post intervention assessment and standardized response means (SRMs) to quantify the magnitude of changes. SRMs were calculated as the difference in mean change scores divided by the *SD* of the change score (Katz, Larson, Phillips, Fossel, & Liang, 1992). SRMs were adjusted for the size of correlation coefficients between the baseline and post-intervention scores (Middel & van Sonderen, 2002) to use Cohen's thresholds for effect sizes (trivial < 0.2, small ≥ 0.2 < 0.5, moderate ≥ 0.5 < 0.8, and large ≥ 0.8) (Cohen, 1988). A two-sided p-value of < 0.05 indicated statistical significance. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 23 for Windows (IBM Corp., NY).

Results

Participants' Characteristics

Out of 1,981 persons screened for eligibility, 1,863 did not meet inclusion criteria due to MMSE criteria ($n = 553$; MMSE >26: $n = 382$, MMSE <17: $n = 102$, MMSE not feasible: $n = 69$), residence >30 km from study center ($n = 241$), medical contraindications ($n = 217$), being recruited for another trial ($n = 211$), inability to walk at least 4 m without a walking aid ($n = 196$), refusal to participate ($n = 123$), nursing home resident or admission ($n = 113$), or other reasons ($n = 209$; e.g., <65 years, lack of German language skills, transfer to another hospital). Thus, the total sample included 118 multimorbid, older, community-dwelling persons with mild to moderate CI with at least two chronic diseases, and predominantly orthopedic and cardiovascular diseases. Detailed participant characteristics are summarized in Table 1.

Construct Validity

The LSA-CI scores showed consistently moderate to high correlations with all OPA variables ($r = .30–.63$), with the lowest correlations for the Life-Space Assessment for Persons with Cognitive Impairment for the maximal life-space score (LSA-CI-M) ($r = .30–.34$) (Table 2). Moderate to high correlations of the LSA-CI scores were also found with almost all (15 of 16) PA variables addressing physical active behavior (i.e., standing, walking, number of walking episodes and steps) ($r = .23–.60$), whereas correlations with PA variables addressing sedentary behavior (i.e., lying, sitting) were consistently lower ($r = -.06$ to $-.40$). Overall, the lowest correlations with PA variables were found for the LSA-CI-M ($r = -.06$ to $-.29$). Except for the LSA-CI-M ($r = |.05–.13|$), LSA-CI scores showed moderate to high correlations with motor status ($r = |.27–.56|$) and fear of falling-related psychosocial variables ($r = -.24$ to $-.44$). For depressive symptoms, only low correlations were found

Table 1. Participant Characteristics

Characteristics	Total sample $n = 118$
Age, years, mean (*SD*)	82.3 (6.0)
Gender, female, *n* (%)	90 (76.3)
Professional education, *n* (%)	
School education only	37 (31.4)
Vocational training or academic studies	81 (68.6)
Diagnoses, number, mean (*SD*)	11.4 (4.4)
Medications, number, mean (*SD*)	9.5 (3.5)
MMSE, score, mean (*SD*)	23.3 (2.4)
SPPB, total score, mean (*SD*)	5.2 (2.3)
Gait speed, m/s, mean (*SD*)[a]	0.45 (0.20)
TUG, s, median (range)[b]	20.5 (8.8–91.0)
At least one fall in the previous year, *n* (%)	79 (66.9)
FES-I, score, median (range)	11 (7–25)
FFABQ, score, mean (*SD*)	18.7 (12.6)
GDS, score, mean (*SD*)	5.3 (3.0)

Note: GDS = Geriatric Depression Scale; FES-I = Falls Efficacy Scale-International, seven-item version; FFABQ = Fear of Falling Avoidance Behavior Questionnaire; MMSE = Mini-Mental State Examination; SPPB = Short-Physical-Performance-Battery; TUG = Timed "Up & Go".

[a]Calculated based on the SPPB gait speed test.

[b]Based on data $n = 113$ as five participants were not able to complete the TUG due to physical limitations.

(r = −.02 to −.16). The LSA-CI scores predominantly (3 out of 4) correlated only weakly with cognitive status (r = .02–.18). Except for the LSA-CI-M (r = |.13–.15|), demographic characteristics showed moderate correlations with the LSA-CI scores (r = |.27–.32|) with older and female participants demonstrating lower life-space mobility. Subgroup analyses for different cognitive status groups (i.e., MMSE >24 vs. ≤24 and >21 vs. ≤21) revealed no significant differences for any LSA-CI score (unpaired t-test: p = .137–.810).

Test–Retest Reliability

Correlations between the two LSA-CI assessments performed by the same interviewer within 2 days indicated good to excellent test–retest reliability for all LSA-CI scores, with ICCs ranging from 0.65 to 0.91 (Table 3).

Sensitivity to Change

LSA-CI scores were significantly different between baseline and post-intervention assessment (p ≤ .001). Small to large SRMs (range 0.35–0.80) over the intervention were found across the LSA-CI scores, with the highest SRM for the LSA-CI-C (0.80) while LSA-CI subscores reached lower SRMs (0.35–0.60) (Table 4).

Feasibility

No participant objected to the assessment procedure, and data documentation was comprehensive, with no missing responses for any LSA-CI item (i.e., 100% completion rate). We excluded 1 of 118 participants (0.8%) from the analysis, because of unrealistic statements, advanced disorientation, and confabulation. Mean completion time (*SD*) to assess the LSA-CI was 4.1 (2.2) min.

No participant obtained the minimum or maximum LSA-CI-C score, with values ranging from 4.5 to 70.0 points, indicating no ceiling or floor effects for this score. No ceiling or floor effects were documented also for the LSA-CI-E, with no participant obtaining the minimum and only 12 participants (10.3%) obtaining the maximum score. For the LSA-CI-M, we found no floor effect (no participant with the minimum score) but a ceiling effect, with 35 participants (29.9%) obtaining the maximum score. For the LSA-CI-I, no ceiling (n = 5 [4.3%] with the maximum score) but a floor effect was identified, with 58 participants (49.6%) obtaining the minimum score.

Discussion

Although older persons with CI represent a high-risk group for life-space restrictions, established interview-based life-space assessment instruments have not yet been adjusted or validated for use in this population. The presented study is the first to modify one of the most frequently used life-space assessment tools (UAB-LSA) for persons with CI and to evaluate its measurement properties in multimorbid older persons with mild to moderate CI.

Construct Validity

Our results indicated moderate to high construct validity of the LSA-CI with measures of demographic characteristics, motor status, fear of falling-related psychosocial factors, and PA and OPA. Lower life-space mobility was associated with female sex, higher age, lower motor status, pronounced fear of falling-related variables, and higher levels of physical active behavior, which is consistent with previous UAB-LSA validation studies (Baker et al., 2003; Curcio et al., 2013; Fristedt et al., 2016; Harada et al., 2010; Ji et al., 2015; Peel et al., 2005) or cohort studies investigating life-space mobility (Portegijs et al., 2015; Tsai et al., 2015) in community-dwelling older people without CI.

We found that motor status was one of the strongest variables associated with LSA-CI scores, confirming results of previous UAB-LSA validation studies, which also reported higher correlations for measures of motor status compared to demographic variables, psychosocial status, and cognitive status (Baker et al., 2003; Curcio et al., 2013; Peel et al., 2005). As previously described for older people without CI (May et al., 1985; Peel et al., 2005), our results documented that physical functioning represents a main determinant of life space mobility also in multimorbid older people with CI.

High correlations were also found among the variables documenting physical active behavior. As expected from previous cohort studies (Portegijs et al., 2015; Tsai et al., 2015), higher life-space mobility was associated with being more physically active (higher PA and OPA) in our study (e.g., higher number of steps, longer outdoor walking distance, being active outdoors). These results might be explained by the facts that (1) for reaching higher levels of the concentric zones within the life-space concept (e.g., outside bedroom, neighborhood) a certain level of (outdoor) PA is necessary and (2) the OPA variables also addressed activity and location of mobility as made by the LSA-CI. Sedentary behavior was not associated with life-space mobility, which was previously shown by (Tsai et al., 2015), indicating that sedentary persons may use more motorized transportation to reach comparable life-space levels or physical active persons organize their daily life within the immediate surrounding. A number of papers have found out similar results for physical activity. Sedentary behavior and low physical activity seem to be independent predictors of worse health outcomes (DiPietro, Jin, Talegawkar, & Matthews, 2017; Klenk et al., 2016; Patel et al., 2010). To the best of our knowledge, our study was the first that successfully demonstrated construct validity of an interview-based life-space assessment instrument based on objectively, sensor-derived PA and OPA behavior.

Table 2. Construct Validity for the Different Scores of the LSA-CI

Variables (n = 117)	LSA-CI-C	LSA-CI-M	LSA-CI-E	LSA-CI-I
Demographic characteristics				
Age, years	**–.32****	–.15	**–.31****	**–.27****
Gender (0 = female, 1 = male)[a]	**.28****	.13	**.32****	**.31****
Cognitive status				
MMSE score	.18	.15	**.21***	.02
Psychological status				
GDS	–.11	–.16	–.11	–.02
FES-I	**–.24****	–.12	–.12	**–.25****
FFABQ	**–.38****	–.15	**–.35****	**–.44****
Motor status				
SPPB total score	**.39****	.05	**.30***	**.52****
Gait speed	**.41****	.13	**.27****	**.56****
TUG	**–.40****	–.08	**–.38****	**–.52****
Physical activity				
Lying (min)	–.13	–.07	**–.25****	–.14
Sitting (min)	–.12	–.06	–.04	–.07
Standing (min)	**.41****	**.28****	**.53****	**.23***
Walking (min)	**.55****	**.27****	**.58****	**.51****
Walking episodes (n)	**.40****	.16	**.42****	**.42****
Steps (n)	**.59****	**.29****	**.60****	**.53****
Outdoor physical activity				
Being active outdoors? (0 = no, 1 = yes)[a]	**.53****	**.30****	**.63****	**.33****
Mean outdoor walking duration (s)	**.54****	**.31****	**.62****	**.37****
Mean walking distance outdoors (m)	**.54****	**.34****	**.63****	**.33****
Outdoor walking episodes (n)	**.54****	**.31****	**.62****	**.32****
Maximum distance from home (m)	**.52****	**.32****	**.63****	**.32****

Note: Presented are Spearman rank correlation coefficients (r_s), except for gender and being active outdoors. FFABQ = Fear of Falling Activity Avoidance Questionnaire; GDS = Geriatric Depression Scale; LSA-CI = Life-Space Assessment for Persons with Cognitive Impairment; LSA-CI = Life-Space Assessment for Persons with Cognitive Impairment; LSA-CI-C = composite life-space; LSA-CI-M = maximum life-space; LSA-CI-E = maximum life-space with equipment; LSA-CI-I = maximum independent life-space; MMSE = Mini-Mental State Examination; SPPB = Short-Physical Performance Battery; TUG = Timed "Up & Go"; FES-I = short Falls-Efficacy-Scale. Correlations coefficients (r): < .20 = low, .20–.50 = moderate, > .50 = high.
[a]Point-biserial correlation coefficients (r_{pb}).
$^*p < .05$. $^{**}p < .01$.

Table 3. Test–Retest Reliability of the LSA-CI Scores

	Mean (*SD*)			
Variable (n^a = 102)	First test session	Second test session	ICC(3,1)	95% CI
LSA-CI-C	29.7 (15.4)	29.0 (15.0)	0.91	0.87–0.94
LSA-CI-M	4.1 (1.1)	3.9 (1.1)	0.80	0.71–0.86
LSA-CI-E	2.8 (1.4)	2.6 (1.3)	0.65	0.53–0.75
LSA-CI-I	1.4 (1.6)	1.4 (1.5)	0.91	0.86–0.94

Note: CI = confidence interval; LSA-CI = Life-Space Assessment for Persons with Cognitive Impairment; LSA-CI-C = composite life-space; LSA-CI-M = maximum life-space; LSA-CI-E = maximum life-space with equipment; LSA-CI-I = maximum independent life-space; ICC = intra-class correlation coefficient (<0.4 = poor, 0.4–0.74 = fair to good, >0.75 = excellent).
[a]Sample size was reduced due to the organization of the study and the timing of the assessment.

Previous UAB-LSA validation studies in community-dwelling elderly reported moderate correlations of life-space mobility with participants' cognitive status (Ji et al., 2015; Peel et al., 2005). In contrast to these studies, these correlations were considerably lower in our cognitively impaired participants. The lower correlations may be related to the relatively small range of cognitive status in our sample, as we included solely persons with mild to moderate CI and excluded those with more severe or without CI. Previous UAB-LSA validation studies included a large number of community-dwelling elderly (n = 100–998; >65 years) without taking into account the cognitive status for an inclusion criterion, which may have resulted in wide-ranging cognitive performance levels among their

Table 4. Sensitivity to Change of the LSA-CI Scores

Variable (n^a = 53)	Mean (*SD*)		*p*-Value	SRM
	Baseline	Post-intervention		
LSA-CI-C	28.4 (14.0)	37.6 (14.5)	<.001	0.80
LSA-CI-M	3.9 (1.1)	4.5 (0.9)	.001	0.60
LSA-CI-E	3.0 (1.2)	3.3 (1.2)	<.001	0.35
LSA-CI-I	1.3 (1.5)	1.8 (1.6)	.001	0.43

Note: LSA-CI = Life-Space Assessment for Persons with Cognitive Impairment; LSA-CI-C = composite life-space; LSA-CI-M = maximum life-space; LSA-CI-E = maximum life-space with equipment; LSA-CI-I = maximum independent life-space; SRM = standardized response mean (<0.2 = trivial, ≥0.2 < 0.5 = small, ≥0.5 <0.8 = moderate, ≥0.8 = large).

[a]Only participants randomly assigned to the intervention group and completing the intervention were included in the analyses.

samples and potentially also in the higher correlations found in these studies.

We found lowest correlations of life-space mobility with depressive symptoms. Previous findings for associations of life-space mobility and depressive symptoms in older people without CI have been ambiguous (Baker et al., 2003; Curcio et al., 2013; Ji et al., 2015; Peel et al., 2005; Polku et al., 2015; Umstattd Meyer, Janke, & Beaujean, 2014). Our results suggest that there seems to be no association of life-space mobility and despressive symptoms in community-dwelling older people with CI.

Across all correlates used for testing construct validity, we found the lowest correlations for the maximal life-space score (LSA-CI-M), which is in line with the results reported in previous UAB-LSA validation studies (Baker et al., 2003; Fristedt et al., 2016). This can be explained by the fact that the LSA-CI-M does not consider a person's own ability to independently reach the maximum life-space (i.e., without personal assistance or equipment). Thus, this score documents a different aspect of life-space mobility which may rather be determined by the availability and the use of assistance from persons or equipment than by personal characteristics such as age, gender, or motor, cognitive and psychological status, or by PA behavior, which may explain the lower correlations (Baker et al., 2003; Fristedt et al., 2016).

Test–Retest Reliability

The LSA-CI demonstrated good to excellent test–retest reliability (ICC = 0.65–0.91) in our sample of multimorbid older people with CI. These reliability results are similar (ICC = 0.72–0.96) (Auger et al., 2009; Baker et al., 2003; Ji et al., 2015; Kammerlind et al., 2014; Portegijs et al., 2014) or even better (ICC = 0.37–0.70) (Curcio et al., 2013) compared to those reported for the UAB-LSA in older persons without CI. The overall good reliability of the LSA-CI might be particularly related to the specific strategy to prevent recall bias as used for the LSA-CI (i.e., shorter assessment period; highly-standardized interview technique), which is highly relevant in older persons with CI.

Sensitivity to Change

For use in clinical settings, it is essential that assessment instruments are able to detect changes over time or effects of intervention studies. To our knowledge, this is the first study that evaluated sensitivity to change of a life-space mobility assessment instrument within an interventional trial including a statistical analysis as suggested for evaluation of responsiveness (Terwee, Dekker, Wiersinga, Prummel, & Bossuyt, 2003).

The significant improvements with a large effect size for the LSA-CI-C score demonstrated the high potential of the LSA-CI to adequately reproduce changes in life-space mobility induced by an intervention on motor performance and physical activity. The LSA-CI subscores seemed to be less sensitive, as documented by the lower effect sizes. This may be related to the smaller scoring range of these scores (range 0–5) compared to the LSA-CI-C (range 0–90) and to the ceiling and floor effects observed for the subscores LSA-CI-M and -I, which generally limit the ability to detect changes over time (Beaton, Bombardier, Katz, & Wright, 2001).

Feasibility

Feasibility of the LSA-CI was excellent in our sample of multimorbid older persons with CI. No participant refused the assessment and life-space mobility could be documented adequately. Although cognitively impaired persons show a variety of limitations regarding the recall of behavior, participants' statements were plausible, except for only one person. These excellent results may be related to the modifications made on the recall period covered by the LSA-CI (only 1 week instead of 4 weeks) and to the use of specific, highly structured face-to-face interview technique, which has been previously demonstrated to be effective in promoting recall and assessing physical activity in older persons with CI (Hauer et al., 2011). Despite the potential challenges of cognitively impaired persons to recall retrospective information, the completion time for the LSA-CI was brief and similar to that reported for the UAB-LSA in older persons without CI (about 5 min) (Peel et al., 2005).

The LSA-CI showed excellent instrument coverage with no floor and ceiling effects for the LSA-CI-C score, indicating that this score covers a wide range of life-space mobility levels without being limited in upper and lower levels even in this vulnerable study sample with relevant motor and CIs. The floor and ceiling effects observed for the subscores LSA-CI-M and LSA-CI-E were consistent with those reported in cognitive intact persons (Auger et al., 2009). The floor effect found for the LSA-CI-I documented the vulnerable status of our study sample as most of the participants were not able to leave the bed without equipment or personal assistance. The ceiling effects for the LSA-CI-M may be explained by its relation to social support (Baker et al., 2003; Fristedt et al., 2016). In this study, community-dwelling persons post-hospitalization were analyzed, discharged to their homes and thus adequately supplied with assistance to remain in their homes, which could explain the large life-space.

Limitations

Results may be marginally influenced by preceding hospitalization of the subjects which is associated with decreasing life-space and varying recovery rates (Brown et al., 2009). The participants were selected according to the inclusion criteria of the intervention study in which the participants were recruited representing former geriatric patients discharged from ward-based rehabilitation to their homes. Although severely impaired persons were excluded in this intervention study, the recruitment of former rehab patients may have influenced results of the presented validation.

Conclusions

The presented study demonstrated good to excellent measurement properties of the LSA-CI representing a modified version of the established UAB-LSA specifically adjusted to older persons with CI. Despite the potential challenges in the assessment of retrospective information in this population, the LSA-CI has shown to be a valid, reliable, sensitive, and feasible questionnaire to assess life-space mobility in multimorbid older people with mild to moderate CI.

Supplementary Material

Supplementary data are available at *The Gerontologist* online.

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Conflict of interest

None reported.

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Publikation IV

Bastian Abel*, **Martin Bongartz***, Tobias Eckert, Phoebe Ullrich, Rainer Beurskens, Sabato Melone, Jürgen M. Bauer, Sallie E. Lamb, Klaus Hauer. Will we do if we can? Habitual Qualitative and Quantitative Physical Activity in Multi-morbid, Older Persons with Cognitive Impairment.

Zur Publikation eingereicht bei S*ensors*.

(*Bastian Abel und Martin Bongartz teilen Erstautorenschaft)

sensors

MDPI

Article

Will we do if we can? Habitual Qualitative and Quantitative Physical Activity in Multi-morbid, Older Persons with Cognitive Impairment

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Abstract: The aim of this study was to describe innovative, qualitative gait characteristics and established, quantitative parameters of habitual physical activity (PA) in community-dwelling, multi-morbid, older persons with cognitive impairment (CI) and to identify determinants of quantitative PA dimensions (duration, frequency, intensity). Quantitative PA and qualitative gait characteristics while walking straight and while walking turns were documented by a validated, sensor-based activity monitor. Univariate and multiple linear regression analyses were performed to delineate associations of quantitative PA dimensions with qualitative characteristics of gait performance and further potential influencing factors (motor capacity measures, demographic and health-related parameters). In 94 multi-morbid, older adults (82.3±5.9 years) with CI (Mini-Mental State Examination score: 23.3±2.4), analyses of quantitative and qualitative PA documented highly inactive behavior (89.6% inactivity) and a high incidence of gait deficits, respectively. The multiple regression models (adjusted R^2=0.395-0.679, all p<0.001) identified specific qualitative gait characteristics as independent determinants for all quantitative PA dimensions, whereas motor capacity was an independent determinant only for the PA dimension duration. Demographic and health-related parameters were not identified as independent determinants. High associations between innovative, qualitative and established, quantitative PA performances may suggest gait quality as a potential target to increase quantity of PA in multi-morbid, older persons.

Keywords: sensor-based, activity behavior, gait, turning, symmetry, regularity, qualitative, determinants.

1. Introduction

Decreased motor capacity, defined as maximal level of functioning under standardized conditions [1], as well as decreased motor performance of physical activity (PA), describing habitual behavior in someone's actual environment [1], are common in older persons [2,3] and associated with various negative health outcomes, such as motor impairments, falls, affected psycho-social status, cardiovascular diseases, or mortality [4-6].

Besides disease- or impairment-related conditions such as stroke, orthopedic disorders, or pain [7], cognitive impairment (CI) stands out as it has been associated with poor qualitative and quantitative measures of gait [8] and a low volume of PA performance [9] with negative consequences on psychological status as well as social deprivation [10,11].

Technical developments in sensor-based activity monitoring allow to overcome previous limitations in questionnaire-based assessments of PA performance and to document the volume of PA performance by established, quantitative dimensions, such as duration, frequency, or intensity, as stated by leading medical associations [12]. Among all PA performance measures, walking has been considered as the key habitual motor activity that is most often reported but mainly assessed by established, quantitative parameters such as number of steps or duration of walking. These parameters have been increasingly complemented by innovative, qualitative measures, including characteristics of straight walking (e.g. symmetry, regularity, or variability of gait) [13] and turning while walking (e.g. duration, angle, or velocity of turns) [14], which enable qualitative analyses of walking as a key feature of habitual PA performance. Such qualitative characteristics allow to better understand the mechanisms of motor failure, such as falls [15], and have been successfully implemented to predict falls in older persons [13,14]. These qualitative variables of PA performance are also related to mild CI [16] and neurodegenerative disorders such as Parkinson's disease [17,18] and multiple sclerosis [19], as documented by cross-sectional analyses comparing middle-aged or older persons affected by these diseases with healthy controls. Furthermore, qualitative measures of walking capacity under laboratory conditions have also shown associations with the psychological status (e.g. depression, fear of falling) [20] and activity restrictions [21], thus documenting their sensitivity for psychological influences and activity behavior.

Turning while walking stands out as a more demanding movement for older persons, compared to straight walking [22,23], and is required in many daily activities [24]. It reflects a high risk situation for serious falls that my lead to hip fractures [25] and has therefore been incorporated in established clinical tests, such as the Timed "Up & Go" Test. For this test, good predictive validity for adverse health outcomes, fear of falling, and future falls has been documented [26-28]. Similar to the detailed analysis of straight walking, the quantitative turning capacity has recently been amended by qualitative characteristics such as turning velocity or turning angle, enabling detailed insights into turning while walking [14,29].

While such qualitative capacity measures have improved the understanding of habitual activity, namely gait-related performance, results of predictive validity are heterogeneous when using exclusively laboratory-based measures [30-32]. Gait characteristics assessed under highly standardized, laboratory-based conditions (walking capacity) differ substantially from gait characteristics measured during non-standardized, habitual PA (walking performance) [33], which may be affected by frequent distractions with potential negative consequences on habitual PA behavior. However, the assessment of qualitative characteristics of PA performance still remains a methodological challenge, especially in multi-morbid, older persons with activity clusters and gait performances that are hard to detect and classify [34]. While qualitative examinations of gait under habitual conditions are getting more and more attention [13,14,29,35], sensor-based assessment methods were predominantly validated in laboratory settings [18,36] with very restricted use in the real-life assessment of frail, older persons [34,37].

The potential of innovative, qualitative characteristics of PA performance have so far mainly been used in discriminative studies to describe motor differences between healthy, high functioning persons as compared to impaired populations [13,14,17,18,29,35]. These studies on specific qualitative characteristics of gait performance in habitual settings of older adults focused on either variables of turning [14,29] or parameters of straight walking [13,35], but did not use the whole range of parameters. While such discriminative, observational studies found significantly decreased qualitative motor performance (e.g. lower gait symmetry or lower turning velocity) in persons with falls [13,14,29,35] as well as in those with Parkinson's disease [17,18], it is interesting that in most of these studies, the quantity of PA performance did not differ as compared to healthy study groups [14,17,29,35]. These findings support the assumption that qualitative characteristics of PA performance are particularly important to complement the more established quantitative parameters.

To represent specific disease-related symptoms, such qualitative measures are of particular interest for specific patient groups such as persons with CI. However, research on qualitative characteristics of habitual PA performance in older persons with CI is scarce. Only three studies with cross-sectional analyses have been identified that considered older persons with CI in subgroups, comparing merely few, individual qualitative characteristics such as variability or regularity of gait performance between older adults with and without CI [16,38,39]. These discriminative studies showed deteriorations in the qualitative motor performance of younger old adults with CI [39] as well as of older persons with fairly preserved motor capacity and CI [16,38] in comparison with age-matched controls.

In previous studies that aimed to identify determinants of PA performance, parameters of socio-demographic, medical, psychological, cognitive, or functional status were used and indicated low to moderate associations with quantitative parameters of habitual PA [40-45]. A restricted number of studies that have analyzed associations of motor capacity, determined by standardized protocols, with quantitative motor performance, documenting habitual activity behavior, showed moderate to high associations [37,46]. However, as such capacity measures deviate substantially from habitual PA performance, an open research question remains, whether qualitative motor performance during habitual activity may best determine quantitative motor performance during habitual activity.

To the best of our knowledge, a research approach to identify determinants of quantitative PA performance with focus on innovative, qualitative characteristics of gait performance in multi-morbid, older persons with motor and cognitive impairment has not been undertaken so far.

Based on low levels of PA performance in older persons with CI [9], the development of specific interventions to increase PA performance and thereby minimize the likelihood of negative health outcomes in this high-risk population is a persistent goal of current geriatric research. In order to implement most effective interventions for these multi-morbid, older adults, it is essential to understand the determinants of quantitative PA performance including duration, frequency and intensity. The association between the quality of habitual activity and the quantity of activity behavior (will we do if we can?) will be most relevant with direct consequences on the development of future training programs.

The main aim of this study therefore was to identify potential determinants of established, quantitative parameters of habitual PA performance by using innovative, qualitative characteristics of gait performance, in addition to established variables such as demographic and health-related parameters and measures of motor capacity, in multi-morbid, older persons with mild-to-moderate CI. A further aim was to describe the innovative, qualitative and established, quantitative variables of habitual PA performance.

2. Materials and Methods

2.1. Study Design and Study Population

The present study is a cross-sectional observational study which used pre-intervention data from a randomized controlled trial (RCT) on effects of home-based training following inpatient rehabilitation [47]. The RCT was registered (ISRCTN82378327), ethically approved (Medical Faculty of the University of Heidelberg: S-252/2015), and performed according to the Declaration of Helsinki. Between September 2015 and April 2017, older participants (age ≥ 65 years) with mild-to-moderate CI

(Mini-Mental State Examination (MMSE) score of 17-26 points; [48]) were consecutively recruited during geriatric rehabilitation. Further inclusion criteria were ability to walk at least 4 m without walking aid, community-dwelling, no delirium, no terminal disease, adequate language ability, residence within 30 km of the study site, and written informed consent.

2.2. Measurements

2.2.1. Demographic and health-related variables

Age, gender, and number of medication were documented from patient charts at discharge from inpatient rehabilitation. Further outcome measures including fall-related self-efficacy (Falls Efficacy Scale-International short version; FES-I short [49]), fall-related avoidance behavior (Fear of Falling Avoidance Behavior Questionnaire; FFABQ [50]), depressive symptoms (Geriatric Depression Scale short form; GDS-SF [51]), and care grade (yes vs. no) were documented by trained assessors in standardized interviews at the participants' home before intervention. Care grade defines benefits of the statutory German long-term care insurance associated to individual, comprehensive care needs as described elsewhere [52,53].

2.2.2. Motor capacity

The Short Physical Performance Battery (SPPB; including subtests of balance, gait, and chair rise capacity [54]), habitual gait speed (based on SPPB), and Timed "Up & Go" Test (TUG [55]) were also assessed at the participants' home under strictly standardized conditions.

2.2.3. Physical Activity Performance

In the participants' home environment, habitual PA performance was measured for 48 hours with the uSense activity monitor (attached to participants' lower back using adhesive bands), a non-commercial activity monitor developed in a large EU-funded project (FARSEEING, FP7/2007–2013, Grant No. 288940), allowing ambulatory, long-term assessment of PA. Construct and concurrent validity, test-retest reliability, and feasibility of the uSense have been proved under habitual conditions in multi-morbid, older persons with motor and cognitive impairment [37], representing the target population of the present study. This small-scaled monitor (42 × 10 × 68 mm, 36 g) includes a 9-axis inertial platform with three different types of motion sensors (accelerometer, gyroscope, and magnetometer) to generate a large variety of parameters of PA performance. These parameters have been distinguished into quantitative variables that describe established parameters of PA and gait performance (activity counts; number of steps; duration of lying, walking, inactive behavior (without lying), and active behavior (without walking); number of lying episodes, walking episodes, sedentary episodes (without lying episodes), and active episodes (without walking episodes); mean metabolic equivalent of task (METs); mean METs per walking episodes; cadence; and step duration) and innovative, qualitative variables that describe characteristics of gait during straight walking (variability of step duration; anteroposterior (AP), mediolateral (ML), and vertical (V) step regularity; Phase Coordination Index; AP, ML, and V harmonic ratio) as well as turning (turning duration, turning angle, turning velocity, and number of turns). Step regularity has been defined as an inter-step autocorrelation coefficient in the AP, ML, and V planes, where a value of 1.0 indicates perfect regularity [56]. Phase Coordination Index, a measure of gait coordination/symmetry expressed in percent, describes the ability to coordinate bilateral sequences of steps within a stride [57], whereby a Phase Coordination Index of 0% reflects perfect left-right coordination [58]. Harmonic ratios quantify the step-to-step symmetry in AP, ML, and V directions, with higher values indicating greater gait symmetry [59]. Raw data was sampled at a frequency of 100 Hz, stored on internal storage, and analyzed offline using MATLAB (R2016a, The MathWorks Inc., Natick, MA). Data processing and detailed definitions of the established parameters of PA performance are described elsewhere [37,60].

2.3. Statistical Analysis

Descriptive data are presented as means and standard deviations, medians and interquartile ranges (IQR), or numbers and percentages. Independent-samples *t*-tests and χ^2-tests were used for the comparison of participant characteristics between persons with valid and invalid uSense measurements.

Based on a scientific statement of the American Heart Association [12], characterizing the volume of PA performance as a product of the quantitative dimensions duration, frequency, and intensity of PA performance in a given time frame, univariate linear regression analyses were performed to delineate potential determinants of these three dimensions. Since walking was identified as key aspect and essential focus of PA performance, the dependent variables of the univariate regressions consisted of the following established and quantitative variables of walking performance: duration of walking (minutes), frequency of walking (number of episodes), and intensity of walking (METs). To allow a more comprehensive analysis, we included an additional dependent quantitative variable, which was not directly derived from walking performance (the average total intensity (METs)), representing the total PA.

The independent variables were classified into following seven different domains, comprising established, quantitative motor and non-motor parameters (domains 1-3), identified as potential determinants in previous comparable studies [4,40-44,61,62], and innovative, qualitative parameters of gait performance (domains 4-7): 1) *demographic variables* (age, gender), 2) *health-related variables* (number of medication, care grade, MMSE, GDS-SF, FES-I short, FFABQ), 3) *motor capacity* (SPPB, habitual gait speed, TUG), 4) *variability of straight walking* (coefficient of variation (CV) of step duration), 5) *regularity of straight walking* (AP, ML, & V step regularity), 6) *symmetry of straight walking* (Phase Coordination Index and AP, ML, & V harmonic ratio), and 7) *qualitative gait parameters of turning while walking* (turning duration, turning angle, mean turning velocity, peak turning velocity). The duration, angle, and velocity of turning were considered as qualitative measures since they document the commonly slower, smaller, and simplified movement strategies used by older persons to maintain their balance and compensate for loss of coordination [63-65].

Based on results of previous research [37], we hypothesized low to moderate associations of demographic and health-related variables as well as moderate to large associations of motor capacity and qualitative gait variables with the quantitative parameters of PA performance.

Subsequently, four multiple linear regression models (stepwise forward, $p \leq 0.05$ to enter) were performed to identify independent determinants of the different quantitative dimensions of walking (duration, frequency, and intensity) as well as the total PA performance (average total intensity). Only the independent variables with the highest, significant regression coefficient within each of the seven different aforementioned domains of the univariate analyses were included in the respective multiple linear regression models.

Potential multicollinearity of independent variables ($r > 0.7$ between independent variables, tolerance value < 0.2, and variance inflation factor (VIF) > 10 [66]) and the compliance of further assumptions for multiple linear regression analyses were considered (homoscedasticity and normality of residuals [67], and autocorrelation (Durbin-Watson-Test).

The multiple regression models were described by the adjusted coefficient of determination R^2 and influences of variables are given as unstandardized (*Beta*) and standardized (*ß*) regression coefficients. A two-sided *p*-value ≤ 0.05 indicated statistical significance. Data analyses were performed using SPSS Statistics 25 (IBM, Armonk, NY, USA).

3. Results

3.1. Descriptive Characteristics

The study sample included 110 multi-morbid (number of medication: 9.6 ± 3.5), older (82.3 ± 5.9 years) persons, discharged from ward-based geriatric rehabilitation, with mild-to-moderate CI (MMSE score: 23.3 ± 2.4 points), advanced motor impairment (SPPB score: 5.2 ± 2.3 points), and moderate concerns about falling (FES-I short: 12.3 ± 4.3 points). Sixteen sensor-based assessments of PA performance were invalid due to technical failure ($n = 1$), refusal to wear the activity monitor ($n =$

3), and premature removal of the uSense by participants (*n* = 12). No significant differences were found between characteristics of participants with valid versus invalid measurements (Table 1).

Table 1. Participant characteristics and comparison of persons with valid and invalid measurements of physical activity performance.

Characteristics	Total sample (*N* = 110)	Group of persons with valid measurements (*n* = 94)	Group of persons with invalid measurements (*n* = 16)	*p*
Demographic variables				
Age (years), mean ± SD	82.3 ± 5.9	82.4 ± 6.0	81.9 ± 5.2	0.757*
Gender (women), number (%)	84 (76.4)	69 (73.4)	15 (93.8)	0.077^
Health-related variables				
Medication (number), mean ± SD	9.6 ± 3.5	9.6 ± 3.6	9.8 ± 3.3	0.811*
Care grade (yes), number (%)	51 (46.4)	47 (50.0)	4 (25.0)	0.064^
MMSE (score), mean ± SD	23.3 ± 2.4	23.3 ± 2.4	23.7 ± 2.2	0.540*
GDS-SF (score), mean ± SD	5.3 ± 3.0	5.3 ± 3.1	5.6 ± 2.7	0.720*
FES-I short (score), mean ± SD	12.3 ± 4.3	12.0 ± 4.2	13.8 ± 4.6	0.113*
FFABQ (score), mean ± SD	18.5 ± 12.6	17.9 ± 12.9	21.9 ± 10.4	0.242*
Motor capacity				
SPPB (score), mean ± SD	5.2 ± 2.3	5.2 ± 2.3	5.3 ± 1.8	0.938*
Habitual gait speed (meter/second), mean ± SD	0.46 ± 0.19	0.46 ± 0.20	0.43 ± 0.17	0.482*
TUG (seconds), mean ± SD	24.4 ± 14.1	24.8 ± 15.0	22.3 ±6.9	0.296*

Note. This table presents descriptive variables of the total study sample and subgroups according to valid vs. invalid activity measurements. SD = Standard Deviation, MMSE = Mini Mental State Examination, GDS-SF = Geriatric Depression Scale - Short Form, FES-I short = Falls Efficacy Scale International - short version, FFABQ = Fear of Falling Avoidance Behavior Questionnaire, SPPB = Short Physical Performance Battery, TUG = Timed "Up & Go" test.

p-values as tested by *independent-samples *t*-test and ^chi-square test are given for the comparison between subgroups with valid vs. invalid activity measurements.

3.2. Physical Activity Performance

In order to describe the PA of the *n* = 94 included study participants with successful 48-hour sensor-based measurements in more detail, PA performances have been classified into quantitative and qualitative parameters.

3.2.1. Quantitative Parameters of Physical Activity Performance

The established, quantitative parameters revealed a predominantly sedentary behavior (43.0 ± 2.4 h (89.6%) inactive vs. 5.0 ± 2.4 h (10.4%) active), distinctive for multi-morbid, older persons with CI. The significantly shorter duration of walking, compared to lying (122 ± 94 minutes vs. 1193 ± 234 minutes, $p < 0.001$), and the considerably higher number of walking episodes, compared to lying episodes (635 ± 453 episodes vs. 66 (median, IQR: 37-116) episodes, $p < 0.001$), are based on the mainly very short bouts of walking and longer bouts of lying. An average cadence of 74 ± 7 steps per minute and average step duration of 0.72 seconds (median, IQR: 0.68-0.79) implied slow habitual walking, also typical for the frail study population. Further details on the description of the quantitative parameters of PA performance are shown in Table 2.

3.2.2. Qualitative Parameters of Gait during Physical Activity Performance

The qualitative gait parameters of straight walking showed a high CV of step duration, low inter-step correlation coefficients, a high Phase Coordination Index, and low harmonic ratios (Table 2).

The investigation of innovative, qualitative gait characteristics of turning while walking revealed a cautious turning behavior with a prolonged average turning duration, a low average turning angle as well as a slow average mean and peak turning velocity (Table 2; Figure 1). The total number of turns during the 48-hour PA performance assessment was 1029 (median, IQR: 310-1946) and the average number of turns per walking episode was 2.1 ± 0.5.

Table 2. Physical activity performance of the 48-hour measurement.

Variables	***n* = 94**
Established, quantitative parameters of physical activity performance	
Total activity (counts/minute), mean ± SD	9662 ± 4177
Total steps (number), median (IQR)	9372 (3604-13947)
Duration	
Lying duration (minutes), mean ± SD	1193 ± 234
Walking duration (minutes), mean ± SD	122 ± 94
Inactive duration without lying duration (minutes), mean ± SD	1389 ± 247
Active duration without walking duration (minutes), mean ± SD	175 ± 80
Frequency	
Lying episodes (number), median (IQR)	66 (37-116)
Walking episodes (number), mean ± SD	635 ± 453
Inactive episodes without lying episodes (number), mean ± SD	3336 ± 1334
Active episodes without walking episodes (number), mean ± SD	3335 ± 1402
Intensity	
Average intensity of total physical activity performance (METs), mean ± SD	1.6 ± 0.1
Average intensity during walking episodes (METs), mean ± SD	2.4 ± 0.3
Innovative, qualitative parameters of gait performance while walking straight or turns	
Variability of straight walking	
Average CV of step duration (%), mean ± SD	29.6 ± 3.5
Regularity of straight walking	
Average AP step regularity (-),mean ± SD	0.37 ± 0.06
Average ML step regularity (-), mean ± SD	0.44 ± 0.10
Average V step regularity (-), mean ± SD	0.32 ± 0.07
Symmetry of straight walking	
Average PCI (%), mean ± SD	38.5 ± 5.0
Average AP harmonic ratio (-), mean ± SD	1.06 ± 0.09
Average ML harmonic ratio (-), mean ± SD	1.43 ± 0.17
Average V harmonic ratio (-), mean ± SD	1.15 ± 0.09
Turning while walking	
Average turning duration (seconds), mean ± SD	2.13 ± 0.50
Average turning angle (°), mean ± SD	62.7 ± 9.9
Average mean turning velocity (°/second), mean ± SD	32.9 ± 7.2
Average peak turning velocity (°/second), mean ± SD	79.5 ± 17.6

Note. This table presents quantitative and qualitative parameters of physical activity performance. SD = Standard Deviation, IQR = Interquartile Range, MET = Metabolic Equivalent of Task, CV = coefficient of variation, AP = anteroposterior, ML = mediolateral, V = vertical, PCI = Phase Coordination Index.
° = degrees. Inactive duration/episodes: METs ≤ 1.5. Active duration/episodes: METs > 1.5.

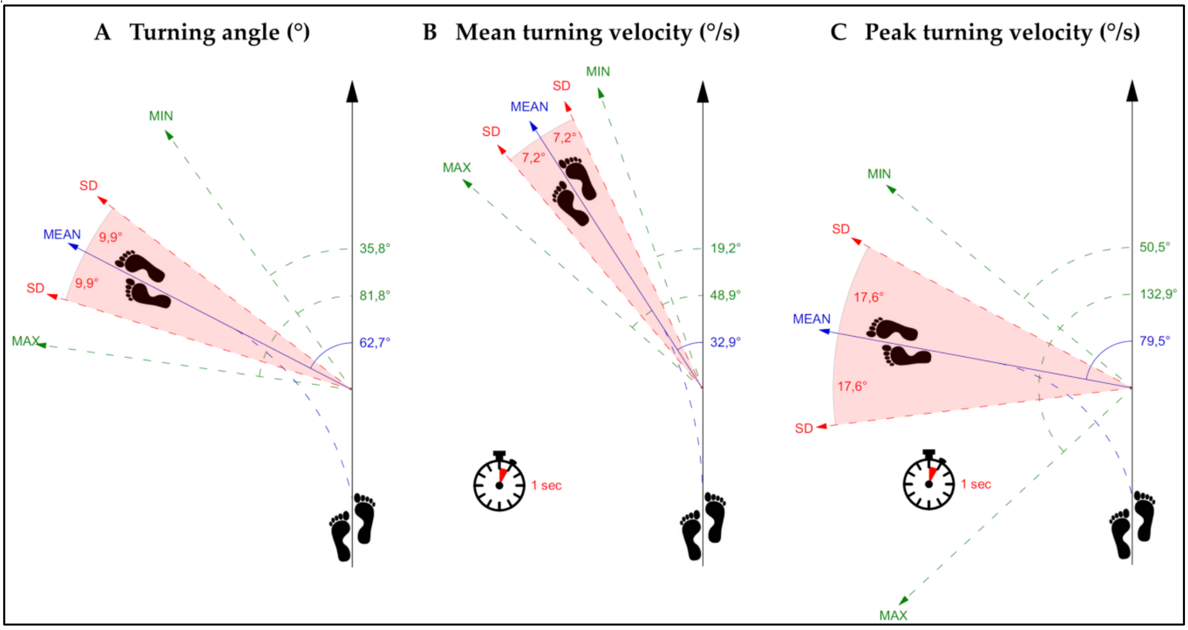

Figure 1. This figure presents the average values of A) turning angle, B) mean turning velocity, and C) peak turning velocity. SD = standard deviation, MIN = minimum, MAX = maximum, ° = degrees.

3.3. Determinants of Physical Activity Performance

To identify determinants of established, quantitative parameters of PA performance, univariate regressions with multi-domain variables were used to detect potential determining variables which were included in the final multiple regression models.

3.3.1. Univariate Regressions

Non-motor variables including demographic variables (age and gender) and health-related variables (e.g. number of medication and care grade as a surrogate marker of multi-morbidity and functional dependency, respectively, or cognitive status (MMSE)) showed moderate and mostly singular associations with the established, quantitative dimensions of PA performance. Only the FFABQ, documenting activity avoidance related to concerns about falling, was moderately associated with all of the quantitative dimensions of PA performance (β: |0.233-0.320|, p: 0.002-0.024). More detailed outcomes of the univariate analyses are given in Table 3.

In contrast, all variables of motor capacity showed moderate to high associations with each of the quantitative dimensions of PA performance (β: |0.347-0.580|, all $p \leq 0.001$; Table 3).

Innovative, qualitative characteristics related to variability, regularity, or symmetry measures of gait performance while walking straight revealed moderate associations with all quantitative parameters of walking and total PA performance; however these associations were heterogeneous. While six out of eight and five out of eight of the qualitative variables of straight walking were associated with the duration and frequency of PA performance, respectively, two out of eight were related to both of the intensity parameters (Table 3).

All qualitative parameters of gait performance while walking turns stood out with predominantly high associations to all quantitative parameters of PA performance (β: |0.299-0.787|, p: < 0.001-0.003; Table 3).

In general, the univariate regressions showed similar results across the established, quantitative dimensions of walking and total PA performance used as dependent variables in the regression models. Within dependent variables, results between duration and frequency and between walking intensity and overall intensity were most comparable.

Table 3. Univariate associations of multi-domain variables with quantitative dimensions of walking and total physical activity.

	Walking performance						Total performance	
	Duration (minutes)		Frequency (number of episodes)		Intensity (METs)		Intensity (METs)	
Independent variables	***β***	***p***	***β***	***p***	***β***	***p***	***β***	***p***
Established, quantitative parameters								
Demographic variables								
Age (years)	-0.209	**0.043***	-0.157	0.130	-0.305	**0.003***	-0.274	**0.008***
Gender (dummy; 0 = women, 1 = men)	0.176	0.089	0.043	0.680	0.197	0.058	0.209	**0.043**
Health-related variables								
Medication (number)	-0.219	**0.034**	-0.210	**0.042**	-0.131	0.206	-0.130	0.210
Care grade (dummy; 0 = no, 1 = yes)	-0.247	**0.016**	-0.238	**0.021**	-0.041	0.694	-0.155	0.137
MMSE (score)	0.132	0.205	0.129	0.214	0.209	**0.043**	0.214	**0.039**
GDS-SF (score)	-0.131	0.207	-0.109	0.298	0.006	0.954	-0.013	0.903
FES-I short (score)	-0.147	0.158	-0.147	0.158	-0.024	0.821	-0.090	0.387
FFABQ (score)	-0.320	**0.002***	-0.272	**0.008***	-0.233	**0.024***	-0.272	**0.008***
Motor capacity								
SPPB (score)	0.507	**< 0.001***	0.506	**< 0.001**	0.377	**< 0.001**	0.535	**< 0.001**
Habitual gait speed (meter/second)	0.491	**< 0.001**	0.507	**< 0.001***	0.419	**< 0.001***	0.580	**< 0.001***
TUG (seconds)	-0.384	**< 0.001**	-0.347	**0.001**	-0.413	**< 0.001**	-0.497	**< 0.001**
Innovative, qualitative parameters								
Variability of straight walking								
CV of step duration (%)	-0.321	**0.002***	-0.234	**0.023***	-0.068	0.516	-0.094	0.367
Regularity of straight walking								
AP step regularity (-)	0.128	0.220	0.080	0.442	-0.264	**0.010**	-0.253	**0.014***
ML step regularity (-)	0.225	**0.029**	0.075	0.474	0.354	**< 0.001***	0.174	0.094
V step regularity (-)	0.373	**< 0.001***	0.283	**0.006***	0.140	0.178	0.170	0.102
Symmetry of straight walking								
PCI (%)	-0.305	**0.003**	-0.257	**0.012**	-0.066	0.525	-0.107	0.303
AP harmonic ratio (-)	0.448	**< 0.001***	0.363	**< 0.001***	0.130	0.213	0.209	**0.043***
ML harmonic ratio (-)	0.124	0.233	0.028	0.787	0.143	0.170	0.048	0.643
V harmonic ratio (-)	0.376	**< 0.001**	0.277	**0.007**	0.132	0.206	0.155	0.137
Turning while walking								
Turning duration (seconds)	-0.299	**0.003**	-0.350	**0.001**	-0.498	**< 0.001**	-0.524	**< 0.001**
Turning angle (°)	0.527	**< 0.001**	0.488	**< 0.001**	0.454	**< 0.001**	0.592	**< 0.001**
Mean turning velocity (°/second)	0.559	**< 0.001***	0.569	**< 0.001***	0.651	**< 0.001**	0.787	**< 0.001***
Peak turning velocity (°/second)	0.315	**0.002**	0.302	**0.003**	0.694	**< 0.001***	0.715	**< 0.001**

Note. This table presents the results of univariate regression analyses between variables of different domains with quantitative measures of walking performance and total performance. MMSE = Mini Mental State Examination, GDS-SF = Geriatric Depression Scale - Short Form, FES-I short = Falls Efficacy Scale International – short version, FFABQ = Fear of Falling Avoidance Behavior Questionnaire, SPPB = Short Physical Performance Battery, TUG = Timed "Up & Go" test, CV = coefficient of variation, AP = anteroposterior, ML = mediolateral, V = vertical, PCI = Phase Coordination Index.

° = degrees. β = standardized regression coefficient indicating low (< 0.2), moderate (0.2-0.5), and high (> 0.5) associations. p-values in bold face indicate significance ($p \leq 0.05$). *included in the respective, subsequent multiple linear regression models.

3.3.2. Multiple Regressions

None of the demographic or health-related measures remained as an independent determinant in any of the multiple regression models (Tables 4-7).

Despite the moderate to high associations in the univariate regressions, the motor capacity measures did also not remain in the multiple regression models with the single exception of the SPPB as an independent determinant for the duration of walking ($\beta = 0.250$, $p = 0.008$; Table 4).

Among the innovative, qualitative characteristics of straight walking, only single measures remained in the multiple regression models. While the AP harmonic ratio was independently associated with the duration and frequency of walking (models 1 & 2, Tables 4 & 5), the ML and AP step regularity was independently associated only with the intensity of walking and total PA performance, respectively (models 3 & 4, Tables 6 & 7). The variability of step duration, the V step regularity, the Phase Coordination Index, the ML harmonic ratio, and the V harmonic ratio did either not remain in any of these multiple models or were not included as the univariate association was lower, compared to other variables within the same domain, or lacking.

With regard to the innovative, qualitative characteristics of walking turns, the mean turning velocity was an independent determinant for the duration and frequency of walking (models 1 & 2) as well as the intensity of total PA performance (model 4), whereas the peak turning velocity was an independent determinant for the intensity of walking (model 3). As either the mean or peak turning velocity showed the highest univariate associations with the established parameters of PA performance within the domain of qualitative gait parameters of turning while walking, the average turning duration and average turning angle were not included in the multiple regression models.

The explained variance was relatively large in all models (adjusted $R^2 = 0.395$-0.679; all $p < 0.001$) given the limited number of determinants and the complexity of potential influences on PA behavior. No multicollinearity (all $r < 0.7$ between independent variables, minimal tolerance: 0.718, maximal VIF: 1.393) or autocorrelation (Durbin-Watson: 1.633-2.027) were present in any of the multiple regression models, indicating the independence of included variables.

Table 4. Independent determinants for the duration of walking performance.

Model 1: Walking duration (minutes)							
Independent variables	Unstandardized coefficients		Standardized coefficients			Collinearity Statistics	
	Beta	***SE***	***β***	***t***	***p***	***tolerance***	***VIF***
Mean turning velocity (°/second)	4.57	1.21	0.351	3.79	**< 0.001**	0.718	1.393
AP harmonic ratio (-)	297.12	90.79	0.273	3.27	**0.002**	0.887	1.127
SPPB (score)	10.07	3.72	0.250	2.71	**0.008**	0.720	1.388

Note. This table presents the results of a multiple regression analyses of variables from different domains with duration of walking performance as dependent variable. AP = anteroposterior, SPPB = Short Physical Performance Battery, Beta = unstandardized regression coefficient, SE = standard error, β = standardized regression coefficient, VIF = variance inflation factor.

Adjusted coefficient of determination (R^2) = 0.427. Durbin-Watson test for autocorrelation = 1.950.

Table 5. Independent determinants for the frequency of walking performance.

Model 2: Walking frequency (number of episodes)							
Independent variables	Unstandardized coefficients		Standardized coefficients			Collinearity Statistics	
	Beta	***SE***	***β***	***t***	***p***	***tolerance***	***VIF***
Mean turning velocity (°/second)	33.86	5.41	0.535	6.25	**< 0.001**	0.918	1.090
AP harmonic ratio (-)	1169.27	440.89	0.227	2.65	**0.009**	0.918	1.090

Note. This table presents the results of a multiple regression analyses of variables from different domains with frequency of walking performance as dependent variable. AP = anteroposterior, Beta = unstandardized regression coefficient, SE = standard error, *β* = standardized regression coefficient, VIF = variance inflation factor.
Adjusted coefficient of determination (R^2) = 0.395. Durbin-Watson test for autocorrelation = 1.633.

Table 6. Independent determinants for the intensity of walking performance.

Model 3: Walking intensity (METs)							
Independent variables	Unstandardized coefficients		Standardized coefficients			Collinearity Statistics	
	Beta	***SE***	***β***	***t***	***p***	***tolerance***	***VIF***
Peak turning velocity (°/second)	0.01	0.001	0.749	12.16	**< 0.001**	1.000	1.000
ML step regularity (-)	0.96	0.18	0.329	5.33	**< 0.001**	1.000	1.000

Note. This table presents the results of a multiple regression analyses of variables from different domains with intensity of walking performance as dependent variable. ML = mediolateral, Beta = unstandardized regression coefficient, SE = standard error, *β* = standardized regression coefficient, VIF = variance inflation factor.
Adjusted coefficient of determination (R^2) = 0.658. Durbin-Watson test for autocorrelation = 2.027.

Table 7. Independent determinants for the intensity of the total performance of physical activity.

Model 4: Intensity of total physical activity (METs)							
Independent variables	Unstandardized coefficients		Standardized coefficients			Collinearity Statistics	
	Beta	***SE***	***β***	***t***	***p***	***tolerance***	***VIF***
Mean turning velocity (°/second)	0.01	0.001	0.795	13.18	**< 0.001**	0.981	1.019
AP step regularity (-)	-0.29	0.12	-0.150	-2.48	**0.015**	0.981	1.019

Note. This table presents the results of a multiple regression analyses of variables from different domains with intensity of total physical activity performance as dependent variable. AP = anteroposterior, Beta = unstandardized regression coefficient, SE = standard error, *β* = standardized regression coefficient, VIF = variance inflation factor.
Adjusted coefficient of determination (R^2) = 0.679. Durbin-Watson test for autocorrelation = 1.666.

4. Discussion

To the best of our knowledge, this cross-sectional analysis is the first showing that innovative, qualitative gait characteristics of straight walking and turning, documented in real-life settings, represent major determinants of established, quantitative dimensions of PA performance in multi-morbid, older persons with motor and cognitive impairment. Established demographic and health-related variables as well as motor capacity measures were not or only in a limited way associated with quantitative PA performance. Besides the highly sedentary behavior, the high incidence of gait deficits under habitual conditions was documented by valid parameters of gait quality not analyzed in such detail in this vulnerable population before.

4.1. Physical Activity Performance

The sedentary behavior and low intensity of walking or total PA performance of multi-morbid, older adults with CI as documented by established parameters in the present study is consistent with findings from comparable samples [9,68] and typical for vulnerable, older persons. To complement such established parameters of PA performance with innovative, qualitative characteristics of gait performance is a novel approach that enables a more detailed insight into habitual physical behavior. These qualitative parameters of gait performance are of particular importance as a low quality of walking under everyday conditions is associated with several health-related aspects in older persons, such as mild CI [16], Parkinson's disease [17,18], or a high risk of falling [13,14].

4.1.1. Variability of straight walking

The variability of straight walking in the present study is high, but benchmarking is limited by missing comparable values for the CV of step duration from real-life settings in older adults with CI. When compared to a laboratory-based reliability study in older persons with CI [69], a substantially higher variability of step duration is visible in the present study. This divergence indicates the importance of separate qualitative measurements during daily activities, which, compared to highly standardized laboratory measurements, are affected by diverse external factors but represent the everyday life and relevant individual habitual activity behavior.

4.1.2. Regularity of straight walking

With regard to the established definition of perfect step regularity, indicated by an inter-step autocorrelation coefficient of 1.0 [56], the step regularity of gait performance in the present study was low (0.32-0.44), no matter whether in AP, ML, or V direction. The step regularity in the present vulnerable, older study sample was lower as compared to the step regularity of habitual gait performance in younger and fitter old persons with and without CI [33], indicating negative effects of higher age, lower motor capacity, and CI.

4.1.3. Symmetry of straight walking

Based on given definitions for the Phase Coordination Index (0% reflects perfect coordination) [57,58] and harmonic ratios (higher values indicate greater symmetry) [59], the left-right coordination (38.5 ± 5.0%) and step-to-step symmetry (1.06-1.43) of gait performance in the present study were low. As no results for the Phase Coordination Index from real-life settings were identified in older persons, laboratory-based studies in octogenarians with and without CI were used for comparison [70-72]. These laboratory studies rate much smaller values of the Phase Coordination Index (6.7-7.0%) as impaired gait coordination, which demonstrates the poor coordination of habitual gait as well as the impact of everyday life on the gait quality in the present vulnerable, older study sample.

The harmonic ratios in the present study were considerably smaller than in previous studies (1.82-2.25) that have examined associations of step-to-step symmetry of habitual gait performance with falls or time to falls in on average seven years younger persons with and without CI [13,73], again confirming effects of higher age and multiple impairments on the gait symmetry of the study sample as discussed above for step regularity.

4.1.4. Turning while walking

Although the mean turning duration in the present study was almost in line with findings from discriminative, observational studies in real-life settings in sixty-five-year-olds with Parkinson's disease [18] or cognitively intact older adults with and without falls [14,29], the mean turning angle was approximately 30° smaller [14,18,29] and the mean turning velocity more than 10°/s slower [29], indicating qualitative compensation strategies for increased deficits in balance and coordination [64,65] in old age or CI.

In addition, the absolute number of turns in the present study was about 350 turns per day lower as compared to an age-matched peer group without CI, better turning performance, and better walking capacity [14]. The descriptive study results therefore suggest that quality and quantity of turning performance are sensitive indicators of motor restrictions in older persons with motor and cognitive impairment, such as the present study sample.

4.2. Determinants of Physical Activity Performance

While habitual PA performance has so far mainly been documented as established, quantitative dimensions in contexts of both scientific and public use, the qualitative characteristics of PA performance played a much lesser role due to methodological limitations for valid assessments in habitual settings. The potential determinants of quantitative PA performance were therefore restricted to established demographic and health-related variables, and parameters of motor capacity.

Accordingly, the main objective of the present study was to identify determinants of PA performance by using innovative, qualitative measures of habitual PA as compared to demographic and health-related variables, and parameters of motor capacity in multi-morbid older persons with CI, in which detailed gait and activity analyses are methodologically challenging but urgently needed.

4.2.1. Univariate Regressions

To identify determinants of quantitative PA performance, a step-wise procedure was used. In a first step, variables from various domains were analyzed in univariate regression models.

• Demographic and health-related variables

As hypothesized, the demographic and health-related variables showed only moderate and singular relationships with the quantitative dimensions of PA performance, documenting lesser associations of generic domains or assessments that have been developed for clinical documentation rather than the prediction of PA. Study results are in line with previous studies, showing low to moderate negative univariate associations of advanced age, female gender, or various health-related variables with habitual PA performances such as overall intensity or activity counts [40,42]. These negative associations may indirectly relate to the lower motor capacity in persons with a poorer health status, higher age, or female gender [54,74], as a relevant restraint to be physically active ("do if we can").

• Motor capacity

The significant associations of all motor capacity variables with all parameters of quantitative PA performance in the univariate analysis verified the hypothesis of a moderate to high association between motor capacity and quantity of PA performance in the study sample with impaired mobility. The study results confirm the moderate associations of various motor capacity measures (e.g. gait speed, SPPB and TUG score) with quantitative variables of PA performance (e.g. walking duration, walking frequency) in younger and fitter older adults [75,76].

Tests of motor capacity like the SPPB or TUG, as used in the present study, have been developed to investigate requirements and activities relevant to everyday life of older persons [54,55]. The moderate to high associations between motor capacity and quantity of PA in the present study confirm this methodological approach and the relevance of motor capacity as a key for habitual PA.

• Innovative, qualitative parameters of straight walking

In 15 out of 32 univariate analyses, qualitative gait parameters of straight walking showed significant associations with quantitative parameters of PA performance. This result partially confirms our hypothesis of moderate to high associations between the quality and quantity of performance and suggests that a better quality of habitual gait implies better motor skills as important prerequisite for a higher quantity of PA. Interestingly, these associations were mainly documented for the duration or frequency of PA performance and less for the intensity measures. This finding may be due to higher energy costs per unit time of intensive activity and the reduced ability to provide this energy in old age [77,78], indicating that high intensity activities are frequently restricted in multi-morbid, older persons such as the present study sample.

Only few studies investigated individual, qualitative variables of laboratory-based gait (qualitative motor capacity) as determinants of the quantity of PA performance in older adults [72,75,79,80], documenting heterogeneous results with generally limited associations: low or moderate negative univariate associations of gait variability with duration and frequency of moderate to vigorous PA or number of activity counts, respectively [79,80], low positive univariate associations of gait regularity with number of activity counts [80], and no or moderate positive univariate associations of gait symmetry with accelerometer-based or self-reported, questionnaire-based PA, respectively [72,75].

However, measures of qualitative capacity and qualitative performance may not be directly comparable [33]. While qualitative gait parameters of straight walking, including variability, regularity, and symmetry, under strictly standardized laboratory conditions predominantly document motor impairments (internal conditions), measures of qualitative performance may additionally cover effects of activity patterns and environmental or social interactions (external conditions) that are directly related to quality and quantity of PA. Qualitative measures of gait performance share the same context and setting with quantitative measures of habitual PA, allowing a high comparability by contrast with qualitative measures of gait capacity.

Besides laboratory-based studies on associations between qualitative capacity measures and quantitative performance measures, studies on associations of qualitative gait performance while walking straight and the quantity of PA performance could not be identified, with the consequence that a direct benchmarking to the present results was not feasible.

- Innovative, qualitative parameters of turning while walking

All qualitative parameters of gait performance while walking turns were significantly and in most cases strongly associated with every quantitative dimension of PA performance in the present study. This result highlights the high proportion of turning during everyday indoor activities [24] and suggests that turning performance in vulnerable older persons represents a very sensitive indicator for the quality of gait in a complex and challenging movement, potentially leading to a higher quantity of PA performance (will we do if we can?).

The higher levels of PA performance in the present study were associated with lower turning duration as well as higher turning angle and velocity, which are usually prolonged or reduced, respectively, in older adults due to a loss of coordination as a compensation strategy to maintain balance [64,65]. Accordingly, walking turns represent challenging movements with high risk exposure for falling in multi-morbid, older persons with motor impairment [14,27,29].

While findings on laboratory-based turning measures (180°-turning of the TUG) in older adults showed only a moderate positive univariate association of turning velocity with the number of activity counts [80], the predominantly high associations between qualitative measures of turning and quantitative dimensions of PA in the present study again indicate the higher relevance of habitual gait quality as compared to laboratory-based gait quality.

As studies on the relationship between qualitative measures of turning performance and quantitative measures of PA performance are lacking, benchmarking of the present findings with previous results was again not feasible.

4.2.2. Multiple Regressions

In a final step, directly competing variables, each with the highest significant coefficients from the univariate regressions of the different domains, were analyzed in multiple regression models to ascertain independent determinants of the quantitative dimensions of habitual PA.

• Demographic and health-related variables

None of the demographic or health-related variables, included in the multiple regression models, remained as an independent determinant for the quantitative dimensions of PA performance. This result affirms the lesser suitability of demographic factors and health status for the determination of the quantity of PA, compared to motor variables, as already indicated by the results of the univariate analyses.

• Motor capacity

Although the measures of motor capacity document key motor functions [54,55] that are mandatory for habitual PA, the singular independent association between the SPPB and walking duration suggests that the measures of motor capacity are inferior in independently determining the quantity of PA performance, when directly compared to specific, selected qualitative parameters of PA performance. This singular or missing independent association between variables of motor capacity and quantitative PA performance may be explained by the generally different conditions of controlled laboratory research and field research [46,81], indicating a lesser degree of similarity between measures of motor capacity and quantitative dimensions of PA performance as compared to qualitative parameters of PA performance.

• Innovative, qualitative parameters of straight walking

The present study identified independent associations between specific qualitative variables of gait performance while walking straight (AP step-to-step symmetry and AP & ML step regularity) and all quantitative dimensions of PA performance, suggesting that qualitative characteristics of habitual gait are relevant independent determinants for the quantity of habitual PA.

The independent association of step-to-step symmetry with duration and frequency of walking may relate to typical deficits of older persons with CI, such as lower levels of PA performance [3] and a lower step-to-step symmetry [82], or the high association between step-to-step symmetry and walking balance [83,84], as a basic precondition of walking and thereby leading to a higher duration and frequency of walking.

In contrast, step regularity may be more important in the context of the PA dimension intensity, as it is indicated by the positive independent association of ML step regularity with intensity of walking and the negative independent association of AP step regularity with intensity of total PA performance. These contrary associations may be due to different reasons. One could be a frequent change in the participants' progression speed that results in a lower AP step regularity but indicates a better ability to quickly adapt/change walking speed, while simultaneously the ML step regularity increases and reflects a better ML stability. This assumption suggests that a better qualitative motor performance enables a higher intensity of PA, which confirms our hypothesis of a strong association between qualitative and quantitative PA performance. Another reason could be the age-related decline in step regularity that only occurs in AP direction [85], assuming that a decreased AP gait control causes a higher energy expenditure, whereas a steady/good ML gait control in old age may facilitate a higher intensity of PA.

• Innovative, qualitative parameters of turning while walking

Either the mean or peak velocity of turning performance was the best independent determinant for all quantitative dimensions of PA performance in the present study, suggesting that qualitative parameters of habitual turning behavior represent superior determinants for the quantity of PA performance, compared to demographic and health-related variables, measures of motor capacity, and qualitative parameters of gait performance while walking straight.

The present findings are coherent since turning while walking represents a more challenging movement for older persons as compared to straight walking [22,23] that places high demands on coordination and balance [64,65], as prerequisites for activity, and accounts for up to almost fifty percent of daily indoor activities [24], which is typical for multi-morbid, older persons.

4.3. Strengths and Limitations

The present study is the first to use successfully validated methods [37] to document innovative, qualitative characteristics of habitual gait performance and to analyze the association of these parameters, besides non-motor variables and measures of motor capacity, with different quantitative dimensions of PA performance in multi-morbid, older adults with CI.

The inconsistent usage of technical terms in the literature (e.g. capacity vs. performance or performance vs. activity behavior, including qualitative as well as quantitative aspects) and the large variety of partially not validated sensor technologies, assessment methods, and outcome characteristics, due to a rapid technical development in the field of motion analysis in recent years, are limiting the benchmarking of the present findings and the comparability between different studies.

5. Conclusions

The present study results identified specific qualitative variables of gait performance, in particular while walking turns, as main determinants for the quantitative dimensions duration, frequency, and intensity of habitual PA (will we do if we can?) in multi-morbid, older persons with generally low gait quality and PA levels. Results indicate that the quality of motor performance may be superior to determine the quantity of motor performance as compared to established measures of motor capacity or demographic and health-related variables.

As qualitative measures of habitual performance are associated with adverse events such as falls [13,14,29], intervention programs with the focus to improve the quality of such performances may not only represent a key to increase the duration, frequency, and intensity of habitual PA but also reduce the risk of falling and thus counteracting a higher risk exposure due to achieved higher PA levels.

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Publikation V

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Life-space mobility in older persons with cognitive impairment after discharge from geriatric rehabilitation

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ABSTRACT

Objectives: To describe life-space mobility and identify its determinants in older persons with cognitive impairment after discharge from geriatric rehabilitation.

Methods: A cross-sectional study in older community-dwelling persons with mild to moderate cognitive impairment (Mini-Mental State Examination, MMSE: 17–26) following geriatric rehabilitation was conducted. Life-space mobility (LSM) was evaluated by the Life-Space Assessment in Persons with Cognitive Impairment (LSA-CI). Bivariate analyses and multivariate regression analyses were used to investigate associations between LSM and physical, cognitive, psychosocial, environmental, financial and demographic characteristics, and physical activity behavior.

Results: LSM in 118 older, multimorbid participants (age: 82.3 ± 6.0 years) with cognitive impairment (MMSE score: 23.3 ± 2.4 points) was substantially limited, depending on availability of personal support and equipment. More than 30% of participants were confined to the neighborhood and half of all patients could not leave the bedroom without equipment or assistance. Motor performance, social activities, physical activity, and gender were identified as independent determinants of LSM and explained 42.4% (adjusted R^2) of the LSA-CI variance in the regression model.

Conclusion: The study documents the highly restricted LSM in older persons with CI following geriatric rehabilitation. The identified modifiable determinants of LSM show potential for future interventions to increase LSM in such a vulnerable population at high risk for restrictions in LSM by targeting motor performance, social activities, and physical activity. A gender-specific approach may help to address more advanced restrictions in women.

1. Introduction

The ability to move independently where and when a person wants to move is relevant for challenges in everyday life (Satariano et al., 2012), quality of life (Metz, 2000), and participation in society and natural environment (Barnes et al., 2007; Rosso, Taylor, Tabb, & Michael, 2013). In the course of progressive cognitive decline complex activities, such as outdoor activities, are the first to be lost (Njegovan, Hing, Mitchell, & Molnar, 2001). Especially older persons are, as a consequence of physical and cognitive decline, at high risk for reduced community mobility (Gill, Gahbauer, Murphy, Han, & Allore, 2012), being homebound (A. R. Smith, Chen, Clarke, & Gallagher, 2016), or institutionalized (Luppa et al., 2010; Sheppard, Sawyer, Ritchie, Allman, & Brown, 2013). To sustain social networks and familiar environment, most of older persons prefer to "age in place" (Gitlin, 2003). Thus maintaining or improving mobility in and out of home is particularly important as a prerequisite for independence.

Webber, Porter, & Menec (2010) developed a theoretical framework, which depicts mobility – broadly defined as life-space mobility (LSM) – to be influenced by physical, cognitive, psychosocial, financial and environmental factors embedded by influences of gender, cultural and biographical aspects (Webber et al., 2010). The framework has been successfully tested in older persons (Umstattd Meyer, Janke, & Beaujean, 2014) and has been supported by empirical research that provide evidence for relationships between the individual factors and LSM in older community-dwelling persons: Associations with LSM have

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been found for relative stable or immutable factors including sociodemographic variables such as age (Al Snih et al., 2012; Suzuki, Kitaike, & Ikezaki, 2014), gender (Peel et al., 2005; Phillips, Dal Grande, Ritchie, Abernethy, & Currow, 2015), marital status (Phillips et al., 2015), educational level (Eronen et al., 2016; Phillips et al., 2015), or financial situation (Peel et al., 2005; Phillips et al., 2015), as well as environmental conditions such as housing standard, living environment (Rantakokko, Iwarsson, Portegijs, Viljanen, & Rantanen, 2015), or weather conditions (Portegijs, Iwarsson, Rantakokko, Viljanen, & Rantanen, 2014). Associations were also found for variable or modifiable factors including health-related factors such as physical performance or medical diagnoses (Al Snih et al., 2012; Peel et al., 2005; Phillips et al., 2015), hospitalization (Brown et al., 2009), which constitutes also a risk factor for institutionalization (Goodwin, Howrey, Zhang, & Kuo, 2011), psychosocial status documented as fear of falling (FOF), depression, apathy, or social involvement (Al Snih et al., 2012; Auais et al., 2017; Peel et al., 2005; Uemura et al., 2013), global cognitive status (Peel et al., 2005), and domain-specific cognitive functions (processing speed) (Uemura et al., 2013). Physical activity (PA), itself influenced by physical, cognitive and psychosocial factors and environmental conditions (Franco et al., 2015; Stubbs et al., 2014), has also been closely linked to LSM (Portegijs, Tsai, Rantanen, & Rantakokko, 2015; Sawyer & Allman, 2010; Tsai et al., 2015), representing - as well as LSM - an aspect of movement behavior. Among the factors that have been related to LSM, motor and functional performance stand out as major determinant for LSM in older adults (Al Snih et al., 2012; Peel et al., 2005). Overall, accumulation of deficits, such as motor and cognitive impairments, might be associated with an accumulation of restrictions in LSM and an extraordinary risk of losing independence and autonomy. Studies in populations associated with multiple risk factors for LSM restrictions are, however, lacking. Previous studies most frequently focused on healthy older individuals (Al Snih et al., 2012; Peel et al., 2005), and only few studies addressed subgroups with single risk factors, such as orthopedic disorders (Suzuki et al., 2014), hospitalization (Brown et al., 2009), or persons with amnestic mild cognitive impairment (Uemura et al., 2013). Some studies assessed life-space (LS) in persons with CI using a questionnaire (Stalvey, Owsley, Sloane, & Ball, 1999) or GPS-based tracking devices (Tung et al., 2014), though these measures do not include frequency, the use of equipment or assistance, or indoor activity and are therefore not comparable. LSM was usually assessed via self-administered questionnaires with rather long retrospective assessment periods (Brown et al., 2009; Peel et al., 2005). However, the use of such questionnaires in cognitively impaired persons may hamper the accuracy of LSM documentation, as declining cognitive abilities (e.g., memory impairment, loss of orientation in time and locus) are associated with relevant recall bias (Bhandari & Wagner, 2006), which may have resulted in the exclusion of older people with cognitive impairment (CI) from most previous studies. To cope with such limitations and to document LSM in persons with CI, an interview-based assessment tool adjusted to their specific requirements has recently been developed and successfully validated for use in this population group closing this methodological gap (Ullrich et al., 2018).

In summary, the objectives of the study were to describe the LSM in older patients with mild to moderate CI after geriatric rehabilitation, representing a highly vulnerable population with multiple risk factors, and to investigate potential determinants of LSM in this population.

2. Methods

2.1. Study design

The present study is based on cross-sectional baseline data from a double-blinded, randomized, placebo-controlled trial (RCT) to improve motor performance and PA in older patients with mild to moderate CI discharged from geriatric rehabilitation (ISRCTN82378327; (Bongartz et al., 2017). The RCT was approved by the ethics committee of the Medical Department of the Heidelberg University (S-252/2015) in accordance with the Declaration of Helsinki and was registered at www.isrctn.com (ISRCTN82378327).

2.2. Recruitment and participants

Participants were recruited consecutively from rehabilitation wards of a German geriatric hospital between September 2015 and April 2017. Eligible participants were assessed for CI using the Mini-Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975). Only individuals with MMSE scores of 17 to 26, indicating mild to moderate CI, were included in the study (Monsch et al., 1995). Further inclusion criteria to participate in the RCT were: age ≥ 65 years; ability to walk at least 4 m without a walking aid; residence within 30 km of the study center; discharge to the patients' home (i.e., no nursing home residents); no terminal disease; no delirium; German-speaking, and written informed consent.

2.3. Measurements

The measurements were conducted right before randomization and start of the intervention. Only tests established in geriatric assessment and validated in older persons and if available in cognitively impaired individuals were used.

2.3.1. Life-space assessment

LSM was assessed using the Life-Space Assessment in Persons with Cognitive Impairment (LSA-CI), a modified version of the University of Alabama at Birmingham Study of Aging Life-Space Assessment (UAB-LSA) (Baker, Bodner, & Allman, 2003) specifically developed and validated for use in persons with CI (Ullrich et al., 2018). The assessment captures the life-space (LS) zones (from bedroom = 0, home = 1, immediate surroundings of one`s home = 2, neighborhood = 3, home town = 4 to unlimited area = 5) within the previous week, the frequency of mobility for each zone (1 = “1–3 times per week”, 2 = “4-6 times per week”, 3 = “daily”), and the assistance needed to travel within a zone (1 = “help of another person”, 1.5 = “use of assistive device only”, 2 = “no assistance”), while using an interview technique specifically developed for older people with CI (Ullrich et al., 2018). A composite score can be calculated by multiplying the zone score with scores for frequency and assistance, and then adding the scores for each zone. The lowest LSA-CI score of 0 indicates total immobility and the maximum LSA-CI score of 90 indicates daily independent out-of-town mobility. The LSA-CI covered also subscores (range 0–5) for (1) the maximum LS zone achieved without any assistance, or with equipment or personal assistance (LSA-CI-M); (2) the maximum LS zone achieved with equipment (e.g. walking sticks, rollator), if needed, but without personal assistance (LSA-CI-E), and (3) the maximum LS zone achieved independently without equipment and without personal assistance (LSA-CI-I). To extract the role of the specific assistance (i.e., equipment, personal assistance) in individual's LS, we developed two new subscores in addition to the established subscores based on the available LSA-CI data. The subscore (a) for the LS increased due to the assistance by another person (LSA-CI-AP) was calculated by subtracting the equipment-assisted from the maximal LS score (i.e. LSA-CI-M – LSA-CI-E) and subscore (b) for the LS increased due to the assistance by equipment (LSA-CI-AE) was calculated by subtracting the independent from the equipment-assisted LS score (i.e. LSA-CI-E – LSA-CI-I). By this approach, we were able to document the specific effect of personal assistance and equipment, respectively, which represents a novel perspective for LSA assessment.

2.3.2. Potential determinants of life-space mobility

Based on the mobility framework by Webber et al. (2010), physical, cognitive, psychosocial, environmental, and financial status and gender, cultural and biographical variables were assessed to examine their associations with LSM. Physical variables included the Short Physical Performance Battery (SPPB) for the assessment of motor performance (Guralnik et al., 1994), the number of diagnoses as documented in patient charts indicating multimorbidity, and the Body Mass Index (BMI) documenting relative weight. Cognitive status was assessed using the Mini-Mental State Examination (MMSE) (Folstein et al., 1975). To assess different domains of psychosocial status we used the Falls Efficacy Scale – International (FES-I) (Hauer et al., 2011), the Fear of Falling Avoidance-Behavior Questionnaire (FFABQ) (Landers, Durand, Powell, Dibble, & Young, 2011; translated according to Beaton, Bombardier, Guillemin, & Ferraz (2000), stage 1–4), the 15-item version of the Geriatric Depression Scale (GDS) (Allgaier, Kramer, Mergl, Fejtkova, & Hegerl, 2011; Greenberg, 2007), the Apathy Clinical Evaluation Scale – Clinical Version (AES-C) (Lueken et al., 2006; Marin, Biedrzycki, & Firinciogullari, 1991), and the total duration of private, unpaid care by family members or friends within the previous three months (one item of a questionnaire for health-related resource use (Seidl et al., 2015)). A questionnaire for the assessment of the social situation (Erhebungsbogen SOziale Situation - SOS) (Nikolaus, Specht-Leible, Bach, Oster, & Schlierf, 1994) with four components was used to measure social contacts (including frequency, quantity and quality of relationships to other persons), social activities (existence and development of hobbies/interests), living situation (including indoor and outdoor aspect of the living situation such as comfort, barriers, infrastructure, duration of residence), and financial status (addressing the self-related sufficiency of actual income and the existence of savings). To complement environmental status in addition to living situation, weather data comprising mean temperature, precipitation height and snow depth for each of the subject`s assessment period were recorded at the weather station closest to the study center. Sociodemographic characteristics including age and gender were documented from patient charts, educational and marital status were assessed by standardized interviews. PA was assessed by the number of steps within 48 h measured with a body-fixed accelerometer (PAMSys™, BioSensics, Cambridge, MA, USA), using a validated algorithm for older persons (Najafi et al., 2003). For sample description, also falls in the previous year were documented by standardized interview (Zieschang, Schwenk, Becker, Oster, & Hauer, 2012).

2.4. Statistical analysis

Descriptive data are presented as frequencies and percentages for categorical variables, and means and standard deviations or median and range for continuous variables as appropriate. Differences in descriptive variables and LSA-CI scores between participants who received and those who did not receive personal assistance or equipment were analyzed by unpaired t-tests for continuous variables and chi-square tests for categorical variables. To identify potential determinants of LSM, we calculated bivariate correlation coefficients (Spearman (r_s) and point-biserial (r_{pb}) correlation coefficients) between LSA-CI composite score and variables for physical (SPPB, number of diagnoses, BMI), cognitive (MMSE), psychosocial (FES-I, FFABQ, GDS, AES-C, social contacts and social activities – SOS, duration of private unpaid care), environmental (living situation - SOS), financial (financial situation - SOS), sociodemographic status (age, gender, marital status, educational level), and total amount of PA (number of steps). Correlation coefficients (r) were interpreted as low ($r < 0.2$), moderate ($r = 0.2–0.5$), or high ($r > 0.5$) (Cohen, 1988). Variables that showed significant correlations ($p < 0.05$) were entered in a standard multiple linear regression analysis to examine independent determinants of LSM. Potential multicollinearity of independent variables was taken into account defined as correlation coefficients among independent variables $r > 0.7$ (Kleinbaum & Kupper, 1978) and a variance inflation factor (VIF) < 10 (Chatterjee & Hadi, 2013). Appropriateness of further assumptions of linear regression models of homoscedasticity and normality of the residuals (Ernst & Albers, 2017) and autocorrelation was considered. Two regression models were constructed: Model 1: a basic model including significant correlated variables for physical, cognitive, psychosocial, environmental, financial status, and sociodemographic influences oriented at the model by Weber et al (Webber et al., 2010); Model 2: all status-based variables from model 1 amended by a quantitative parameter for movement behavior (number of steps). Beta weights for all independent variables included in the regression equations (range of values: −1 to 1) and adjusted R^2 (including p-values for significance) for the total model were analyzed. A p-value < 0.05 was considered statistically significant. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 23 for Windows (IBM Corp., NY, USA).

3. Results

3.1. Participant characteristics

Out of 1981 patients screened for eligibility, 118 community-dwelling individuals were enrolled according to predefined inclusion criteria. The study sample comprised multimorbid (number of diagnoses = 11.4 ± 4.4), older patients (82.3 ± 6.0 years) with motor (SPPB = 5.2 ± 2.3) and cognitive impairment (MMSE = 23.3 ± 2.4), and mild depressive (GDS = 5.3 ± 3.0) and apathetic (AES-C = 40.2 ± 9.1) symptoms approximately 7.5 weeks (45.7 ± 47.1 days) after discharge from geriatric rehabilitation. Further sample characteristics are detailed in Table 1.

3.2. Description of life-space mobility

Based on 117 participants (one participant was excluded due to unrealistic statements, advanced disorientation, and confabulation), the mean LSA-CI composite score was 23.9 ± 13.2 within a range of 4.5 to 70 out of a maximum score of 90 (Table 2) with mainly highly restricted and dependent persons as well as a few relatively unrestricted and independent persons (Fig. 1). Results for LSA-CI subscores differed substantially (Table 2), depending on the degree of assistance with the highest scores when support by equipment or another person was included (LSA-CI-M), substantially lower scores for the LS achieved with equipment but without personal assistance (LSA-CI-E), and very low scores for the LS achieved independently without any assistance by equipment or another person (LSA-CI-I). The maximum LS achieved (LSA-CI-M), independent of the degree of assistance, indicated an activity area between the neighborhood (= LS zone 3) and the hometown (= LS zone 4) (LSA-CI-M = 3.7 ± 1.2). Despite support from another person or equipment, seven participants (6.0%) were completely homebound (LSA-CI-M ≤ 1) and 38 participants (32.5%) were restricted to their neighborhood (LSA-CI-M ≤ 3; Table 3). The equipment-assisted LS score (LSA-CI-E) showed that without personal assistance LS decreased substantially by more than one LS zone (-1.1 ± 1.3) and covered an area between the immediate surroundings of the home (= LS zone 2) and the neighborhood (= LS zone 3) (LSA-CI-E = 2.5 ± 1.2; Table 2). Further analysis of the LS achieved with equipment showed that more than half of the participants (n = 70, 59.8%) were bound to the immediate surroundings of the home (≤ LS zone 2), and more than three fourths (n = 90, 76.9%) were restricted to the neighborhood (≤ LS zone 3; Table 3). The LS achieved independently without any assistance (LSA-CI-I) was on average restricted to the home (= LS zone 1) (LSA-CI-I = 1.1 ± 1.4; Table 2). A closer look at the independent LS revealed that - without equipment or personal assistance - half of all participants (n = 58, 49.6%) were not able to leave their bedroom, overall 84.7% (n = 99) were restricted to the immediate surroundings of the home (LSA-CI-I ≤ 2), and 92.4% (n = 108) were restricted to their neighborhood (LSA-CI-I ≤ 3; Table 3). The analysis of the specific benefit from personal assistance (LSA-CI-AP) revealed that more than half of all participants (n = 63,

Table 1
Sample characteristics.

Characteristics	Variables	n = 118
Physical status	SPPB Score (0–12), mean (SD)	5.2 (2.3)
	Number of diagnoses, mean (SD)	11.4 (4.4)
	Body Mass Index, mean (SD)	27.3 (5.3)
	At least one fall in the previous year, n (%)	79 (67)
Cognitive status	MMSE Score (0–30), mean (SD)	23.3 (2.4)
Psychosocial status	Social Contacts Score (0–6; SOS), mean (SD)	5.4 (0.7)
	Social Activities Score (0–5; SOS), mean (SD)	2.5 (1.1)
	FES-I Score (7–28), median (range)	11 (7-25)
	FFABQ Score (0–56), mean (SD)	18.5 (12.6)
	GDS Score (0–15), mean (SD)	5.3 (3.0)
	AES-C Score (18–72), mean (SD)	40.2 (9.1)
Environmental status	Living situation (0–11), mean (SD)	8.7 (1.4)
Sociodemographic status	Age (years), mean (SD)	82.3 (6.0)
	Gender (female/male), n (%)	90(76.3) / 28(23.7)
	Marital status (married/not married), %	30.5/69.5
	Educational level (only school/vocational education/ university or comparable), %	31.4/50.0/18.6
Physical activity	Number of steps per day, mean (SD)	2843 (2264)

Presented are the characteristics of the study sample. *Abbreviations:* AES-C: Apathy Evaluation Scale – Clinical Version; FES-I: Falls Efficacy Scale – International; FFABQ: Fear of falling Avoidance Behavior Questionnaire; GDS: Geriatric Depression Scale; MMSE: Mini Mental State Examination; SOS: Questionnaire on social status; SPPB: Short Physical Performance Battery.

Table 2
Results of life-space assessment in persons with cognitive impairment.

LSA-CI score	Mean	(SD)	Median	Range
LSA-CI composite score (-C)	23.9	(13.2)	20.5	4.5–70
LSA-CI maximal score (-M)	3.7	(1.2)	4.0	1–5
LSA-CI equipment assisted score (-E)	2.5	(1.2)	2.0	1–5
LSA-CI independent score (-I)	1.1	(1.4)	1.0	0–5

Presented are results of the LSA-CI composite score and subscores; n = 117, one measurement had to be excluded due to unrealistic statements by the patient. *Abbreviations:* LSA-CI = Life-Space Assessment for Persons with Cognitive Impairment.

Table 3
Subscore analysis - Life-space zones and part of persons that reached maximal the respective zone.

Life-space zone	LSA-CI-M	LSA-CI-E	LSA-CI-I
0 (bedroom)	0 (0.0)	1 (0.9)	58 (49.6)
1 (home)	7 (6.0)	19 (16.2)	20 (17.2)
2 (immediate surroundings of the home)	20 (17.1)	50 (42.7)	21 (17.9)
3 (neighborhood)	11 (9.4)	20 (17.1)	9 (7.7)
4 (home town)	45 (38.5)	17 (14.5)	5 (4.3)
5 (unlimited area)	34 (29.1)	10 (8.5)	4 (3.4)

Presented are subscore analyses and the number of persons (percentage of persons) that reached maximal the respective zone; Abbreviations: LSA-CI-M = maximum life-space with equipment or personal assistance if needed; LSA-CI-E = maximum life-space with equipment if needed; LSA-CI-I = maximum independent life-space without equipment or personal assistance.

53.8%) increased their maximal LS through personal assistance, with more than two thirds of them (n = 45) showing an increase of at least two LS zones (Table 4). Participants who benefitted from personal assistance showed a significantly higher maximal LS (LSA-CI-M, $p < 0.001$), but a lower equipment-assisted (LSA-CI-E, $p < 0.001$) and independent LS (LSA-CI-I, $p = 0.004$), a lower motor performance (SPPB) ($p = 0.038$), and were mostly female ($p = 0.015$) compared to those who did not receive personal assistance (n = 54, 46.2%), indicating that personal assistance may be related to decreased functional status. No significant differences between these two groups were found

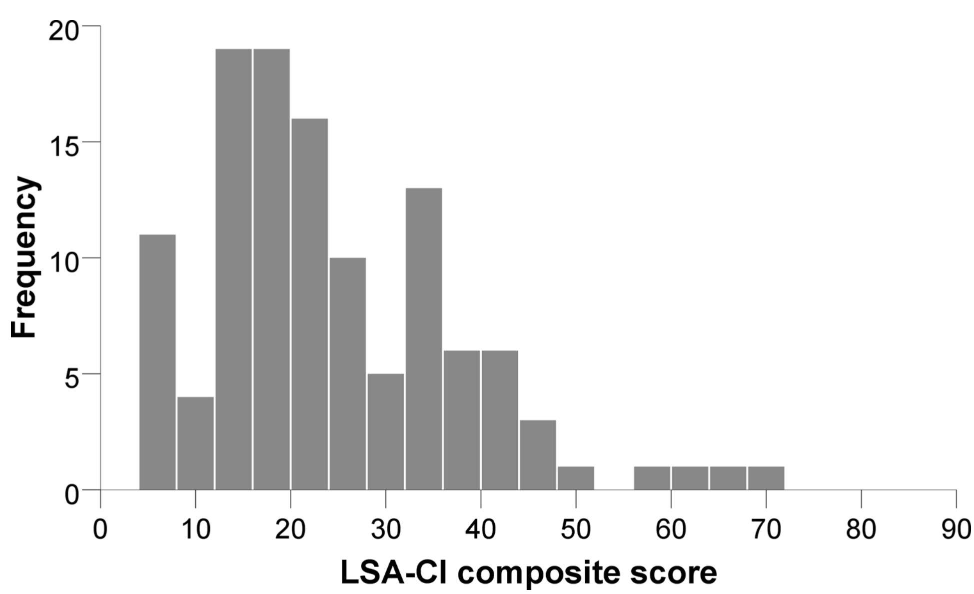

Fig. 1. Histogram of the LSA-CI composite score for the sample of 117 multimorbid, older people with cognitive impairment.

Table 4
Use of and benefit from personal assistance and equipment.

Increase of life-space zone by…	LSA-CI-AP, n (%)	LSA-CI-AE, n (%)
+ 0	54 (46.2)	38 (32.5)
+ 1	18 (15.4)	20 (17.1)
+ 2	24 (20.5)	41 (35.0)
+ 3	18 (15.4)	8 (6.8)
+ 4	2 (1.7)	8 (6.8)
+ 5	1 (0.9)	2 (1.7)

Presented are increases in life-space zones due assistance by a person or equipment. Abbreviations: LSA-CI-AP = life-space increased in persons with cognitive impairment due to assistance by a person; LSA-CI-AE = life-space increased in persons with cognitive impairment due to assistance by equipment.

Table 5
Differences between persons using and benefitting from personal assistance (LSA-CI-AP) and persons using and benefitting from equipment (LSA-CI-AE).

	LSA-CI-AP		LSA-CI-AE	
Group difference with respect to:	LSA-CI-AP ≥ 1 vs. LSA-CI-AP = 0	p	LSA-CI-AE ≥ 1 vs. LSA-CI-AE = 0	p
LSA-CI-C	23.0 vs. 25.0	.409	26.9 vs. 22.5	.113
LSA-CI-M	4.2 vs. 3.0	**< .001**	3.6 vs. 3.7	.794
LSA-CI-E	2.1 vs. 3.0	**< .001**	2.5 vs. 2.6	.820
LSA-CI-I	0.8 vs. 1.5	**.004**	2.5 vs. 0.4	**< .001**
age	83.0 vs. 81.5	.192	81.0 vs. 82.9	.125
gender (female)	85.7% vs. 66.7%	**.015**	85.5% vs. 63.2%	**.014**
diagnoses	11.8 vs. 10.8	.247	11.0 vs. 11.6	.464
MMSE	23.1 vs. 23.5	.347	22.9 vs. 23.5	.189
SPPB	4.8 vs. 5.7	**.038**	6.4 vs. 4.6	**< .001**
social activities	2.5 vs. 2.5	.951	2.5 vs. 2.5	.837
falls	1.1 vs. 1.0	.715	0.9 vs. 1.2	.141
FES-I	12.4 vs. 12.1	.749	11.1 vs. 12.8	**.035**
FFABQ	20.4 vs. 16.7	.118	13.1 vs. 21.3	**.001**
GDS	5.3 vs. 5.3	.966	5.0 vs. 5.4	.417
AES-C	22.2 vs. 21.9	.868	23.2 vs. 21.5	.375
PA (steps)	2538 vs. 3191	.127	3363 vs. 2591	.074

Presented are differences between groups according to use and benefit with respect to life-space zones due assistance by a person or equipment. Abbreviations: LSA-CI-AP = life-space increased in persons with cognitive impairment due to assistance by a person; LSA-CI-AE = life-space increased in persons with cognitive impairment due to assistance by equipment.

for the LSA-CI composite score and other descriptive variables (Table 5). Over two thirds of all participants (n = 79, 67.5%) specifically benefited from the use of equipment (LSA-CI-AE), with 59 (74.7%) of them showing an increase of at least two LS zones (Table 4). These participants showed significantly lower independent LS (LSA-CI-I, $p < 0.001$) and motor performance ($p < 0.001$) compared to those who did not use equipment (n = 38, 32.5%), but showed higher levels of FOF ($p = 0.035$) and avoidance behavior due to FOF ($p < 0.001$) and were mostly female ($p = 0.014$). No significant group differences were found in other LSA-CI scores or in other descriptive variables (Table 5).

3.3. Determinants of life-space mobility

As basis of the regression models, bivariate correlational analyses revealed that physical activity (PA) showed the highest correlations with LSA-CI score (PA/number of steps: $r_s = 0.590$; $p < 0.001$), followed by moderate correlations with social activities (social activities – SOS), motor performance (SPPB), FOF (FES-I), FOF-related avoidance behavior (FFABQ), age, gender, and living situation (living situation – SOS) ($r = |0.233\text{-}0.435|$; $p = < 0.001–0.012$). Correlations with duration of private unpaid care and cognition (MMSE) were low although reaching significance($r = |0.186\text{-}0.199|$; $p = 0.031\text{-}0.045$). Significant variables were included in the subsequent regression models. No significant correlations ($r = |0.005–0.141|$; $p = 0.129–0.961$) were found for number of diagnoses, BMI, measures of social contacts (social contacts - SOS), depressive and apathetic symptoms (GDS, AES-C), weather, financial status, marital status and educational level (Table 6). Regression model 1 (without PA) revealed that higher motor performance (SPPB), more social activities and being male were independently associated with higher LSA-CI-C scores, with the highest β-weight for motor performance, while cognition, FOF-related factors (FFABQ, FES-I), duration of private unpaid care, living situation and age were not independently associated with the LSA-CI-C score (Table 7). No multicollinearity between included variables or

Table 6
Correlation between life-space mobility and related factors.

Factors	Variable	r_s or r_{pb}	p
Physical status	SPPB Score	**.387**[**]	< .001
	Number of diagnoses	.015	.875
	Body Mass Index (BMI)	−.028	.766
Cognitive status	MMSE Score	**.186**[*]	.045
Psychosocial status	Social Contacts Score (SOS)	−.028	.762
	Social Activities Score (SOS)	**.435**[**]	< .001
	FES-I Score	**−.238**[**]	.010
	FFABQ Score	**−.380**[**]	< .001
	GDS Score	−.108	.246
	AES-C Score	−.141	.129
	Private unpaid care	**−.199**[*]	.031
Environmental status	Living Situation Score (SOS)	**.233**[*]	.012
	Weather: Average temperature	−.005	.961
	Weather: Precipitation height	.007	.940
	Weather: Average snow depth	−.080	.392
Financial status	Financial Status (SOS)	−.021	.825
Sociodemographic factors	Age	**−.321**[**]	< .001
	Gender[a]	**.282** [**]	.002
	Marital Status[a]	−.074	.431
	Educational Level	.072	.442
Physical activity	Number of steps[b]	**.590**[**]	< .001

Presented are Spearman coefficients rho between LSA-CI composite score and associated factors; n = 117; except for [a]point biserial correlation (dichotomous measures); [b]n = 114; [c]n = 112; [d]n = 108. Correlations coefficients (r): < 0.20 = low, .20–.50 = moderate, > 0.50 = high. Bolding indicates significant correlations; $^{*}p < .05$; $^{**}p < .01$. *Abbreviations:* AES-C: Apathy Evaluation Scale – Clinical Version; FES-I: Falls Efficacy Scale – International; FFABQ: Fear of falling Avoidance Behavior Questionnaire; GDS: Geriatric Depression Scale; LSA-CI: Life-Space Assessment for Persons with Cognitive Impairment; MMSE: Mini Mental State Examination; SOS: Questionnaire for social status; SPPB: Short Physical Performance Battery.

Table 7
Regression model for determinants of life-space mobility.

	Model 1 (n = 117)	Model 2 (n = 114)
adjusted R^2	.363	.424
Variable	ß	ß
MMSE	.076	.064
SPPB	**.341****	**.243****
Social activities (SOS)	**.296****	**.257****
FES-I	.083	.025
FFABQ	−.076	−.064
Living situation	.058	.033
Gender	**.218****	**.182***
Age	−.109	−.102
Private unpaid care	.007	.027
No. of steps	–	**.265****

Bolding indicates significant correlations; $^{*}p < 0.05$; $^{**}p < 0.01$.
Presented are linear regression analyses for LSA-CI composite score and potential determinants. Bolding indicates significant factors. Abbreviations: FES-I: Falls Efficacy Scale – International; FFABQ: Fear of falling Avoidance Behavior Questionnaire; LSA-CI = Life-Space Assessment for Persons with Cognitive Impairment; MMSE: Mini Mental State Examination; SOS: Questionnaire for social status; SPPB: Short Physical Performance Battery.

autocorrelation was found (highest r = 0.642 for FES-I and FFABQ; max VIF = 2.045; Durbin-Watson 1.920). Model 1 explained a variance of 36.3% in the LSA-CI-C score (adjusted R^2 = 0.363). When the activity behavior-related variable for PA was additionally included in the regression model 2, higher motor performance (SPPB), more social activities, being male and higher amount of PA were independently associated with higher LSA-CI-C scores, with the highest β-weight for PA. No multicollinearity between included variables was found also for this model (max VIF = 2.019; Durbin-Watson 2.096). By adding PA into model 2, the total amount of explained variance increased from 36.3% to 42.4% (adjusted R^2 = 0.424, Table 7).

4. Discussion

To the best of our knowledge, this is the first study to investigate LSM and its determinants in multimorbid, older patients with CI after discharge from geriatric rehabilitation, a highly vulnerable population with multiple risk factors for LSM restrictions. Study results show that: 1) LSM is highly restricted in such a population, which becomes particularly apparent when analyzing the LS achieved independently without assistance of another person or equipment. 2) Higher motor performance, increased PA, more social activities, and male gender were identified as important determinants for increased LSM, explaining a considerable part of the LSA-CI´s variance.

4.1. Description of life-space mobility

The mean LSA-CI-C of 23.9 out of maximal 90 scores demonstrated that LSM was substantially limited among the study population. The majority of the participants were highly restricted and dependent on personal assistance as well as equipment. Previous studies in cognitively intact community-dwelling older adults have shown that average maximal LS covered an activity area between the hometown (= LS zone 4) and areas beyond (= LS zone 5) (maximal LS: 4.2–5.0) (Baker et al., 2003; Curcio et al., 2013; Fristedt, Kammerlind, Bravell, & Fransson, 2016). As expected, due to the impaired physical, cognitive and psychological status and the preceding hospitalization of the vulnerable study population, average maximal LS only ranged between neighborhood (= LS zone 3) and hometown (= LS zone 4) (LSA-CI-M: 3.7) in this study. The restricted mobility status in our population became particularly obvious when support mechanisms (personal assistance and use of equipment) were excluded, indicating a higher dependence on transportation support and a higher number of unfulfilled transportation needs (Cvitkovich & Wister, 2001). Without any assistance, the vast majority of persons were restricted to the home area, which is associated with decreased opportunities for participation in social and community activities (Szanton et al., 2016).

The use of equipment and personal assistance seem to play a key role in the LSM of multimorbid, older persons with motor and cognitive impairment as demonstrated by the newly introduced subscores LSA-CI-AP and LSA-CI-AE that enabled us to document separately the effect of personal assistance or equipment. The majority of participants used equipment and received help of another person, thus increasing their LSM to a level comparable to that of persons without the need for personal assistance or equipment. Interestingly, the participants receiving assistance and/or using equipment were those with a lower independent LS, lower motor performance, higher FOF, and higher avoidance behavior due to FOF, indicating that such limitations can successfully be compensated by personal assistance and equipment. Both, personal assistance and equipment, have been crucial to broaden the LSM in the multimorbid sample and therefore represent potential targets for increasing the mobility in vulnerable populations with multiple risk factors for LSM restrictions (Bertrand, Raymond, Miller, Martin Ginis, & Demers, 2017; Latham, Clarke, & Pavela, 2015), for example promoting the use and acceptance of existing equipment, examining the need of specific additional equipment, or encouraging relatives or caregivers to support outdoor mobility.

4.2. Determinants of life-space mobility

Based on the theoretical mobility framework by Webber et al. (2010), we considered a high number of potentially relevant factors to provide a comprehensive analysis of LSM in our sample. To our best knowledge, only one study in a large sample of older community-dwelling persons examined a comparable range of potentially relevant factors to analyze community mobility, identifying physical, cognitive, environmental and sociodemographic variables, but not psychosocial and financial factors, as independent determinants of mobility with physical health as strongest predictor (Umstattd Meyer et al., 2014). The current study conducted in multimorbid, older persons with motor and cognitive impairment focused, for the first time, on a specific population at high risk for restricted LSM, dependency, and institutionalization. Study results revealed that only variables addressing the participants' physical and (psycho-) social status, gender, and PA were independent determinants of LSM, accounting for a considerable part of the LSA-CI´s variance, while cognitive, financial, environmental, cultural and biographical factors as assessed in this population were negligible.

Among the physical variables, a comprehensive assessment for key motor functions (SPPB) was identified as an independent determinant of LSM, representing also the strongest factor in the first regression model. The result is in accordance with previous studies investigating multiple, potential factors of LSM in mixed populations of older adults with and without CI, that also identified functional and motor performance as the most powerful determinants of LSM (Al Snih et al., 2012; Peel et al., 2005). LSM was not significantly associated with number of medical diagnoses as a surrogate marker for multimorbidity, nor with the moderate BMI in our sample, thus supporting previous results observed in older adults with and without CI (Al Snih et al., 2012; Sawyer & Allman, 2010). In contrast to functional status as indicated by the SPPB, diseases or body characteristics seem to play rather a minor role for LSM. This is consistent with the World Health Organization's International Classification of Functioning, Disability and Health and its basic idea that a disease itself provides an incomplete perspective on health status and disability. Instead, the impact of diseases on an individual's functional status and impairment level as shown by the motor performance status is important for engagement in everyday life (Escorpizo et al., 2013).

Global cognitive status was not independently associated with LSM in our study population which was homogenous in this respect with a small-ranging mild to moderate CI level (MMSE range 17–26). Previous studies investigating associations between cognitive status and LSM showed conflicting results (Beland et al., 2018). Cross-sectional studies that showed associations between cognitive status and LSM included samples that covered the full range of cognitive performance including cognitively intact and severely impaired persons (MMSE range 0–30) (Al Snih et al., 2012; Peel et al., 2005), which might explain the different study results. Differences in outdoor activity might be more obvious in cognitive demanding outdoor activities (Wettstein et al., 2015), however, these differences with respect to the cognitive demand of an activity cannot be assessed using the LSA-CI. Our study design did not allow analysis of the risk of developing cognitive impairment as investigated in previous studies (Beland et al., 2018; James, Boyle, Buchman, Barnes, & Bennett, 2011).

Among the variables for psychosocial factors, we identified social activities as a significant and independent determinant of LSM, corresponding to results reported for cognitively healthy adults using a questionnaire assessing only LS, more specifically spatial distances (Barnes et al., 2007). Given that social activities are based on the volition of an individual to get around outside the own home and participate in the community or society (Levasseur, Richard, Gauvin, & Raymond, 2010) and that social activities had been identified to account for a substantial proportion (about 20%) of trips outside the home among older adults (Mollenkopf et al., 1997), this finding is reasonable. Thus, our results support the idea of the LSM concept depicting not only spatial-temporal movement patterns, but also reflecting participation in the society (Parker, Baker, & Allman, 2002). Social contacts as documented by the SOS questionnaire and private unpaid care were not identified as independent determinants of LSM, even though the initial descriptive analysis of LSM showed that the assistance provided of another person increased LS substantially in our sample (LSA-CI-E = 2.5 ± 1.2 vs. LSA-CI-M = 3.7 ± 1.2). This might be explained by the assessment of social contacts and private unpaid care that was more likely to cover passive forms of social interaction that were mainly located in the home as suggested by Dale et al. (Dale, Saevareid, Kirkevold, & Soderhamn, 2008), while assessment of social activities included questions on active engagement (existence and development of hobbies/interests), thus better reflecting outdoor activity. FOF-related factors (FES-I and FFABQ) were bivariately associated with LSM, but these associations were not statistically independent of other determinants as shown by the regression analysis. These findings contrasted with previous studies demonstrating independent associations of LSM and FOF in older adults with (Uemura et al., 2013) and without CI (Auais et al., 2017). The effects may be mediated by motor performance and PA, as these variables were moderately correlated with FOF (Denkinger, Lukas, Nikolaus, & Hauer, 2015), or compensated by the use of equipment as suggested by the descriptive analysis with higher benefit by equipment in persons with higher levels of FOF. No associations between LSM and depressive or apathetic symptoms were found in our study sample, in contrast to previous studies in older mixed populations with and without CI (Al Snih et al., 2012; Peel et al., 2005). Apathy and depression may especially affect higher-level daily activities (e.g., shopping, public transportation) (Fitz & Teri, 1994; Kazama et al., 2011; Yeager & Hyer, 2008), and to a less extent lower-level activities of daily living (e.g. food preparation, doing the laundry), which might be the focus in everyday life in our vulnerable study population.

Environmental factors did not significantly influence the LSM of our sample. The living situation and weather conditions may have an influence on higher outdoor LSM, however, due to the low outdoor activity observed in our sample, the potential impact of such factors may have been reduced in our study.

Out of the sociodemographic factors (financial, cultural, biographical factors) only gender was identified as an independent determinant of LSM in our study population, with females showing lower LSM than males. The influence of gender on LSM was previously also reported for persons with orthopedic diseases (Suzuki et al., 2014), or unspecific populations (Peel et al., 2005; Phillips et al., 2015) and might be related to the generally higher disability level (Gill, Gahbauer, Lin, Han, & Allore, 2013), lower physical activity level (L. Smith, Gardner, Fisher, & Hamer, 2015) or to a preference for home leisure activities in older women (Gagliardi et al., 2007). Age was not independently associated with LS, which may be due to mediation effects of motor performance and PA that are in turn predicted by age (Browning, Sims, Kendig, & Teshuva, 2009; Guralnik et al., 1993).

PA behavior was identified as the strongest independent determinant of LSM in our second regression model. High associations of PA with LSM have also been previously reported by studies in older persons without CI, showing that a higher amount of PA is accompanied by greater spatial extension of mobility (Portegijs et al., 2015; Sawyer & Allman, 2010; Tsai et al., 2015). PA and LSM both represent aspects of movement behavior, with PA focusing on activity regardless of location and target and LSM focusing on the location and spatial extent of activity regardless of physically active or passive locomotion. Thus, the results were in line with our expectations of PA to explain a large amount of the LSA-CI´s total variance, which was the reason for calculating a second regression model with PA in addition to the first model, including only status-based variables. Furthermore, it might be also argued that the number of steps (i.e., walking), by which we quantified PA in our study, is a prerequisite to moving through LS zones independently (Collia, Sharp, & Giesbrecht, 2003; Satariano et al., 2012).

In summary, the theoretical mobility framework by Webber et al. (Webber et al., 2010), successfully tested in older persons (Umstattd Meyer et al., 2014), may only have a relevance for specific variables in multimorbid, older people with motor and cognitive impairment, as not all model assumptions were met in our study sample. However, our comprehensive analysis of LSM revealed independent determinants that were modifiable, except for gender. Previous studies have already demonstrated that physical training is feasible and effective to improve motor performance in older people with and without CI (for review, see (Heyn, Johnson, & Kramer, 2008), that social interventions (e.g., support interventions, home visiting, service provision) can promote social activities in older people (for review, see (Dickens, Richards, Greaves, & Campbell, 2011), and that physical home training (Hauer et al., 2017) or specific behavior change intervention techniques (goal setting, social support, using a credible source) (Nyman, Adamczewska, & Howlett, 2018) can increase PA. Thus, interventions that address motor performance, social activities, and PA may also have a high potential to increase LSM in a vulnerable population of multimorbid older adults with motor and cognitive impairment. Women were identified as a high risk subgroup for LSM restriction with a potential accumulation of converging negative factors, indicating a special need for interventions with focus on women.

Future studies could include differentiated analyses of social contacts, activities and support, specific diseases and cognitive subdomains or behavioral factors (activities of daily living). As a limitation of the study, we have to mention that the SOS was not validated in persons with cognitive impairment. However, as the documentation of the SOS was interview-based and performed by trained assessor, representing an established procedure to compensate potential record bias in persons with cognitive impairment, we assume that the documentation meets established documentation standards.

5. Conclusions

LSM was substantially restricted in a multimorbid, vulnerable population of older persons with CI following geriatric rehabilitation. Equipment and personal assistance played a key role for LSM in this population, as dependency on both is highly prevalent, providing opportunities for increasing LSM by improving the availability and use of equipment or by providing personal assistance. The identified determinants of LSM show potential for future interventions to increase LSM in such vulnerable persons at high risk for LS restrictions by targeting motor performance, social activities, and PA.

Conflict of interest

The authors declare that there is no conflict of interest.

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Publikation VI

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ORIGINAL INVESTIGATION

Promoting physical activity in geriatric patients with cognitive impairment after discharge from ward-rehabilitation: a feasibility study

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Abstract

The aim of the present study was to examine adherence and acceptance of a home-based program to promote physical activity (PA) in older persons with cognitive impairment (CI) following inpatient rehabilitation. Sixty-three older persons (≥ 65 years) with mild to moderate CI (Mini-Mental State Examination score 17–26), allocated to the intervention group of a randomized, controlled intervention trial underwent a 12-week home-based PA intervention including (1) physical training and outdoor walking to improve functional fitness and (2) motivational strategies (goal-setting, pedometer-based self-monitoring, social support delivered by home visits, phone calls) to promote PA. Training logs were used to assess adherence to physical training, outdoor walking and to motivational strategies (goal-setting, pedometer-based self-monitoring). Acceptance (subjective feasibility and effectiveness) of the program components was assessed by a standardized questionnaire. Mean adherence rates over the intervention period were 63.6% for physical training, 57.9% for outdoor walking, and between 40.1% (achievement of walking goals), and 60.1% (pedometer-based self-monitoring) for motivational strategies. Adherence rates significantly declined from baseline to the end of intervention (T1: 43.4–76.8%, T2: 36.1–51.5%, *p values*<.019). Most participants rated physical training, outdoor walking, goal-setting, and pedometer self-monitoring as feasible (68.2–83.0%) and effective (63.5–78.3%). Highest ratings of self-perceived effectiveness were found for home visits (90.6%) and phone calls (79.2%). The moderate to high adherence to self-performed physical training and motivational strategies proved the feasibility of the home-based PA program in older persons with CI following inpatient rehabilitation.

Keywords Adherence · Feasibility · Physical activity · Geriatrics · Transitional care · Cognitive impairment

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Introduction

Cognitive impairment (CI) is a crucial factor for rehabilitation success in geriatric patients, as individuals with CI are at a high risk for poor functional recovery during rehabilitation (McGilton et al. 2016) and experience more often caught in the downward spiral of decreased outdoor mobility after discharge (Brown et al. 2009), loss of autonomy, and functional independence (Portegijs et al. 2014). Despite the urgent necessity to increase functional fitness and to promote physical activity (PA), this vulnerable group is mostly excluded from interventions targeting care continuity in the community following ward-based rehabilitation (Chenoweth et al. 2015).

High adherence to exercise is a prerequisite of successfully implemented interventions in mobility impaired older adults (Fairhall et al. 2012; Taylor et al. 2017), but is reduced in persons with CI participating in home-based rehabilitation compared to their cognitively intact counterparts (Moseley et al. 2009). Nonetheless, high adherence to physical training was achieved in home-based and supervised programs with caregiver support in cognitively impaired elderly (Prick et al. 2016; Suttanon et al. 2013; Teri et al. 2003; Wesson et al. 2013). A previous home-based study demonstrated high adherence to autonomously performed physical training by cognitively and functionally restricted individuals following inpatient rehabilitation (Hauer et al. 2017), although deteriorating health is known to mitigate adherence to home exercise (Fairhall et al. 2012). Decreasing adherence to individually tailored training over time indicate the challenge of achieving a long-lasting increase in PA in this target group (Taylor et al. 2017). This may be hampered by CI-specific barriers, such as impaired executive function, reduced awareness of own deficits, and apathetic behavior (David et al. 2012; Jacus 2017).

With respect to these multiple barriers, interventions are needed that promote PA as part of daily routine (Heyn et al. 2004). To facilitate a change of activity-related behavioral patterns, behavioral change techniques (BCT; Abraham and Michie 2008) are implemented across PA interventions in diverse adult populations. Two reviews narratively synthesized the efficacy of a variety of BCT (named as motivational strategies in the following) on levels of PA in intervention studies among persons with CI (Nyman et al. 2018; van der Wardt et al. 2017). Within the audited studies, there is cautious evidence for the impact of goal-setting and self-monitoring in terms of high adherence to training and elevated levels of PA. Goal-setting and self-monitoring of own activity behavior led to gains of step counts among individuals without CI (Rosenberg et al. 2012), whereas both strategies were associated with limited efficacy and higher dropout in individuals with CI (Kerse et al. 2008; Vidoni et al. 2016). Home visits and phone calls provided by professionals are useful sources for social support and essential components for the success of activity promotion in elderly (Suttanon et al. 2012). Particularly, dementia-specific communication was beneficial in PA promotion among elderly with CI (Hauer et al. 2012).

Most of the interventions which aimed to change PA behavior using a motivational concept followed a continuously supervised approach. This supervision comprised either the use of caregivers as training partners (Taylor et al. 2017; Teri et al. 2003) or group-based sessions within a nursing care setting (Olsen et al. 2015; Phillips and Flesner 2013). Programs without continuous supervision, fostering the autonomous engagement in physical training and walking, were exclusively implemented in elderly with subjective memory complaints or very mild CI (Cox et al. 2013; Dannhauser et al. 2014; Lautenschlager et al. 2008). Interventions to promote PA in cognitively impaired individuals solely reported adherence to the exercise regimen, but did not provide information about the adoption of motivational strategies for PA promotion. Only Cox et al. (2013), examining the completion of worksheets, reported modest adherence to the general behavior counseling concepts to promote home-based PA in adults with memory complaints. This approach does not allow testing the feasibility of the unique motivational strategies.

By use of qualitative designs, a few studies conducted in cognitively impaired samples described participants' and coaches' experiences of participating in activity promotion programs rather than testing the feasibility of motivational strategies underlying the PA promotion (Olsen et al. 2015; Phillips and Flesner 2013; Suttanon et al. 2012). Within an intervention to promote independent walking intervention, elderly without CI were satisfied with motivational program components, also including pedometer-monitoring, as evaluated by use of a questionnaire (Rosenberg et al. 2012). However, none of those studies used quantitative methods in terms of evaluating adherence to autonomously performed training and motivational strategies over time as well as testing the subjective feasibility as a measure of participants' acceptance in a sample of individuals with motor and cognitive impairment. The measurement of adherence to PA promotion programs might help to understand participants' attitude toward exercise and PA (Hawley-Hague et al. 2016).

Therefore, the aim of this study was to examine the feasibility, adherence over time, and acceptance of a home-based program to promote PA in older persons with CI following geriatric rehabilitation.

Methods

Study design

This feasibility study is part of a blinded, randomized-controlled 12-week intervention trial (RCT) with a 12-week follow-up period to improve functional fitness and to promote PA in older persons with CI after discharge from ward-rehabilitation (ISRCTN82378327). The RCT was approved by the ethics committee of the Medical Department of the University of Heidelberg and was conducted according to the Declaration of Helsinki. The present study uses patient-reported data of adherence and feasibility from participants allocated to the intervention group (IG).

Participants

Participants were consecutively recruited from geriatric rehabilitation wards of a German geriatric hospital. Inclusion criteria were: age ≥ 65 years, a score of 17–26 on the Mini-Mental State Examination (MMSE; Folstein et al. 1975) indicating mild to moderate cognitive impairment (O'Bryant et al. 2008), ability to walk ≥ 4 m without a walking aid, residence within 30 km of the study center, discharge to the patient's home, no terminal disease, no delirium, German-speaking, and written informed consent.

Intervention

The home-based intervention program included (1) physical training to improve functional fitness and (2) a comprehensive motivational concept to promote PA behavior. The intervention was implemented by skilled trainers (sport scientists) within five home visits with decreasing frequency and weekly phone calls beginning after the second home visit.

Physical training

The physical training included strength (tiptoe stance, stair climbing, sit-to-stand transfers), static balance exercises (i.e., side by side, semi-tandem, tandem), and outdoor walking. During the first home visit, participants were introduced in the training program by the trainer. To set graded tasks, the physical exercises were adjusted to participants' individual needs and functional abilities. To remind and instruct participants to execute the physical training, a large poster, containing pictures of the exercises and advices about safety, was fixed in a central position of the home. Participants were encouraged to autonomously perform the physical training and outdoor walking each day. More detailed information about the study design and the physical training has been published previously (Bongartz et al. 2017).

Motivational concept

To increase motivation and adherence to PA, theory-based behavioral change techniques (Abraham and Michie 2008) have been adapted to a CI-specific comprehensive motivational approach, which encompassed following strategies:

1. Provision of information about the benefits of regular training and PA (manual, trainer)
2. Encouragement to engage in daily activity (CI-specific communication by trainer within home visits)
3. Provision of instructions about how and where to perform the exercises (given by the trainer during home visits, poster)
4. Setting graded tasks (tailoring of the intervention to participants' needs and functional abilities)
5. Goal-setting and planning of a walking path in participants' home environment to transfer activity goals in specific and measurable behavior (structured procedure to set indoor and outdoor walking goals; planning and realization of the walking path during home visits)
6. Self-monitoring of behavioral outcomes (pedometer, training log)
7. Regular review of goals (pedometer, training log)
8. Barrier identification and problem solving (home visits, phone calls)
9. Feedback and positive reinforcement (home visits, phone calls)

These nine specific motivational strategies were conflated to the three core motivational components of goal-setting, self-monitoring, and social support. Since the strategy of setting graded tasks is an inherent feature of the individually tailored physical training, this strategy was described as part of the physical training program.

Goal-setting

To involve participants in the goal-setting process, a blinded assessor performed a modified version of Talking Mats (Murphy et al. 2005), which is a semi-structured and pictorial measurement tool developed for cognitively impaired individuals with communication disability. To identify individual meaningful activity goals, each participant was asked to rank prescribed indoor (cooking; self-care; daily activities/homework; self-formulated activity) and outdoor activities (gardening/letterbox; doctor/pharmacy; grocery/bakery/post office; self-formulated activity), which were visualized by pictures.

Since key motor functions such as standing, walking, sit-to-stand transfer, and walking stairs are major prerequisites of mobility, participants additionally evaluated their importance, self-perceived competence, and chance of success on a visual analog scale with range of 0–100. The evaluation of importance refers to the individual value of the key motor function, and the perceived competence captures beliefs about own abilities to perform the corresponding function. The chance of success reflects participants' view to which degree they can improve based on the estimated levels of importance and competence.

Based on the evaluation of the predefined target activity (e.g., going to the bakery) and the key motor functions during the first home visit, trainer and participants collaboratively planned an individualized walking path in the environment around participants' home. As part of the training sessions, the walking path was practiced by participants under the supervision of the trainer and its feasibility was tested with respect to the distance, environmental characteristics (e.g., slippery ground, stairs), and participants' need for assistive devices.

Self-monitoring

To provide feedback about walking behavior and to increase the motivation to engage in daily walking, participants were encouraged to monitor daily step counts by use of simple pedometers (YAMAX Digiwalker CW 700). The trainer instructed participants how to use the pedometer and gave haptic support for attaching it on the waist. The training log was also applied to derive information about personal progress and daily execution of physical training and walking. If participants failed to achieve daily execution of training and the defined walking path, trainer and participant collaboratively tried to identify barriers hampering regular walking and solutions to overcome these barriers during the phone calls and home visits.

Social support

Social support in our study was delivered by trainers within the home visits and phone calls. The professionals served as credible source for information about benefits of regular training and PA by means of a CI-specific communication, which involved simple and repetitively used instructions, haptic support, and picturesque language to encourage persons to integrate training in daily routines (Hauer et al. 2012). Positive feedback was given by the trainer to reinforce participants to maintain their efforts (9). Participation in a local exercise group in a geriatric hospital was offered to each participant as an additional option for regular training and social support by peers.

Measurements

Outcome measures

Main outcomes of the present study were the a) feasibility of goal-setting and professional social support (home visits, phone calls), b) adherence to training and the motivational strategies of goal-setting and self-monitoring by pedometers, and c) patient-rated feasibility and effectiveness of the program.

Feasibility of social support and goal-setting

The feasibility of goal-setting was defined as the proportion of participants (in %), who were able to nominate at least one activity. Comprehensive feasibility was achieved, if participants nominated both indoor and outdoor goals. Partial feasibility was achieved, if participants nominated at least one activity goal. To determine the feasibility of professional social support provided by the research team, the number of performed home visits and phone calls were documented by trainers in standardized protocols.

Adherence to training and motivational strategies

Adherence was documented by participants throughout the 12-week intervention by use of training logs in a simple calendar format. Participants were instructed to daily record the execution of physical training sessions, outdoor walking sessions, achievement of walking goals, and execution of self-monitoring via the pedometer. The amount of step counts was not included as a measure of adherence due to possible inaccuracy regarding the detection of step counts by this simple piezoelectric pedometer. The training logs were returned at the end of the intervention period. The mean weekly adherence rates (in %) to physical training, outdoor walking, achieved walking goals, and pedometer-use were calculated as: number of sessions executed / number of possible sessions * 100. These adherence rates are reported at week 2, 12, and for the total intervention period. As in some cases, the introduction of the pedometer and the implementation of the walking path were performed in the second training session, we defined week 2 as the baseline reference of the intervention. Based on adherence rates, participants were classified as persons with (i) low adherence (0.0–33.3%), (ii) moderate adherence (33.4–66.6%), and (iii) high adherence (66.7–100%).

Acceptance

After the intervention, participants completed a questionnaire specifically designed to document participants' acceptance of the program components (training, outdoor walking, self-monitoring by pedometers, walking-related goal-setting, training group, home visits, phone calls) capturing the two subscales of perceived feasibility (e.g., “Were you able to use the pedometer?”) and effectiveness (e.g., “Did the pedometer help you to improve yourself?”). Subjects responded on a 4-point Likert scale with a range of 1 (“not”), 2 (“rather not”), 3 (“rather yes”), and 4 (“yes”). The components’ feasibility/effectiveness was classified according to the amount of participants with a score ≥ 3 for the respective component and expressed in percentage.

Descriptive variables

Socio-demographic and clinical characteristics including age, gender, body mass index (BMI), number of medications, number of diagnoses, and education were documented from patient charts or by standardized interviews. Education was categorized as primary school or none (low educational level), vocational or other secondary school (middle educational level), and university or vocational postsecondary school (high educational level). Functional fitness was assessed by the Short Physical Performance Battery (SPPB) (Guralnik et al. 1994). For PA behavior, the number of steps was measured within 48 h using an established, ambulatory sensor system (PAMSys™, BioSensics, Cambridge, MA, USA), based on an algorithm validated among older adults (Najafi et al. 2003). To capture different aspects of psychological status, apathy was assessed via the Apathy Evaluation Scale-Clinical Version (AES-C) (Marin et al. 1991) and depression by the 15-item Geriatric Depression Scale (GDS) (Allgaier et al. 2011; Greenberg 2007). To describe the proportion of persons with clinically relevant apathetic syndrome, a cutoff score (>40.5; range 18–72) was used which has been ascertained within a cognitively impaired sample of community-dwelling elderly (Clarke et al. 2007).

Statistical analyses

Descriptive data were presented as frequencies and percentages for categorical variables, means (*M*), and standard deviations (SD) or medians and interquartile ranges (IQR) for continuous variables. Unpaired *t* tests, Mann–Whitney *U*-tests, and Chi-square tests were used for baseline comparison between dropouts and completers according to the data distribution. Paired *t* tests were performed to test for differences regarding mean adherence rates between beginning (week 2) and end of intervention (week 12).

Results

Participant characteristics

Out of 1981 patients screened for eligibility, 118 individuals were enrolled to the original RCT according to predefined inclusion criteria, of whom 63 participants were allocated to IG (see Fig. 1). The present sample comprised multi-morbid, sedentary, cognitively, and physically impaired older adults with more than the half showing apathetic symptoms (for sample description see Table 1).

Fifty-four subjects completed the intervention program and were therefore eligible for analyses of adherence and acceptance of the program. Reasons for dropout were death, fall-related fractures, and other serious medical events unrelated to the intervention program. When dropouts ($n = 9$) were compared with those participants who stayed in the study until the end of the intervention ($n = 54$), no significant differences in baseline characteristics were found ($p >$ .05), except for age ($M = 86.2$, SD = 4.0 years [dropouts] vs. $M = 81.5$, SD = 5.9 years [completers]; $p < .025$) and physical performance (SPPB total score, $M = 4.0$, SD = 1.3 [dropouts] vs. $M = 5.7$, SD = 2.2 [completers]; $p < .030$).

Feasibility of social support and goal-setting

In those participants completing the study, in median 5 (IQR = 5–5) home visits and 9 (IQR = 8–10) telephone calls were conducted. Goal-setting was feasible for 62 participants. Comprehensive feasibility was achieved in 57 individuals and partial feasibility in 4 persons. Due to cognitive deficits, one participant was not able to engage in goal-setting. Mean time to complete goal-setting was 11.3 min (SD = 3.1), with a range of 6–19 min.

More than half of the participants ($n = 35$, 55.6%) rated “washing and having a shower” the most important indoor activity, followed by “cooking a meal” ($n = 21$, 33.3%) and “doing housework” ($n = 4$; 6.3%). Going to the “doctor/pharmacy” was the most rated out-of-home-activity ($n = 24$, 38.1%). Just slightly fewer participants ranked “doing shopping” the highest priority outdoor walking ($n = 18$, 28.6%). Key motor functions were rated as highly important, while the level of perceived competence was comparatively low. The chance of success to improve present abilities was in between the level of perceived competence and the level of importance (see Table 2).

Adherence

Of the 54 study completers, three subjects were excluded from analyses of adherence to training and motivational

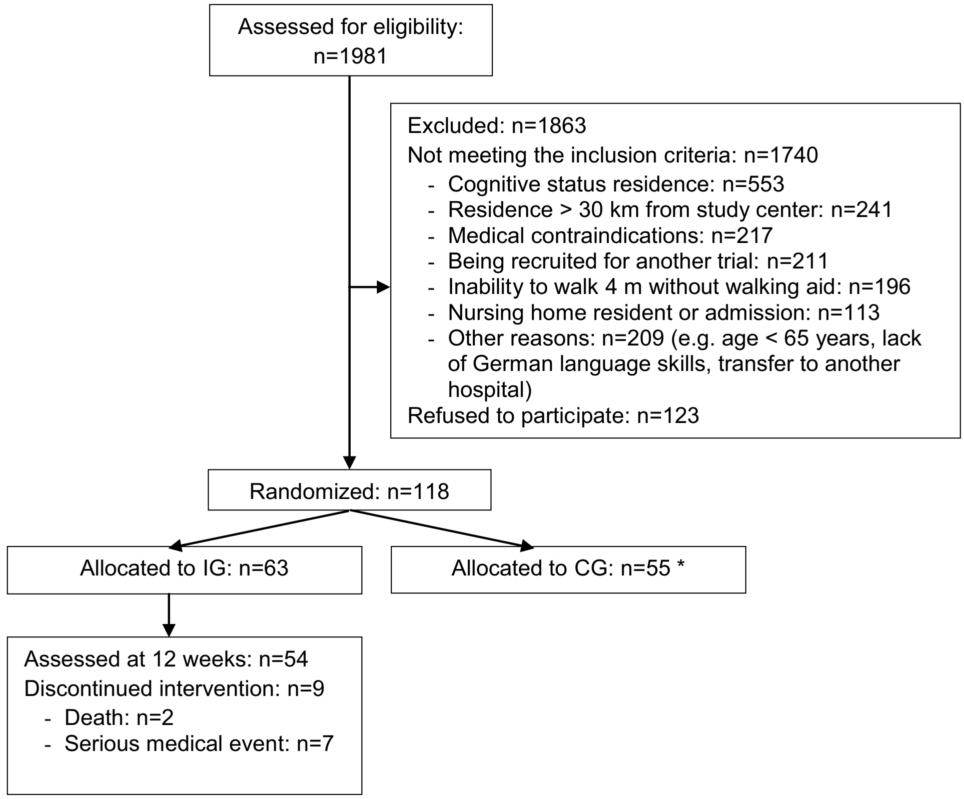

Fig. 1 Flowchart of the recruitment process and course of the intervention trial. *IG* intervention group. *CG* control group, *As the participants in the CG did not receive the physical training and motivational strategies to promote physical activity as the core of the present article, the CG was not included in the analysis

Table 1 Baseline characteristics of intervention group

Characteristics	Intervention group (N = 63)
Age (years), *M* (SD)	82.2 (5.8)
Sex, females, *n* (%)	48 (76.2)
Educational level (low/middle/high), %	33.3/47.6/19.0
MMSE, score (range 0–30), *M* (SD)	23.3 (2.7)
Number of diagnoses, *M* (SD)	11.3 (3.6)
Number of medication, *M* (SD)	9.4 (3.3)
SPPB, total score (range 0–12), *M* (SD)	5.4 (2.1)
Habitual gait velocity (m/s), *M* (SD)	0.50 (0.21)
Number of steps/day, *Mdn* (IQR)[a]	2662.5 (1175.1–4686.5)
Geriatric Depression Scale, score (range 0–15), *M* (SD)	5.2 (3.0)
The presence of apathetic symptoms (AES-C score > 40.5), *n* (%)	33 (52.4)

M mean, *SD* standard deviation, *Mdn* median, *IQR* interquartile range, *MMSE* mini-mental state examination; *SPPB* short physical performance battery; *m/s* meters per second, *AES-C* apathy evaluation score clinical version

[a]$n = 62$, missing sensor-based activity data for one person

strategies due to impaired vision ($n = 1$), not able to write in German language without support by others ($n = 1$), and loss of training log ($n = 1$).

Adherence to physical training and outdoor walking

Mean adherence rates over the total 12-week intervention period were 63.6% (SD = 33.8) for physical training and 57.9% (SD = 35.2) for outdoor walking, with about half of the participants exhibiting high (≥ 66.7%) adherence rates (physical training: $n = 26$, 51.0%; outdoor walking: $n = 23$, 45.1%). Adherence to physical training and outdoor walking was highest at the beginning of the intervention, showing significant declines over the intervention period ($p \leq .001–.019$) (see Fig. 1; see Table 3).

Adherence to motivational strategies

Mean adherence rates over the intervention period were 40.1% (SD = 38.5) for achievement of walking goals and 60.1% (SD = 37.7) for self-monitoring by pedometers, with half of the participants displaying high adherence to self-monitoring ($n = 26$, 51.0%) and 18 individuals (35.4%) highly adhering to goal achievement. Adherence rates to self-monitoring by pedometers ($M = 66.7\%$, SD = 41.8) and goal achievement ($M = 43.4$, SD = 40.7) were also highest at the intervention start and decreased over time, whereas the decline was significant for self-monitoring by pedometers ($p = .017$) and was close to level of significance for goal achievement ($p = .098$) (Fig. 2).

Table 2 Subjective importance, competence, and chance of success of key motor functions

	Importance (range 0–100)			Competence (range 0–100)			Chance of success (range 0–100)		
	n	*M*	(SD)	*n*	*M*	(SD)	*n*	*M*	(SD)
Standing	56	83.0	(17.2)	62	55.6	(22.0)	61	73.4	(20.2)
Walking	59	84.2	(20.4)	62	53.0	(23.0)	58	72.5	(19.2)
Sit-to-stand transfer	59	86.6	(13.4)	62	61.6	(21.4)	58	79.2	(17.4)
Walking stairs	59	82.7	(23.3)	62	52.0	(25.0)	58	72.1	(21.1)

M mean, *SD* standard deviation

Table 3 Adherence to physical training, outdoor walking, and motivational strategies over the total intervention period, at week 2, and week 12

Adherence Parameters	Total (Week 1–12)	Week 2	Week 12	Difference week 2 vs. 12
	M % (SD)	*M* % (SD)	*M* % (SD)	*p* value
Training	63.6 (33.8)	76.8 (32.7)	51.5 (47.9)	< .001***
Outdoor walking	57.9 (35.2)	61.6 (38.2)	46.5 (45.1)	.019*
Achievement of walking goals	40.1 (38.5)	43.4 (40.7)	36.1 (46.4)	.098
Self-monitoring by pedometers	60.1 (37.7)	66.7 (41.8)	51.5 (49.5)	.017*

M mean, *SD* standard deviation; adherence as mean percentage during total intervention, week 2 and week 12 in intervention group with complete adherence data based on training log (n=51); *$p < .05$, **$p < .01$, ***$p < .001$ based on paired t tests to test for differences between week 2 and 12

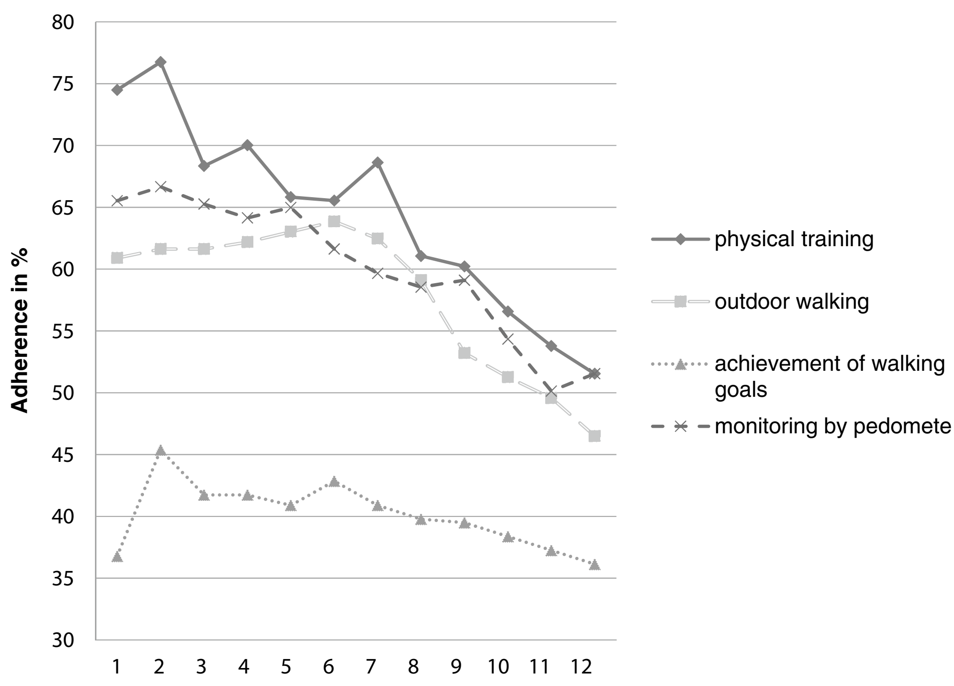

Fig. 2 Weekly adherence to the home-based physical activity promotion program

Acceptance

Questionnaire data to evaluate the patient-rated acceptance of the program components were available for 53 participants, as one study completer did not send back the questionnaire. Regarding the feasibility, the highest rated program component was physical training (M = 3.3, SD = 0.9, 83%).

The components walking-related goal-setting (M = 3.0, SD = 1.2, 73.0%), self-monitoring by pedometers (M = 3.1, SD = 1.2, 68.2%), and outdoor walking (M = 2.9, SD = 1.1, 67.9%) were also rated to be feasible by the majority of the present sample. The participation in the training group was only rated as feasible by six persons (M = 1.3, SD = 1.0, 11.8%), but those who were able to participate in the center-based group rated this component as effective (M = 3.7, SD

= 0.8, 85.7%). Home visits (M = 3.6, SD = 0.8, 90.6%) and phone calls (M = 3.1, SD = 1.1, 79.2%), which were delivered by professionals, achieved highest rates for effectiveness. Self-monitoring by pedometers was the component rated as the least effective (M = 2.9, SD = 1.2, 63.5%) (see Table 4).

Discussion

The present results describe a successful home-based program to promote PA in cognitively and physically restricted community-dwelling older persons post-discharge from ward-rehabilitation. All program components achieved high acceptance leading to an initially high adherence to autonomously performed physical training, outdoor walking, and to the frequent uptake of the motivational strategies of goal-setting and self-monitoring which declined over time.

Physical training and outdoor walking

Adherence to home-based, self-performed physical training was initially high, indicating good feasibility of the individually tailored home-based approach. Within a previous home-based physical exercise program following discharge from rehabilitation including a mixed sample concerning cognitive status, the adherence in individuals with CI was lower compared to their cognitively intact counterparts (Moseley et al. 2009). This emphasizes the challenge to ensure high adherence to autonomously performed physical training in this vulnerable group.

Study results were comparable to the adherence rates of an exercise in sample of cognitively impaired and non-impaired individuals following discharge from rehabilitation (Salpakoski et al. 2014), to caregiver-supported functional training (Prick et al. 2016; Suttanon et al. 2013; Taylor et al. 2017), and walking programs in community-dwelling persons with CI (Lowery et al. 2014; McCurry et al. 2005).

We assume that the individual tailoring of the physical training and planning of a walking path respective to participants' physical abilities and environmental conditions as applied in the present study potentially facilitated high initial adherence. Study participants lived in the urban area in and around the city of Heidelberg, a university town with no major environmental barriers, easy access to public transportation and a wide variety of green areas. These environmental characteristics refer to a high perceived walkability which is associated with low concerns to fall and higher levels of PA (Harada et al. 2017). The initially high adherence to training declined over time simultaneously with the decreasing frequency of our home visits confirming decreasing adherence rates in previous PA studies in diverse samples of older adults (Cox et al. 2013; Taylor et al. 2017). This finding might indicate the need of continuous supervision of training especially in multi-morbid populations.

Motivational strategies

The autonomous engagement in PA without any external supervision has so far been promoted only in populations with subjective memory complaints, representing cognitively less affected individuals (Cox et al. 2013; Dannhauser et al. 2014; Lautenschlager et al. 2008). Only one of these studies tested the adherence to a comprehensive motivational approach by reporting the completion rate of worksheets in a PA promotion program, but not the adherence to the specific strategies, documenting a modest adoption of a motivational concept into participants' daily routines (Cox et al. 2013). In contrast, the present study allows a detailed insight into different motivational strategies, documenting a comparatively high feasibility and adherence considering the sample of sedentary older adults with low functional fitness,

Table 4 Subjective feasibility and efficacy of program components

Intervention component	*M* (SD) (range 1–4)	% of participants with feasibility score ≥ 3	*M* (SD) (range 1–4)	% of participants with effectiveness score ≥ 3
Physical training	3.3 (1.0)	83.0[a]	3.4 (1.0)	78.3[a]
Outdoor walking	2.9 (1.1)	67.9[a]	3.1 (1.1)	75.0[b]
Goal-Setting	3.0 (1.1)	73.0[c]	3.1 (1.1)	75.0[b]
Self-monitoring by pedometers	3.1 (1.2)	68.2[d]	2.9 (1.2)	63.5[d]
Training group	1.3 (1.0)	11.3[e]	3.7 (0.8)	85.7[f]
Home visits	n.a.	n.a.	3.6 (0.8)	90.6[b]
Phone calls	n.a.	n.a.	3.1 (1.1)	79.2[b]

Presented are mean scores and standard deviations on the feasibility and effectiveness of the implemented program components as well as the proportion of participants with scores ≥ 3

M mean, *SD* standard deviation, *n.a.* not applied

[a]*n* = 53; [b]*n* = 52, [c]*n* = 48; [d]*n* = 50, [e]*n* = 47; [f]*n* = 7

moderate depressive, and high apathetic symptoms. Deteriorating physical function was identified as main barrier for adherence to a PA program in older adults after discharge from ward-rehabilitation (Fairhall et al. 2012). Depressive symptoms and apathy are psychological correlates showing close associations with decreased levels of PA among individuals with CI (David et al. 2012; Yuenyongchaiwat et al. 2018). In consideration of these PA-related barriers in our vulnerable sample, the adherence to motivational strategies over the intervention period can be rated as high.

Goal-setting

The comprehensive approach of goal-setting, including the identification of goals as measure of feasibility and the achievement of goals as measure of adherence, showed heterogeneous results in the present study. The high rate of identified goals indicated feasibility of the structured goal-setting approach, while the rate of achieved goals was considerably lower. These results are in line with the studies testing the feasibility and the adherence of goal-setting in diverse older populations including persons with CI (Kerse et al. 2008) and without CI (Fairhall et al. 2012; Smit et al. 2018; van Seben et al. 2019).

The present positive results with respect to the identification of goals in the present study indicate that individuals with CI may have profited from the use of talking mats as previously demonstrated (Murphy et al 2005), representing a structured, nonverbal strategy, while more complex instruments have shown limited feasibility in patients with CI (Stevens et al. 2013). With the talking mat method also problems in goal-setting were avoided as experienced by stroke patients with communicative and cognitive problems, which reported the goal-setting process be driven by the therapist rather than participants (Smit et al. 2018). Considering those findings, it was remarkable that the participants of the present study were able to give reliable information about the priority of goals and the subjective importance, control, and chance of success of key motor functions. Study results contrast to a previous study which reported problems to formulate specific and realistic behavioral goals in reports of geriatric patients without CI (van Seben et al. 2019).

While the identification of subjective goals represents a relevant but not sufficient objective, it is the transfer into action which is crucial to test the effectiveness of motivational strategies. In the present study, the rate of achieved walking goals was moderate, confirming previous studies on adherence to walking goals in older adults without (Fairhall et al. 2012) and with CI (Kerse et al. 2008). The discrepancy between high rate of identified goals and a moderate rate of achieved walking goals may emphasize the difficulty to implement the initially set goals into daily routines due to the high physical restrictions in the group of geriatric patients with CI. The high presence of functional deficits in the transitional stage after admission to home environment may have led to a shift of goals over time, as some individuals tended to choose too ambitious long-term goals after discharge from ward-rehabilitation given their physical abilities (van Seben et al. 2019). These individuals may have set their activity goals based on their prior abilities to perform activities of daily living before hospitalization, which resulted in these goals being unrealistic in the stage post-discharge from ward-rehabilitation. This could also be true for some individuals in the present study who highly ranked outdoor goals (e.g., going to the doctor), which were not viable for them in consideration of their degree of functional restrictions.

The only moderate rate of adherence to walking goals over the intervention period might explain the limited effects of goal-setting on physical function during geriatric inpatient rehabilitation, as demonstrated by a recent meta-analysis (Smit et al. 2019). Therefore, future interventions might incorporate standardized instruments to continuously monitor the adaption of initially set goals, which could help to optimize strategies to realize walking goals into practice and therefore to increase adherence to goal-setting over time.

Self-monitoring by pedometers

In the present study, self-monitoring of activity behavior by pedometers was shown to be a useful tool to increase motivation to PA for most participants as indicated by high adherence and acceptance.

Previous pedometer-based interventions to promote PA in persons with CI showed heterogeneous results with respect to the impact on PA, albeit they did not test the daily adherence (Logsdon et al. 2009; Vidoni et al. 2016). In one study, a high rate of dropouts limited the efficacy of a technology-assisted pedometer driven intervention, also leading to limited efficacy (Vidoni et al. 2016). The study by Logsdon et al (2009) also reported a restricted manageability of such technical advices due the lack of fine motor skills and memory complaints in some participants with more severe CI, whereas usability was adequate for the majority of participants leading to increased PA-levels. Since the primary purpose of the pedometer was to provide feedback and to increase the participant's motivation rather than measuring the true walking distance, we selected simple to use and robust pedometers to achieve high self-perceived feasibility.

Social support

In the present study, professional social support as documented for home visits and telephone calls was highly appreciated in the vulnerable group of participants, confirming results from previous qualitative studies conducted in persons with

CI (Olsen et al. 2015; Phillips and Flesner 2013; Suttanon et al. 2012). The face-to-face contact within home visits was rated as the most effective program component in this PA program. This finding indicates that health care professionals may serve as a valuable source to provide information how to perform training and which benefits can be expected (Olsen et al. 2015). High subjective effectiveness of phone calls also supports previous results which also demonstrated high satisfaction with phone calls in older adults without CI (Rosenberg et al. 2012) and with subjective CI (Cox et al. 2013). The trainers in our program were skilled in CI-specific communication, which might be a key strategy of the successful implementation of home visits as rated by participants. Positively framed messages focusing on the benefits of PA behavior may have induced elevated motivation to PA compared to negatively framed messages informing about the risk of being non-active (Notthoff et al. 2016). Such supportive communication, including positive reinforcements, has the potential to strengthen the perceived competence to exercise in a group of cognitively impaired persons (Tortosa-Martínez et al. 2017).

The provision of frequent external sources of motivation as provided by a more continuous supervision might be a key factor for the maintenance of adherence to PA in this trial. The program implementation by peers or lay trainers as trustful training partners and motivators is recommended as a promising strategy to increase the participant's self-efficacy and to ensure maintenance of PA within older adults (Matz-Costa et al. 2019). A regular frequency of contact with professionals was effective in PA promotion in nursing home residents (Jansen et al. 2015) as well as in sedentary community-dwelling women (Poulsen et al. 2007).

Limitations

One limitation of the present study is the relatively small sample size explicitly including participants of the intervention group. As the control group was not included in the intervention program, no information about adherence was available in the control condition. Our analysis of adherence was based on self-reports which may represent a limiting factor for the accuracy of adherence to PA in elderly with CI (Visser et al. 2014). As adherence to training and outdoor walking only included the daily frequency of exercise, physical training, and outdoor activities executed several times per day were not considered, with the potential consequence of underreporting actually performed PA.

Conclusion

Study results indicated a comparatively high adherence to the present PA promotion program proving the feasibility of the individually tailored program in vulnerable, multi-morbid persons with relevant motor and cognitive impairment. Successful participation was further documented by high patient-rated feasibility and effectiveness of the program components. Continuous supervision delivered by professionals might constitute an essential ingredient for maintaining adherence to PA promotion in elderly with multiple restrictions, as this study revealed a decline of adherence to the intervention program concomitant with decreasing frequency of home visits.

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Compliance with ethical standards

Conflicts of interest The authors have no conflicts of interest to declare.

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Publikation VII

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Research Article

Increasing Life-Space Mobility in Community-Dwelling Older Persons With Cognitive Impairment Following Rehabilitation: A Randomized Controlled Trial

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Abstract

Background: Community-dwelling older persons with cognitive impairment (CI) following discharge from geriatric rehabilitation are at high risk of losing life-space mobility (LSM). Interventions to improve their LSM are, however, still lacking. The aim of this study was to evaluate the effects of a CI-specific, home-based physical training and activity promotion program on LSM.

Methods: Older persons with mild-to-moderate CI (Mini-Mental State Examination: 17–26 points) discharged home from rehabilitation were included in this double-blinded, randomized, placebo-controlled trial with a 12-week intervention period and 12-week follow-up period. The intervention group received a CI-specific, home-based strength, balance, and walking training supported by tailored motivational strategies. The control group received a placebo activity. LSM was evaluated by the Life-Space Assessment in Persons with Cognitive Impairment, including a composite score for LSM and 3 subscores for maximal, equipment-assisted, and independent life space. Mixed-model repeated-measures analyses were used.

Results: One hundred eighteen participants (82.3 ± 6.0 years) with CI (Mini-Mental State Examination: 23.3 ± 2.4) were randomized. After the intervention, the home-based training program resulted in a significant benefit in the Life-Space Assessment in Persons with Cognitive Impairment composite scores (b = 8.15; 95% confidence interval: 2.89–13.41; p = .003) and independent life-space subscores (b = 0.39; 95% confidence interval: 0.00–0.78; p = .048) in the intervention group (n = 63) compared to control group (n = 55). Other subscores and follow-up results were not significantly different.

Conclusions: The home-based training program improved LSM and independent life space significantly in this vulnerable population. Effects were not sustained over the follow-up. The program may represent a model for improved transition from rehabilitation to the community to prevent high risk of LSM restriction.

Keywords: Clinical trials, Exercise, Home care, Physical activity, Post-ward rehabilitation

Life-space mobility (LSM) refers to the ability to move within one's environment, such as one's home, neighborhood, town or areas beyond, and considers the extent and frequency of moving, and the need for assistance in order to be mobile (1,2). The ability of moving, whenever and wherever a person wants to move, is relevant for activities of everyday life (3), social participation (4), quality of life (5), and is of high personal relevance for frail older persons (6,7). A reduced LSM can have severe consequences for older persons' lives, as it is associated with adverse health outcomes such as functional impairment (8), falls and fractures (9), institutionalization (10), and increased mortality (11). Mobility also contributes to healthy aging (12). Outdoor mobility is mandatory for maintaining physical function in frail older persons (8,13,14).

Multimorbid older persons with cognitive impairment (CI) recently discharged home from inpatient rehabilitation settings are associated with numerous factors that negatively affect LSM, such as advanced age, physical impairment (15), CI (15,16), and recent hospitalization (17), resulting frequently in severely restricted LSM (18,19). Despite the feasibility of interventions to improve physical function after hospitalization (20), interventions to support transition from hospital to home settings often excluded persons with CI (21,22). In particular, mobility in and around the home as well as social participation, aspects that are all covered by LSM, represent important care gaps in the postdischarge phase for vulnerable older persons (23).

Previous randomized controlled trials (RCTs) with LSM as a study outcome did not focus on the transition phase after hospitalization (24–32) and/or excluded or did not focus on persons with CI (24–27,33). In those RCTs that did include cognitively impaired persons, CI and its sequelae were not specifically addressed, although the presence of CI is associated with relevant behavioral and cognitive changes. These changes require adaptations of intervention programs (34), such as the implementation of adequate motivational strategies, including CI-specific communication, goal setting, barrier management, and self-monitoring strategies to foster a change of activity-related behavioral patterns with a focus on sustainability (35). This is of particular relevance if individuals live independently in the community with limited social support. Hence, it is not surprising that we identified only one RCT that included persons with CI and evaluated a home-based training approach in a community setting (30).

Beyond the lack of comparable RCTs with respect to population, setting, and timing of the interventions, there is limited evidence of the effectiveness of existing interventions on LSM. Study results were heterogeneous, with only a few studies documenting improvements on LSM (29,30,33), while most studies reported no significant effects on LSM (24–28,31,32). Effects on life space, focusing solely on the spatial distance from home and allowing a detailed insight on the area achieved with and without support, are not reported. Follow-up studies are scarce, and sustainable effects on LSM following the end of training have not been shown (25,26,28,29). None of these studies included interventional strategies to promote habitual, autonomous physical activity with a clear focus on the sustainability of intervention effects on LSM after cessation of active programs.

Within the context of heterogeneous results on the effect of interventions on LSM, as reported in previous RCTs, the analyses of factors that may influence training response are of high clinical relevance. The outcome is a better understanding of the training impacts, contributing to the development of future studies to improve LSM, which in turn can enhance treatment effectiveness, or improve the selection of persons with a larger likelihood of response to an LSM-enhancing program. Analyses in previous studies included adherence as a measure of training response (30,32) and additionally cognition and frailty (30). An evidence-based, comprehensive analysis including a wide range of potentially relevant predictors of training response, such as cognitive, psychosocial, physical, and sociodemographic factors, all of which have been identified to influence LSM in a comprehensive theoretical mobility model (2) and through an epidemiological study (18), has been lacking.

The aim of this study was to determine whether a standardized, home-based training and activity promotion program, specifically developed for persons with CI after discharge from rehabilitation, can improve LSM and whether intervention effects can be sustained during follow-up in this vulnerable population. Additionally, feasibility aspects of the intervention and predictors of training response for LSM were investigated.

Method

The present study analyzed secondary outcomes of a single-center double-blinded, randomized, placebo-controlled 12-week intervention trial with a 12-week follow-up period to improve physical function and physical activity in older persons with mild-to-moderate CI, recently discharged home from geriatric rehabilitation in Heidelberg, Germany (http://www.isrctn.com/ISRCTN82378327). Neither the assessors nor the participants were aware of group identity. The RCT was performed according to the Helsinki declaration and was approved by the ethics committee of the Medical Department of the Heidelberg University (S-252/2015). The study design and methods were previously described in detail (36).

Participants

Older people (aged ≥65 years) with mild-to-moderate CI as indicated by a Mini-Mental State Examination (MMSE) score of 17–26 (37,38) were consecutively recruited from rehabilitation wards of a geriatric hospital during an individualized multidisciplinary, geriatric rehabilitation program consisting of physiotherapy, occupational therapy, language and speech therapy, psychological and social support and counseling according to the individual patient needs. Further inclusion criteria were the ability to walk at least 4 m without walking equipment as a safety criterion for independent, unsupervised training at home; residence within 30 km of the study center; discharge to community settings; no terminal disease or severe medical conditions; no delirium; adequate language level; written informed consent. Individuals meeting these inclusion criteria were allocated using urn randomization (39) stratified by gender to either a home-based intervention group (IG) or a home-based control activity group (CG) after baseline assessment with a 1:1 allocation rate.

Intervention

The home-based training program of the IG was specifically tailored for geriatric patients with CI after geriatric rehabilitation and has been shown to be feasible and effective to improve physical function and physical activity in older adults with CI in a pilot study (40). As the intervention program included a multimodal activity promotion program, we hypothesized an intervention-based positive effect on LSM.

The training included 3 balance and 3 strength exercises, allowing the proper progression of intensity, and an individualized walking course in the participants' immediate home environment to enhance physical activity (36). Individual walking courses, as part of the activity promotion program, were tested together with trainers to ensure training stimulus, to prevent exhaustion, and to familiarize the participants with walking equipment as well as characteristics and safety aspects. Participants were instructed to independently perform the training and walking course as a daily routine depending on the participants' functional status and motivation. A large poster with the exercises and a printed manual, which were deliberately designed to be simple and easy to follow, were issued to each participant. The training was amended by a

CI-specific motivational approach developed to support training adherence and behavioral changes, including validation, social support, goal setting, identification and removal of barriers to exercise and walking, and self-monitoring via a training diary and pedometer (35). The intervention was implemented and the training progress was supported by trained sports scientists experienced in geriatric rehabilitation.

Participants in the CG received a training manual including unspecific flexibility and strength exercises in a sitting position at home and newsletter-based information on nutrition and relaxation.

All participants, including those of the CG, were supported by 5 home visits with decreasing frequency and weekly phone calls. The CG received the same amount of support to control for psychosocial effects induced by the visits of the trainers or regular phone calls. During the follow-up period, both groups did not receive any support or contact.

Measurements

The assessments were performed after discharge from rehabilitation in the participants` home before randomization (T1), at the end of the 12-week training period (T2), and after the 12-week follow-up period (T3). Sociodemographic characteristics including age, gender, and number of diagnoses and medications were documented from patient charts at discharge. Educational status, marital status, and history of falls in the previous year were assessed by standardized interviews. Physical function was assessed with the Short Physical Performance Battery (SPPB) (41). To assess psychosocial status, the Geriatric Depression Scale Short Form (GDS-SF) (42), the Apathy Clinical Evaluation Scale—Clinical Version (AES-C) (43), and Short Falls Efficacy Scale—International (Short-FES-I) (44) were used. Physical activity (documented by the number of steps) was determined using a validated activity monitor attached to the participants' chest for a 48-hour assessment period (PAMSys; BioSensics, Cambridge, MA) (45). Adherence was assessed in the IG as part of the motivational strategy using training diaries filled by the participants, considering the number of days with training, outdoor walking, achieved walking goals, and self-monitoring by pedometer (35).

LSM was assessed by the Life-Space Assessment in Persons with Cognitive Impairment (LSA-CI) representing an interview-based, self-report measure that has been specifically developed and successfully validated for use in older persons with CI (46). The LSA-CI extends the original University of Alabama at Birmingham Life-Space Assessment (UAB-LSA) (1) by an adjusted interview strategy, taking into account the resources and limitations of older persons with CI (ie, informal conversation, precise questions, and response options, structuring the observation period, highlighting landmark events). The assessment period is also condensed from 4 weeks to 1 week to reduce recall bias. The LSA-CI assesses LSM in 6 life-space zones (from bedroom = 0, home = 1, immediate surroundings of one's home = 2, neighborhood = 3, home town = 4 to unlimited area = 5) within the previous week, the frequency of mobility for each zone (1 point: 1–3 times per week, 2 points: 4–6 times per week, and 3 points: daily), and the assistance needed to travel within a zone (1 = "help of another person," 1.5 = "use of equipment only," and 2 = "no assistance"). A composite score, representing total LSM, is calculated by multiplying the zone score with scores for frequency and assistance and adding the scores for each zone. Zero indicates total immobility and 90 indicates daily independent out-of-town mobility. Three additional subscores document the spatial reach, including maximal life space (LSA-CI-M; independent, with equipment or personal support), equipment-assisted life space (LSA-CI-E; independent or with equipment), and independent life space (LSA-CI-I; without equipment or personal support) achieved within the previous week (each range 0–5).

Statistical Analysis

This study presents a secondary analysis of existing data and therefore the calculation of the required sample size is based on a different outcome. The details of the sample size calculation were reported in the work of Bongartz et al. (36). Taking into account an expected drop-out rate of 15%, a total of n = 116 participants with equal allocation was targeted. This study focused primarily on the intervention's effect on the LSA-CI composite score. The associated subscores were also examined.

Descriptive data were presented as absolute and relative frequencies for categorical variables and mean and standard deviation or median and range for continuous variables as appropriate. Unpaired t tests and Mann–Whitney U tests were applied to determine differences between participants who did not complete the intervention or the follow-up period.

To address the main research question, a linear mixed-model repeated-measures analysis was used to model the LSA-CI measures and compare the differences across groups and changes over time (47–49). The mixed-effects model therefore included group (IG vs CG) and time (T1, T2, and T3), as well as its interaction, and the covariates gender and baseline LSA-CI scores as fixed effects. Gender was included as a covariate because it was part of the randomization mechanism. Participants were treated as a random effect. The within-group correlation of participants across different time points was estimated from the data using a general structure. The model was estimated using restricted maximum likelihood which, following the intention-to-treat (ITT) principle, handles missing data and includes all randomized participants (50). We provided the model-based group effects in mean change with 95% confidence intervals and associated p values. Using the model-based means, group trajectories were also graphically displayed in an interaction plot. While the focus was on the LSA-CI composite score, the same modeling strategy was also applied to its subscores.

Analyses with respect to clinically relevant categories (increased, decreased, or stable LSM or life space) and thresholds (the ability to move outside the neighborhood using equipment if needed (1) and the ability to move outside the own bed independently (8,13)) were presented descriptively, including only available cases.

To determine predictors of training response, bivariate correlational analyses (Spearman [r_s] and point-biserial [r_{pb}] correlation coefficients) were performed between LSM changes (LSA-CI composite score between T1 and T2) of the IG and potentially associated variables. Variables that have been shown to determine LSM in a comprehensive model for mobility (2) and a cross-sectional study in the target group (18) included sociodemographic factors (age, gender, marital status, educational level, number of diagnoses, and medications), cognitive status (MMSE), physical function (SPPB, falls in the previous year), psychosocial status (Short FES-I, GDS, AES-C), physical activity (number of steps), baseline LSM, and variables for adherence to the training (number of days with training, outdoor walking, achieved walking goals, and pedometer use) (35). The variables with significant correlations of $p < .01$ were considered for the standard linear regression analysis to examine independent determinants of LSM. In this analysis, missing data were handled by pairwise deletion.

Except for the aforementioned variable selection process in the sensitivity analyses, $p < .05$ (two-sided) was considered statistically significant. Reported p values are to be interpreted as descriptive. Statistical analyses were performed using R version 3.6.1 (51) and IBM SPSS Statistics version 23 for Windows (IBM Corp., Armonk, NY).

Results

Recruitment

Out of 1981 persons screened for eligibility, n = 118 participants were enrolled according to the predefined inclusion criteria between August 2015 and April 2017. Primary causes for exclusion were inappropriate cognitive status (n = 553), residence more than 30 km from study center (n = 241), and medical contraindications (n = 217; Figure 1).

Study Sample

The study sample included multimorbid (medical diagnoses: n = 11.4 ± 4.4) older persons (82.3 ± 6.0 years) with cognitive (MMSE score: 23.3 ± 2.4 points) and physical impairment (SPPB score: 5.2 ± 2.3 points). Sixty-three participants were randomized to the IG and 55 to the CG. Baseline characteristics were balanced between the groups (Table 1). The main reasons for hospital admission were predominantly related to cardiovascular diseases (20%), degenerative joint diseases (18%), neurological diseases (16%), and consequences of falls (14%). Dropouts (attrition rate: 11% at T2 and 22% at T3) were related to serious medical events (n = 12), death (n = 4), lack of motivation (n = 8), loss of contact (n = 1), or refusal of relatives (n = 1; Figure 1) and were evenly distributed between the study groups (dropouts from each group n = 13). Adverse events were related to preexisting comorbidities and not directly or indirectly attributable to the training program. When participants who stayed in the study until the end of follow-up (n = 92) were compared with those who dropped out (n = 26), no significant differences for any baseline variables were found except for physical function and apathetic symptoms (Supplementary Table S1). Absolute results for the measurements are given in Supplementary Table S2.

Effects of the Intervention

At the post-intervention measurement, the mean treatment effect for the LSA-CI composite score resulted in a significant benefit of 8.15 score points for the IG compared to the CG (95% confidence interval [CI] 2.89–13.41, p = .003; Table 2). A significant improvement in the IG compared to the CG by 0.39 score points could also be documented for 1 of 3 subscores of the LSA-CI, the independent life space (95% CI 0.00–0.78, p = .048). Benefits for the other subscores were not significantly different between the IG and CG (LSA-CI-M: Difference 0.33 score points, 95% CI −0.18–0.84, p = .208; LSA-CI-E: Difference 0.43 score points, 95% CI −0.11–0.98, p = .122). Training gains decreased after the intervention, with no significant differences between the groups during the follow-up period. The benefit observed in the LSA-CI composite score was 3.03 (95% CI −2.39–8.46, p = .274), with a range between −0.02 and 0.35 for the subscores (Table 2). The model-based trajectories of LSA-CI scores for the groups across the different time points are also graphically displayed in Figure 2 and Supplementary Figures S1–S3.

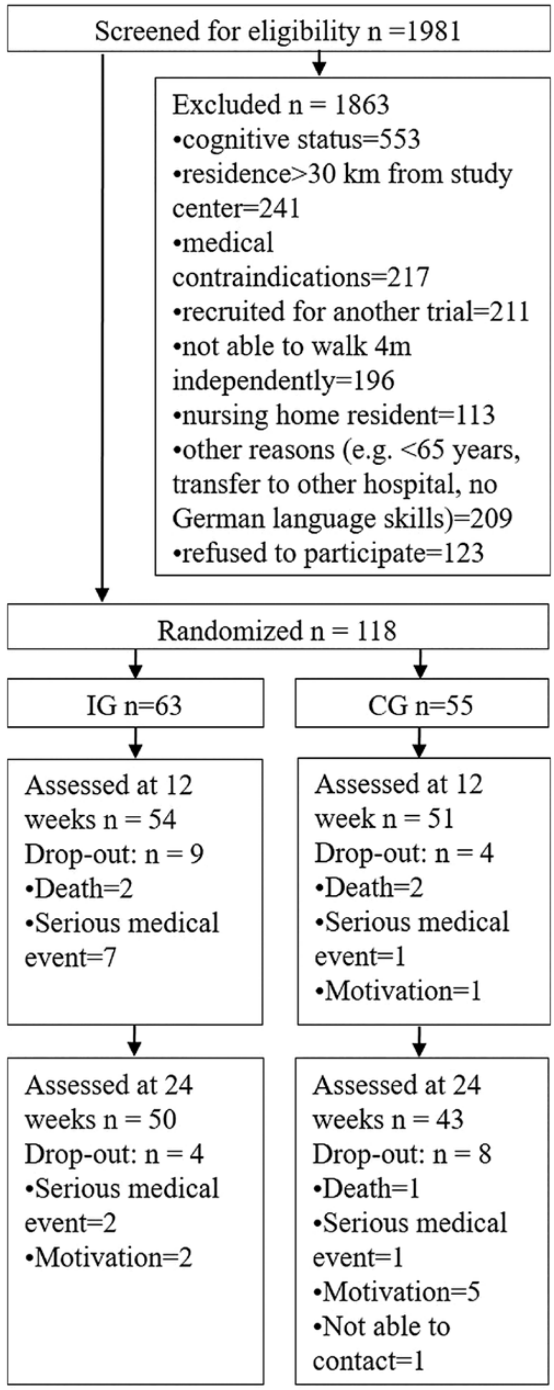

Figure 1. Flowchart of the screening process, enrollment, allocation, and follow-up of the study. CG = control group; IG = intervention group.

Additional Analyses

Results for changes in clinically relevant categories were also analyzed, to further describe the effects of the intervention. After the intervention, a considerably larger proportion of participants increased their LSA-CI composite score in the IG (75%) compared to the CG (40%), while decreases of the LSA-CI composite score were lower in the IG (19%) compared to the CG (44%). Similar results were achieved for the LSA-CI subscores: 36%–43% of participants of the IG in contrast to 16%–30% of the CG were able to improve their life space, and decrease of life space was shown for only 11%–17% participants of the IG versus 14%–22% of the CG (Supplementary Table S3). The number of individuals able to move beyond the immediate neighborhood (>life-space level 3) without personal assistance but with equipment, as well as the ability to get out of bed independently (≥ life-space level 1), increased in the IG (from 34% to 45% and from 58% to 72%), while the number of participants in the CG stagnated (from 18% to 20% and from 42% to 42%; Supplementary Table S4). The highest possible maximal life-space level 5 was achieved at baseline by 28% in the IG and 16% in the CG, indicating a potential ceiling effect for the subscore LSA-CI-M.

Predictors of Training Effects

Bivariate correlation analyses revealed baseline LSA-CI composite score ($r_s = -0.433$, $p = .001$), and adherence with respect to days with pedometer monitoring ($r_s = 0.471$, $p = .001$) to be significantly associated ($p \leq .01$) with a change in LSM during the intervention period (T1–T2; Supplementary Table S5).

In the regression model, baseline LSA-CI composite and adherence were identified as predictors of change in LSM for the intervention period and accounted for 21.8% of the variance (Table 3). Exclusion of subgroups according to baseline status did not alter our main findings. Results suggest a lower baseline LSM and higher self-monitoring by pedometer to be associated with higher training response for LSM.

Discussion

The present RCT demonstrates that the home-based physical training and activity promotion program were effective and improved LSM as well as independent life space in older multimorbid persons with CI in the phase after discharge from geriatric rehabilitation. However, effects decreased and were not significantly different after the follow-up period.

Effects of the Intervention

Participants in the IG improved the LSA-CI composite and independent scores, demonstrating the effectiveness of the trialed home-based training and activity promotion program, reflecting an increased spatial range of mobility, increased frequency of actual mobility behavior, and/or decreased use of assistance after the intervention period. An improvement of 8 score points for the composite LSM score corresponds, for example, with the ability to reach zone 3 (neighborhood) on 1–3 days a week with only equipment instead of being only mobile in zone 1 (own home); or with the ability to reach life space zone 4 (out of the neighborhood) instead of zone 3 (within the neighborhood) on most days of the week with personal assistance. From a clinical point of view, the surpassing of a previous life-space zone can be regarded as a notable and practically relevant improvement. These achievements suggest that the home-based training program might be effective to support autonomous living at home and to increase participation in the community in older adults with CI following discharge from rehabilitation, thus contributing to improvements in emotional well-being and overall quality of life (3–5). The success of the intervention might be due to its multimodal focus, targeting motivation, improvements of physical function, and physical activity promotion, with attention paid specifically to factors that have been shown to determine LSM in older adults with

Table 1. Baseline Sample Characteristics for Study Groups

Characteristics	IG (*n* = 63)	CG (*n* = 55)
Age (years), mean (*SD*)	82.2 (5.8)	82.4 (6.2)
Gender (female/male), %	76.2/23.8	76.4/23.6
Marital status (yes/no), %	27.0/73.0	34.5/65.5
Educational level*, %	33/48/19	29/53/18
Number of diagnoses (*n*), mean (*SD*)	11.3 (3.6)	11.4 (5.3)
Number of medications (*n*), mean (*SD*)	9.4 (3.3)	9.6 (3.7)
MMSE score (0–30), mean (*SD*)	23.3 (2.7)	23.3 (2.1)
SPPB score (0–12), mean (*SD*)	5.4 (2.1)	5.0 (2.4)
≤1 fall in the previous year, %	76	56
Short FES-I score (7–28), median (range)	11 (7–25)	11 (7–25)
GDS score (0–15), mean (*SD*)	5.2 (3.0)	5.4 (3.1)
AES-C score (0–54), mean (*SD*)	21.9 (8.9)	22.5 (9.5)

Notes: AES-C = Apathy Evaluation Scale—Clinical Version; CG = control group; FES-I = Falls Efficacy Scale—International; GDS = Geriatric Depression Scale; IG = intervention group; MMSE = Mini-Mental State Examination; *n* = number; SD = standard deviation; SPPB = Short Physical Performance Battery. Presented are baseline comparisons between study groups as randomized. Scoring range is given in bracket.

*Only school/vocational education/university or comparable.

Table 2. Model-Based Effects of the Intervention on Life-Space Mobility for the Postintervention (12 weeks) and Follow-up Period (24 weeks) in the IG (*n* = 63) Compared to the CG (*n* = 55)

	Model-Based Difference Between Groups Controlled for LSA-CI Baseline Score and Gender			
	Postintervention (12 weeks)		After Follow-up (24 weeks)	
	Mean difference (95% CI)	*p* Value[†]	Mean difference (95% CI)	*p* Value[†]
LSA-CI-C	8.15 (2.89 to 13.41)	**.003****	3.03 (−2.39 to 8.46)	.274
LSA-CI-M	0.33 (−0.18 to 0.84)	.208	−0.16 (−0.69 to 0.37)	.553
LSA-CI-E	0.43 (−0.11 to 0.98)	.122	0.35 (−0.21 to 0.90)	.220
LSA-CI-I	0.39 (0.00 to 0.78)	**.048***	0.29 (−0.15 to −0.72)	.195

Notes: CG = control group; CI = confidence interval; IG = intervention group; LSA-CI = Life Space Assessment in Persons with Cognitive Impairment, M = maximal life space (achieved independently, with equipment or another person), E = equipment-assisted life space (achieved independently or with equipment), and I = independent life space (achieved independently); *n* = number. Presented are data for the effects of the intervention for the measurement times post-intervention (12 weeks after baseline) and for follow-up (24 weeks after baseline).

[†]*p* Values are based on the mixed-model estimates and therefore controlled for gender and baseline LSA-CI.

Bold indicates statistically significant with *$p < .05$, **$p < .01$.

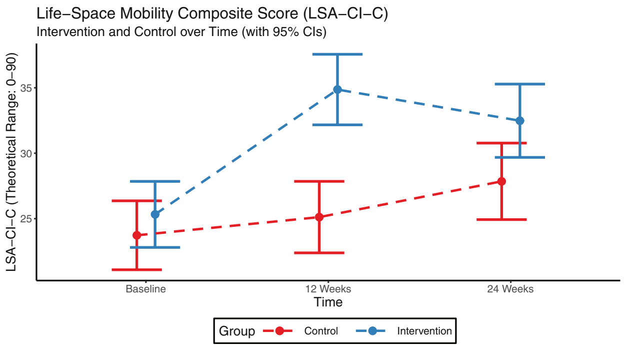

Figure 2. Life-space mobility (LSA-CI-C) results in the IG compared to the CG over time. *Note:* The model-based means for the life-space mobility composite score (LSA-CI-C) with 95% confidence intervals (CIs) in the IG compared to the CG over the measurements (baseline, postintervention, and after follow-up period) are presented. CG = control group; IG = intervention group; LSA-CI = Life-Space Assessment in Persons with Cognitive Impairment.

Table 3. Regression Model for Predictors of Change in Life-Space Mobility During the Intervention Period for the IG

Adjusted R^2			.218	
Variable	β	*B*	SE_B	95% CI for *B*
Baseline LSM (LSA-CI composite score)	−0.337*	−0.282	0.116	−0.516 to −0.049
Adherence (number of days with pedometer use)	0.296*	0.124	0.058	0.007 to 0.241

Notes: IG = intervention group; LSA-CI = Life Space Assessment in Persons with Cognitive Impairment; LSM = life-space mobility. Presented is linear regression analysis for the change in LSM (LSA-CI composite score of ΔT1–T2) with potential predictors for participants of the IG with completed intervention and complete adherence data (n = 53). The general fit of the model is reported by the adjusted coefficient of determination R^2. Effects are reported as unstandardized (*B*) and standardized regression coefficients beta (β).

Bold indicates statistically significant with $*p < .05$, $**p < .01$.

CI (18). Enrollment targets were achieved, despite the target group being difficult to reach and typically excluded from intervention trials (21,22). No adverse events were associated with the intervention, and the dropout rate was relatively low, considering the high age and impaired health status of the target population, indicating the feasibility of the intervention. Training adherence, as previously reported in detail (35), was slightly higher than in comparable RCTs on home-based training and LSM in predominantly cognitively intact persons (30,52), documenting the acceptance of the intervention in the study population. Previous RCTs evaluating LSM as an outcome measure reported no positive intervention effects (24–28,31,32), except for 3 RCTs specifically targeted at LSM improvements, which showed significant intervention-induced improvements in LSM (29,30,33). However, these RCTs did not focus on older people with CI (30,33) or were conducted in institutionalized settings (29). To the best of our knowledge, the present study is the first to demonstrate that LSM can also be increased by a home-based physical training and activity promotion program in cognitively impaired community-living older persons after geriatric rehabilitation. In all studies reporting positive intervention effects on LSM, the intervention was, as in the present study, implemented after a preceding acute medical event (29,30,33), resulting in an acute loss of LSM (17) with high opportunity for improvements in LSM. While this loss is associated with an urgent need to regain this highly relevant mobility domain, a low health status also represents a barrier to physical activity (53). A comprehensive intervention approach, with motivational strategies to encourage behavioral changes (eg, self-monitoring, goal setting, and barrier management) as applied in the present study, may be highly relevant to successfully promote LSM. Previous studies with similar intervention approaches also showed improvements in LSM (30,33). Studies without an individual specified motivational strategy (25,26,29,31) or with minimal individualized motivational strategies could not document such positive effects (24,27,28,32). This suggests that the successful implementation of CI-specific motivational strategies (35) was the key factor for the substantial benefits on LSM in the present study. None of the RCTs with LSM as a study outcome reported intervention effects on life space achieved with personal assistance, equipment, or independently, as represented by the LSA-CI subscores. Significant improvements in the IG, over the intervention period, for the independent life-space subscore underline the positive impact on the home-based training program. In line with previous research, assuming that the subscore for maximal life space (LSA-CI-M; with personal support and equipment) would not be sensitive to document intervention-induced changes (15), no significant benefits could be shown for this subscore, with a possible ceiling effect (54). For the equipment-assisted life space (LSA-CI-E), a significant effect could not be documented. However, the successful training of physical function can be reflected by the significant benefits in the independent life space (LSA-CI-I) after the intervention period. This indicates that the exercises of the home-based physical training program successfully improved physical function and autonomy. It can also be related to adaptive task modifications of walking, which has been shown to be a solution to postpone decline in outdoor mobility (55). Considering the health outcome priorities of multimorbid older persons, with independence cited as the most important outcome (6), the significance of independent life space as a relevant study outcome in this population becomes apparent. The additional analyses underline the positive impact on LSM induced by the intervention. The improvements in the IG with respect to clinically relevant categories (increased, decreased, or stable LSM or life space) compared to the slow recovery of LSM in the CG emphasize the trainability of LSM even in a multimorbid population. The IG program also led to advantages over the CG program regarding 2 clinically relevant thresholds. These are important, as the ability to be mobile beyond one's own neighborhood without personal assistance enables an individual to have independence in engaging in activities of everyday life or social participation (1). The ability to independently walk outside the home has been considered to be the minimum level of mobility to maintain physical function and mobility (8,13). Previous RCTs on LSM in older adults including long-term follow-up assessments of 12 weeks to 11 months showed no sustainable intervention effects on LSM in older adults (25,26,28,29). Similarly, benefits of the intervention also decreased in the present study with no significant differences in the IG and the CG after the 12-week follow-up period. Previous study results indicate that recovery of LSM after hospitalization is an ongoing process (17). The present study shows that recovery of LSM is modifiable, but suggests that ongoing support may be required to foster sustainable benefits on LSM.

The substantial increases of LSM and independent life space for large parts of the study population imply that the rehabilitation potential was not exploited—or not targeted—during ward-based rehabilitation. Our study results further suggest that LSM can be included as a crucial but also feasible objective for post-ward interventions to fully exploit rehabilitation potentials and to extend rehabilitation goals to activity behavior at home. This is particularly important, as maintaining mobility in and around the home has been shown to be of high personal relevance for vulnerable older persons (6,23).

Predictors of Training Effects

Lower LSM at baseline was identified as an independent predictor of improvement in LSM. This inverse relationship between the magnitude of benefits in LSM and the baseline LSM status is in accordance with the rate-dependency phenomenon and general training principles that indicate intervention response rates are highest in those individuals with the lowest baseline values (56,57). Because of their more restricted LSM, participants with the lowest LSM profit most, in cases where the inclusion and training of these most affected individuals are feasible.

High adherence as measured by pedometer monitoring was predictive for positive training response on LSM, which is in accordance with a previous study result on the influence of adherence on LSM change (32). The present study result adds to the evidence for the previously reported positive impact of pedometer monitoring as a successful motivational strategy on the mobility behavior of adults (58). Within the levels of mild-to-moderate CI, MMSE scores were not associated with the training response on LSM, which is in accordance with a previous study (30). In contrast to this previous study, which revealed an influence of frailty status on training response (30), surrogate markers for frailty, for example, physical impairment and multimorbidity, did not predict training response in the present study. Overall, our results suggest that a notable training response can be achieved despite relevant physical impairment and CI.

In spite of the evidence-based, comprehensive analysis of a wide range of potential predictors of training response, based on a complex mobility model (2) and a previous cross-sectional study of LSM determinants in the target population (18), identified predictors explain only parts of the total variance in the regression models.

Strengths and Limitations

The present study is the first to demonstrate the effectiveness of an activity promotion program for multimorbid older persons with functional and cognitive impairment, which are typically excluded, and difficult to reach. The feasibility of the intervention was the basis for its success and needs to be acknowledged with respect to the older, multimorbid study population. Influencing mobility behavior in this population is also difficult. The specific intervention, as well as the related assessment strategies, tailored to the multimorbid target population, enabled the complexities and challenges of this study population to be overcome, and lead to extended and more independent LSM. However, our study has limitations. The LSA-CI represents an assessment method relying on the self-reporting of participants. Although successfully validated in the multimorbid target group with motor and cognitive impairment (46), we cannot completely rule out incorrect responses despite methodological precautions such as the tailored development for the study sample and assessment by experienced and intensively trained assessors. The dropout rates of 11% for the intervention and 22% for the follow-up period might appear to be high; however, these are readily explained by the vulnerability of the study population with high age and impaired health status. Additionally, the groups of individuals who completed the training and those who dropped out were fairly comparable. The results were documented in a study population predefined by strict and transparent inclusion criteria. Although the intervention program could also be effective in other settings, the effectiveness and feasibility have shown to work in the described sample, limiting the overall representativeness of results.

Conclusions

The study results document the feasibility and effectiveness of the home-based training to improve LSM and independent life space in multimorbid older persons with both physical impairment and CI. Given the negative effects of restricted mobility on health, these results are highly relevant for the promotion of independence and social participation in such a vulnerable population. The results of the predictor analysis encourage the inclusion of persons with relevant LSM restrictions, as these persons have a great need of improvement alongside a high potential for a positive training response. The home-based training program can therefore represent an appropriate model for extended rehabilitation to fill the gap between ward-based rehabilitation and independent living. This can improve the transition from rehabilitation to the home in this vulnerable, older population with CI and an extraordinary high risk of activity restriction and loss of independence. Ongoing support seems to be required to sustain benefits on LSM.

Supplementary Material

Supplementary data are available at *The Journals of Gerontology, Series A: Biological Sciences and Medical Sciences* online.

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Conflict of Interest

None declared.

Author Contributions

P.U. drafted the manuscript. The primary analysis of the data was carried out by A.S. and P.U. Secondary analyses were carried out by P.U. C.W., K.H., B.A., and A.S. critically revised the article. K.H. is responsible for the conception of the study and study design. M.B., T.E., and R.B. participated in data collection. All authors read and approved the final manuscript.

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Publikation VIII

Tobias Eckert, Pamela Wronski, **Martin Bongartz**, Phoebe Ullrich, Bastian Abel, Rainer Kiss, Michel Wensing, Jan Koetsenruijter, Klaus Hauer. Cost-effectiveness and cost-utility of a home-based exercise program in geriatric patients with cognitive impairment.

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Cost-effectiveness and cost-utility of a home-based exercise program in geriatric patients with cognitive impairment

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Running Title

Cost-effectiveness of home-based exercise in geriatric patients with cognitive impairment

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Abstract

Introduction: There is a substantial lack of home-based exercise programs in the highly vulnerable group of geriatric patients with cognitive impairment (CI) after discharge from ward-rehabilitation. Beyond clinical effectiveness, the cost-effectiveness of intervention programs to enhance physical performance is not well investigated in this target group.

Objective: To determine the cost-effectiveness of a 12-week home-based exercise intervention following discharge from ward-rehabilitation compared to unspecified flexibility training for geriatric patients with CI from a societal perspective.

Methods: This cost-effectiveness study was conducted alongside a randomized placebo-controlled trial. A total of 118 geriatric patients with CI (Mini Mental State Examination score: 17-26) were randomized either to the intervention group (IG, n = 63) or control group (CG, n = 55). Participants in IG received a home-based individually tailored exercise program to increase physical performance, while participants in CG received unspecific flexibility training (placebo control). Health care service use, physical performance (Short Physical Performance Battery, SPPB) and quality of life (EQ-5D-3L) were measured over 24 weeks. The Net Monetary Benefit (NMB) approach was applied to calculate incremental cost-effectiveness of the exercise intervention compared to CG with respect to improvement of a) physical performance on the SPPB and b) quality adjusted life years (QALYs).

Results: Physical performance was significantly improved in IG compared to CG (mean difference at 24 weeks: 1.3 points; 95% Confidence Interval [95 % CI] = 0.5 to 2.2; $p = 0.003$), while health-related quality of life did not significantly differ between groups at 24 weeks (mean difference: 0.08; 95% CI = -0.05 to 0.21; $p = 0.218$). Mean costs to implement the home-based exercise intervention were €284 per patient. The probability of a positive incremental NMB of the intervention reached a maximum of 92% at a willingness to pay (WTP) of €500 per point on the SPPB. The probability of cost-utility referring to QALYs was 85% at a WTP of €5,000 per QALY.

Conclusion: The home-based exercise intervention demonstrated high probability of cost - effectiveness in terms of improved physical performance in older adults with CI following discharge from ward-rehabilitation, but not in terms of quality of life.

Introduction

The demographic change in western societies with its growing number of older persons is a major challenge for the sustainability of the public health care systems as persons aged 75 years or older raise on average 5.5 times as many costs as young adults in the age of 20-34 years [1]. Cognitive decline is common in old age and even more pronounced in more vulnerable populations such as hospitalized geriatric patients (≥65 years) with about the half of this group showing signs of cognitive impairment (CI) [2]. Cognitively impaired geriatric patients show an increased risk of poor functional recovery during ward-rehabilitation [3], loss of functional independence post-discharge to home environment, institutionalization, and mortality [4]. The increased number of adverse medical events in this vulnerable patient group also represents a societal economic burden due to high demand on formal [5] and informal care [6]. This constitutes the major care contribution in persons with CI, also leading to productivity losses in employed caregivers [7].

Despite this urgent need of effective physical rehabilitation to increase physical performance in the transitional stage following ward-rehabilitation to home environment, geriatric patients with CI are often excluded from physical rehabilitation programs. Meta-analytic findings provided preliminary evidence for the clinical effectiveness of specified physical training in persons with CI in terms of improved ability to perform activities of daily living (ADL) [8]. However, methodological limitations concerning the inclusion of heterogeneous study design and study samples with respect to cognitive status limit the evidence of exercise on physical performance in elderly with CI. A previous home-based exercise and physical activity (PA) promotion intervention demonstrated impact on physical performance and self-reported PA in cognitively impaired patients recently discharged from ward-rehabilitation to home-environment [9].

Assuming that physical exercise interventions after discharge from hospital are clinically effective in patients with CI, it is important to assess the costs and cost-effectiveness to support decision-making on the allocation of resources in these interventions. Therefore, there is a high need to design clinically effective as well as cost-effective programs for patients with concurrent physical and cognitive restrictions. However, the economic value of physical exercise interventions among elderly populations has been primarily determined within fall prevention programs, conducted in community-dwelling elderly without acute medical illness and CI [10]. Only a few economic analyses have been carried out with a clear focus on home-based exercise interventions, including high risk populations, such as multi-morbid geriatric patients post-discharge from ward-rehabilitation [11–13] and cognitively impaired samples [14, 15]. None of these studies included the highly vulnerable group of geriatric patients with simultaneous physical and cognitive impairment.

The methodology of economic evaluation studies across elderly populations varied widely in regard to the outcomes. The most frequently used outcome of cost-effectiveness was quality-adjusted life years (QALYs), referring to a broad conceptualization of cost-effectiveness of health care interventions, specifying cost-utility. The evidence on cost-utility of exercise in vulnerable patient groups is limited, as no intervention effects were found on health-related quality of life [11, 12, 14]. In contrast, the use of specific clinical outcomes as comparators of cost-effectiveness, such as physical performance (e.g., Short Physical Performance Battery total score) [11], frailty [12] or dementia-specific behavioral symptoms [15], demonstrated incremental cost-effectiveness related to the impact on these clinical outcomes measures.

In the present study a concurrent economic evaluation with data on costs and effectiveness outcomes, collected during a home-based exercise intervention trial to increase physical performance in patients with CI, was performed. As recent literature on economic evaluations in health care interventions suggests the use of clinical variables related to the study's primary objective [16] the primary aim was to determine cost-effectiveness of a home-based exercise program with respect to changes of physical performance. Secondary aim was to estimate cost-utility concerning gains of QALYs. According to recommendations for economic evaluations [17] the present economic evaluation was conducted from a societal perspective, including costs incurred by informal care.

Methods

Participants and Setting

The home-based exercise intervention was a double-blinded, randomized, placebo-controlled intervention trial (RCT), including cognitively impaired geriatric patients after discharge from ward-rehabilitation (http://www.isrctn.com/ISRCTN82378327). The study was conducted in accordance with the principles stated in the Declaration of Helsinki and was approved by the ethics committee of the Medical Department of the University of Heidelberg (S-252/2015). Participants were recruited from a Geriatric Rehabilitation Center during ward-rehabilitation. Inclusion criteria were: age ≥65 years; a score of 17-26 on the Mini-Mental State Examination (MMSE); living in the community or in assisted living (no residential care); residence within 30 km of the study center, able to walk 4 m independently with a walking aid; no terminal disease; no delirium; German-speaking and written informed consent given by the participant or a legalized guardian.

Intervention and Control

All participants had normal access to routine healthcare additional to study program. Routine healthcare comprises inpatient and outpatient medical treatment, outpatient non-physician services (e.g. physiotherapy, logopedics), formal inpatient and outpatient care as well as informal care by proxies. However, currently no specified physical rehabilitation programs in home environment are implemented in routine healthcare.

After baseline measurement (T1) participants were randomly allocated either to intervention group (IG), or to control group (CG). Assessors were blinded to randomization status. Participants in IG received a 12-week, home-based individually tailored physical training, including balance, strength and walking. The program was based on a motivational approach to promote adherence to autonomously performed physical training and regular PA. The motivational approach incorporated: implementation of a daily training routine, activity-related goal-setting, self-monitoring by pedometers, the implementation of an individualized walking path adjusted to each participant's home environment, and dementia-specific communication strategies (supported by a brief manual and a large poster). Five home visits and weekly phone calls were administered by graduated sport scientists (Master's Degree or equivalent) to provide ongoing supervision during intervention. Participants in CG received unspecific flexibility training in a sitting position (placebo control) and were also supervised by the study staff within five home visits and weekly phone calls, but did not receive motivational support and individually tailored training. The flexibility program did not aim to enhance physical performance, but served as a control for psychosocial effects. As this flexibility program is not part of routine healthcare and to avoid a potential overestimation of cost-effectiveness, we did not calculate costs for implementing the CG program. Detailed information about design, recruitment and the intervention has been published elsewhere [18].

Measures

Outcome Measures

The primary outcome measures for the original RCT were physical performance using the Short Physical Performance Battery (SPPB) and PA measured by two ambulatory sensor systems. Assessments were carried out in participants' homes after discharge from ward-rehabilitation (T1), after the 12-week intervention period (T2) and following a 12-week follow-up period after completion of the program (T3).

The SPPB includes subtests of key motor features such as static balance (side-by-side, semi-tandem, tandem), walking, and sit-to-stand performance which are summed to a total score (0-12) [19]. Health-related quality of life was assessed by participants using the EuroQol EQ - 5D - 3L, which captures the following five health-related domains: ‚mobility', ‚self-care', ‚usual activities', ‚pain/ discomfort', ‚anxiety/depression' [20]. Response categories were: no problems (1), some or moderate problems (2) and severe or extreme problems (3). The five scores for each dimension were converted to the single EQ-5D-3L index score based on preferences of a representative sample of the German general population [21]. The EQ-5D-3L index score has a range between -.207 (severe problems in all domains) and 1 (no problems in all domains), with 0 representing death and 1.0 representing full health; values below 0 indicate health states worse than death.

Sociodemographic and clinical measurements

To describe sample characteristics at baseline in more detail, sociodemographic (age, sex, living status, educational level, care status) clinical parameters (number of diseases, number of medications, history of falls during last 12 months) and cognitive function (MMSE) [22] were assessed via interview. Clinical parameters were taken from patient charts.

Health care service use

Health care service use was assessed by using the questionnaire for the use of medical and non-medical services in old age (*Fragebogen zur Erhebung von Gesundheitsleistungen im Alter* [FIMA]) [23]. The FIMA uses a 3-month retrospective time horizon and covers inpatient treatment (acute hospital, intensive care unit, ward-rehabilitation), outpatient treatment including outpatient surgery (e.g. general practitioner, orthopedist, urologist), and outpatient therapies (physical therapist, occupational therapist, logopedics, podiatrist), assistive devices (e.g. walking aids, bath lift), inpatient and outpatient care (body care, household, 24-hour care) and informal care. To take account of recall bias, lists of possible services were represented (e.g., every outpatient service was addressed specifically in the questionnaire). If the patient was not able to give reliable information about service use, interviews were conducted by caregivers/proxies (e.g. family members).

Data Analysis

Descriptive data are based on original data and presented as means and standard deviations (SDs) and were conducted using the software package SPSS 25.0 (IBM, Chicago, Il, USA). Cost-effectiveness analyses were performed using R (R Core Team, Vienna, Austria) and missing data were imputed. The level of significance was set α = 0.05.

Calculation of Costs

We conducted the study from a societal perspective. Costs were not discounted, as the time horizon of the present economic evaluation covers 24 weeks. Therefore, direct costs and costs of informal care were included. Indirect costs due to productivity losses were regarded as irrelevant in the present sample of retired geriatric patients. Standardized unit costs within the German health care system were used for monetary valuation of the utilized health care sources [24]. Standardized unit costs were not used for informal care. The valuation of informal care was based on the wage for the care of elderly persons, derived from the registry of the German Federal Statistical Office [25]. All costs incurred were inflated to price levels of 2016 by a factor of 1.053 obtained from the national consumer price index of the German Federal Statistical Office [26].

Mean costs to deliver the individually tailored exercise program, were calculated using data on intervention costs for each participant, including variable and fixed cost categories. Variable costs were derived from the frequency and duration of home visits, travel times, travel distances as well as frequency and duration of phone calls, which were documented by trainers. To estimate intervention costs reimbursed for staff, total duration of the respective categories (e.g. duration of home visits) was multiplied by unit costs (e.g., costs per hour of contact for trainer) which were derived from the German public services wage agreement (*Tarifvertrag für den Öffentlichen Dienst*; TVÖD) [27]. As the exercise program is intended to be implemented within real-life conditions the estimation of staff costs was based on the employment of physiotherapists (TVÖD 9b/2). Employee on-costs including insurance costs and taxes were estimated at a level of 28% of wage costs and added to wage. Travel costs were calculated based on the number of kilometers travelled multiplied by the German tax-deductible rate (€0.30/kilometer). Fixed costs were summed up by reimbursement for pedometers, posters and manuals.

We did not calculate overhead costs, as neither additional rooms were rented nor additional workforce was utilized for program coordination. We excluded the use of medication from further analyses due to a high amount of invalid information.

Calculation of QALYs

Effects on health-related quality of life were assessed using QALYs which are based on the changes in the EQ-5D-3L index score. QALYs were calculated using the area-under-the curve method [28]. We weighted each time interval (before T1; T1-T2; T2-T3) by the individual's utility score during this period.

Missing Values

Multiple imputation by chained equations (MICE) with predictive mean matching was performed to impute missing data for costs and effect outcomes (EQ-5D index score, SPPB total score), taking into account the covariates of age, sex, treatment allocation, living status, care level, fall status, SPPB baseline scores, and EQ-5D baseline scores. We performed the imputation 20 times, roughly reflecting the number of cases with missing data. Standard errors for the health and cost analyses, cost-effectiveness analyses, and cost-utility analyses were computed according to the "Rubin's rule" [29].

When participants died, they were allocated zero costs, zero EQ-5D utility score and zero SPPB total score and were not classified as missing. In the case of dropout due to institutionalization, we estimated long-term care costs for the time period after the date of institutionalization until study end. Health care service use (e.g. inpatient and outpatient physician services) during the period of institutionalization was treated as missing and was imputed as described above.

Health and Cost Analysis

Differences on health-related outcomes at T2 and T3 between IG and CG were tested using linear regression models, adjusted for baseline values (T1). Costs were calculated per category and summed as total costs. Differences on costs at T2 and T3 between IG and CG were tested using a generalized linear model with a gamma distribution and log-link, as we did not assume normal distribution for cost data. We did not adjust for baseline costs as they did not differ between groups.

Cost-effectiveness and Cost-utility Analyses

The present economic evaluation comprises a) cost-effectiveness analyses (change of physical performance) and b) cost utility analyses (change of health-related quality of life) of the 12-week exercise intervention compared to the control condition.

SPPB total score was included as comparator of cost-effectiveness related to the objective of the study. Based on previous literature conducted among older adults an increase of one point on the SPPB total score was defined as a substantially meaningful change [30]. Total costs, including the intervention and health care costs, were used to calculate incremental cost-effectiveness. The net-monetary benefit (NMB) approach was used to estimate incremental cost-effectiveness [31]. NMB values for cost-effectiveness and cost-utility were calculated by the formulas:

$$NMB_i = SPPB_{i\,\Delta T3-T1}\, x\, WTP - C_i \text{ and } NMB_i = QALY_i\, x\, WTP - C_i.$$

$QALY_i$ and $SPPB_{i\,\Delta T3\text{-}T1}$ represent the effects for each participant, C_i represents costs for each participant, and WTP is the health care provider's willingness to pay for an additional QALY or one point on the SPPB score. So, NMB expresses the added value of the intervention in monetary terms minus the costs given the WTP for an improvement of one point on the SPPB or on a QALY. The intervention alternative (IG or CG) with the highest NMB value is assumed to be the most cost-effective given a healthcare payers' WTP, specified as the incremental NMB (IG minus CG). WTP thresholds represent hypothesized values, as there are no established WTP thresholds in Germany, because it is not compatible with German law.

Sensitivity Analyses

As economic analyses underlie different uncertainties, cost-effectiveness acceptability curves (CEACs) were generated to plot the probabilities of cost-effectiveness, as indicated by positive incremental NMB, of the exercise intervention for different WTP thresholds. A linear regression method to calculate *p*-values was used instead of bootstrapping, as this method combined with multiple imputation appears to be a robust alternative with sufficient statistical performance [32]. The *p*-values were used to calculate the according probabilities of cost-effectiveness by the formula: 1-(*p*/2) [33]. Further sensitivity analyses were performed. First, economic analyses were repeated using a complete-case-scenario, including participants with complete health care use data after follow-up. Second, as cost outliers have potential impact on cost-effectiveness, outliers (≥ 3 SD above total mean costs) were removed from the cost-effectiveness analyses. Third, a prespecified subgroup examined the cost-effectiveness of the intervention stratified by cognitive status (MMSE score: ≤24), as we expect that our intervention may have more impact on individuals with a low cognitive status.

Results

Sample Characteristics

Out of 1981 patients screened for eligibility, 118 individuals were enrolled to the RCT according to predefined inclusion criteria (Figure 1). Primary causes for exclusion were cognitive status (n = 553), residence >30 km from study center (n = 241), and medical contraindications (n = 217) (Figure 1).

insert **Fig. 1**

The present sample consisted of multi-morbid and physically restricted older adults with CI. Age (IG: *M* = 82.2, SD = 5.8; CG: *M* = 82.4, SD = 6.2), cognitive status (IG: *M* = 23.3. SD = 2.7; CG: *M* = 23.3, SD = 2.1) and the degree of multi-morbidity in terms of number medications (IG: *M* = 9.4, SD = 3.5; CG: *M* = 9.6, SD = 3.9) and diseases (IG: *M* = 11.3, SD = 3.6; CG: *M* = 11.4, SD = 5.3) were similar in both groups. Physical performance was slightly better in intervention participants than in control participants (IG: *M* = 5.4, SD = 2.1; CG: *M* = 5.0, SD = 2.4).

The usage of health care services was based on proxy-report in n = 41 (35%) at T1, 49 (48%) at T2 and n = 54 (61%) at T3. Health care service costs at baseline were high in both groups, as indicated by mean health care service use costs per capita of €14,456 (SD = 10,284) in IG and €13,800 (SD = 11,695) in CG during the 3 months before start of intervention (Table 1).

Resource use and respective unit costs are presented in Table 2.

insert **Table 1**

insert **Table 2**

Health-related outcomes

The between-group difference at 12 weeks following the intervention period on the primary outcome was 1.8 points (95% CI = 1.0 to 2.6; $p < 0.001$) on the SPPB total score in favour of the IG. This positive intervention effect on physical performance remained significant at 24 weeks with an estimate of 1.3 points (95% CI = 0.5 to 2.2; $p = 0.003$). By calculating the area under the curve (AUC), the probability that the effect over the 24 weeks is substantial meaningful (>1.0 point) was found to be 76%. For health-related quality of life, the group differences were non-significant both at 12 weeks (mean difference = 0.07; 95% CI = -0.04 to 0.18; $p = 0.203$) and 24 weeks (mean difference: 0.08; 95% CI = -0.05 to 0.21; $p = 0.218$) for the EQ-5D-3L index score. In consequence, the gain of health-related quality of life, as indicated by QALY, was not significantly different between the groups (mean difference: 0.04; 95% CI = -0.02, 0.07; $p = 0.259$) (Table 3).

insert **Table 3.**

Costs

Mean costs per patient to deliver the intervention program are €284, with home visits representing the major investment (72%, €204) (Table 4). Mean total costs per capita, including health care service use costs and intervention costs, are €1,533 lower in the exercise group compared to CG (95% CI = -4,447 to 1,381; $p = 0.295$).

insert **Table 4.**

Cost-effectiveness and cost-utility

Incremental cost-effectiveness with respect to effects on the SPPB total score demonstrated higher NMB values at every WTP threshold in the range between 0 and €5,000 in IG than in

CG and a significant incremental NMB is shown above a WTP of €2000 (Table 5). In consequence, the probability of cost-effectiveness was 92% given a decision maker's WTP of €500 per one-point gain on the SPPB total score and reached a level of 99% at a WTP of €2000 (Figure 2).

In regard to QALYs, although NMB values were higher in IG than in CG, no significant incremental NMB was found in favour of the exercise intervention (Table 4). Subsequently the probability of cost-utility was 85% given a WTP of €5,000 per QALY and leveled off at 90% given WTP above €20,000 (Figure 3).

insert **Table 5**

insert **Figure 2.**

insert **Figure 3.**

Sensitivity Analyses

Analyses of complete cases (n = 89) demonstrated a probability of cost-effectiveness of 90% with respect to improvement of physical performance and QALYs, given a WTP of €0. This is higher than the values found within our primary analysis including dropouts (Figure 2 and 3). After removal of two cost outliers (≥3 SD above mean total costs; 2 CG participants), the probability of cost-effectiveness with respect to physical performance also reached a level of 100%, but at a higher WTP compared to primary analyses (Figure 2). The probability of cost-effectiveness in regard to QALYs for outlier analysis was lower across different WTP and reached a lower ceiling value (Figure 3). Cost-effectiveness analyses with respect to cognitive status showed, that the effect sizes were (not significantly) higher in participants with lower cognitive status (MMSE ≤24) than in the total sample (data not shown).

Discussion

To the best of our knowledge, we present the first economic evaluation of an individually tailored exercise intervention in the vulnerable group of cognitively impaired geriatric patients post-discharge from ward-rehabilitation. The present results demonstrate a high probability that the 12-week home exercise program is cost-effective with respect to improved physical performance, as indicated by incremental net monetary health benefits in the IG compared to the CG. Cost-utility cannot be assumed as the exercise intervention did not achieve gains in quality-adjusted life years compared to control condition.

Our individually tailored home-based exercise intervention represents a low-cost program with mean costs of €284 per participant, as the value of money reimbursed for material and staff was low in comparison with other home-based exercise programs in mobility-impaired older adults [11, 12]. For example, a previous multifactorial intervention for mobility impaired elderly required higher expenditures for multidisciplinary staff (including the employment of dieticians and psychiatrists), resulting in mean delivery costs of A$1529 per capita (€1028, based on the exchange rate of January 1, 2016) [12]. In contrast to this multifactorial intervention approach, an economic study, investigating the costs of 3-month exercise-based rehabilitation program for hip-fracture patients, described delivery costs of £231 (€272, based on the exchange rate of January 1, 2016) similar to the present program (€284) [13]. Like in the study by Williams et al. (2016), the exercise programs only involved the use of physiotherapists to deliver the individually tailored exercise as well as the motivational approach. This allows for the integration of exercise into daily routines, leading to high adherence to autonomously performed exercise and PA [34]. The autonomous performance of exercise in the home-environment might reduce costs in comparison to continuously supervised exercise programs, requiring transport and staff costs.

With respect to the clinical outcome, a significant impact on physical performance was revealed at 24 weeks by the 12-week home-based physical training (1.3 points on the SPPB total score), representing a substantial meaningful change according to the established cut-off point of 1.0 points [30]. The difference of 0.5 points on the lower bound of the 95% CI interval, found in the present results, also indicates at least a minimal meaningful change of physical performance [30]. In consequence, the improved physical performance as well as slight reductions of costs in the intervention group resulted in incremental NMB values in favour of the home-based physical training group, indicating high probability of cost-effectiveness. This is in line with prior economic evaluations in home-based exercise interventions in older adults with mobility restrictions [11, 12] and CI [15], using clinical parameters as study outcomes of cost-effectiveness. For example, the results of Farag et al. (2015) [11] indicated a probability of 80% that the exercise intervention was cost effective at a WTP threshold of A$48,000 (€32,272, based on the exchange rate of January 1, 2016) per person showing a mobility improvement on the SPPB compared to routine healthcare. In the present study the probability of cost-effectiveness was even higher, exceeding a probability of 92% at WTP of only €500.

In contrast to improved physical performance, no significant positive impact was found for health-related quality within our study, supporting results made in previous exercise interventions in geriatric patients after discharge from ward-rehabilitation [12, 13]. The lack of significant intervention effects on the EQ-5D-3L might be related to low sensitivity to change of generic measures of health-related quality of life in old age [35]. Although the present results did not show any impact of the exercise intervention in health-related quality of life, the probability of cost-utility was about 90% at WTP thresholds above €20,000 per additional QALY. This was mainly caused by lower health care costs in the IG. Improved physical performance may have led to a decreased risk of hospitalization, emergency visits [36] and outpatient services [37]. Nonetheless NMB values of €20,000 per additional QALY might exceed the decision makers' maximum WTP for multi-morbid older adults with a relatively short life expectancy. In consequence, utility-based measures might be discriminative against older adults.

The inclusion of clinical instruments is potentially more suitable for the valuation of cost-effectiveness of a specific exercise intervention to increase physical performance in the group of elderly with physical constraints, as they are sensitive to changes related to the intervention. The SPPB as objective measure of physical performance is associated with life-space, representing an indicator of the person’s autonomy [38], and predicts the risk of re-hospitalization and mortality [19, 30].

The present study extends empirical findings on the economic value of exercise in the high-risk population of elderly with CI who are often excluded from physical rehabilitation programs. The positive results regarding the clinical effectiveness as well as cost-effectiveness emphasize the importance of rehabilitation strategies, which are easy of access and tailored to the needs of cognitively impaired individuals post-discharge from ward-rehabilitation. One economic study conducted among cognitively impaired samples demonstrated cost-effectiveness of a structured walking intervention referring to a reduction of CI-specific behavioral symptoms [15], while no previous study supplied evidence for cost-effectiveness of individually tailored exercise to improve physical performance in a sample of individuals with CI. We also allow for the challenges arising from the self-report measurement of resource use in this specific study population. When participants were not able to give reliable information on resource use, caregivers/proxies were included.

The varying probabilities of cost-effectiveness found between previous economic analyses of exercise intervention trials and the present study also refer to the utilization of different statistical methods to calculate cost-effectiveness. The use of an aggregated value of cost-effectiveness, such as the incremental cost-effectiveness ratio (ICER) or NMB is necessary to determine cost-effectiveness in case of non-significant differences of costs or/and health-related outcomes between the groups. In contrast to previous studies, using ICERs to determine incremental cost-effectiveness [11, 12], we used the NMB approach. As the present cost-effectiveness analysis showed positive effects on health-related outcomes and non-significant cost savings in favour of the IG, the ICER would have been negative, resulting in limited interpretability [31].

The sensitivity analyses proved the robustness of the primary cost-effectiveness analyses with respect to physical performance, representing a major strength of our study. The probabilities of cost-effectiveness across different WTP was not substantially curtailed by the exclusion of cost outliers, as incremental NMB values were mainly driven by the intervention impact on physical performance and only to a little extent by the variation of costs. The exercise intervention was even more likely to be cost-effective in study completers compared to the primary analysis also including dropouts. The subgroup-analysis of individuals with lower cognitive status indicate higher clinical and economic benefits, contradicting previous studies [11, 12] and confirm that our program was suitable to the target population. The data analysis was based on multiple imputation which constitutes the method the most accurate to handle missing data in economic evaluations [39], also strengthening the present findings.

We also note for the limitations of the study. We did not include travel costs of patients and caregivers, not allowing to estimate all societal costs. The present analyses did not involve the expenditures on medication which constitute a frequently used health care source in multi-morbid persons [40]. Further, patients' travel times and distances for the usage of health care resources were not captured by the FIMA, so that not all relevant societal costs could be estimated. We used patient- and proxy-reports to assess resource use, potentially leading to differential recall bias. As the participants in the placebo control group also received an unspecified flexibility training within home visits, we were not able to eliminate potential impact of social contact between the participants and trainers on health-related quality of life. In consequence, the impact of the individually tailored exercise intervention on health-related quality of life might be underestimated in the present study as a substantial decline of health-related quality of life can be assumed without any additional social support. The short time horizon of this study may have limited the effects on quality of life. However, the intervention program on which the cost estimation is based on, focused on improvement of physical performance with quality of life only representing a secondary outcome, leading to restricted effects on quality of life. The estimation of QALYs was based on self-reported quality of life, which is shown to be higher as compared to proxy ratings [41]. This limits the external validity of QALYs reported in this study, however, it does not influence the results of our cost-utility analysis. The costs to educate physiotherapists for program delivery are not estimated in the present study, which is needed for further implementation in real-life conditions.

Conclusion

The home-based exercise intervention demonstrated high probability of cost-effectiveness with respect to the improvement of physical function, representing a major and well-established objective of rehabilitation, in a vulnerable group of cognitively and physically impaired geriatric patients post-discharge from ward-rehabilitation. Economic benefits in terms of QALYs, representing a rather generic objective for rehabilitation not specifically targeted in this intervention program, seem to be more unlikely, as the exercise intervention did not reveal significant impact on health-related quality of life.

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Statement of Ethics

The study conforms to the latest version of the Helsinki Declaration and was approved by the Ethics Committee of the Medical Department at the University of Heidelberg. All participants or their legalized guardians have given their written informed consent.

Disclosure Statement

The authors have no conflicts of interest to declare.

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Author Contributions

T.E.: acquisition of participants, conducting the exercise program, study management, data analysis, interpretation of data, preparation of the manuscript. P.W.: trial economist, selection of methods, statistical design, interpretation of data, M.B.: assessment of data. P.U.: acquisition of participants, conducting the exercise program. R.K.: assessment of data. M.W.: trial economist, end control of the manuscript, J.K.: statistical design and data analysis. K.H.: study concept, design, and management, supervision of data collection, end control of the manuscript. All authors contributed to interpretation of data, drafting the article, and final approval of the version to be published.

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Figure Legends

Fig. 1. Flowchart of patient recruitment. Presented is the recruitment and randomization process (between 08/2015 and 04/2017) and the course of observation.

Fig. 2. Cost-Effectiveness Acceptability Curves (CEAC) for improvement of physical performance among the total sample (solid line), complete-case analysis (dotted line) and analysis without outliers (grey line).

Fig. 3. Cost-Effectiveness Acceptability Curves (CEAC) for quality-adjusted life years (QALYs) among the total sample (solid line), complete-case analysis (dotted line) and analysis without outliers (grey line).

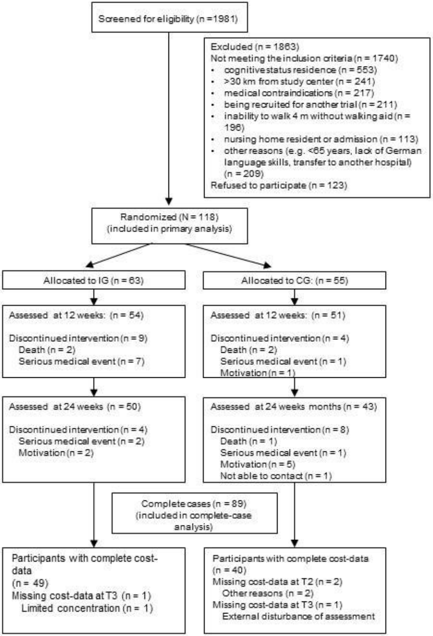

Screened for eligibility (n =1981)
Excluded (n = 1863)
Not meeting the inclusion criteria (n = 1740)
• cognitive status residence (n = 553)
• >30 km from study center (n = 241)
• medical contraindications (n = 217)
• being recruited for another trial (n = 211)
• inability to walk 4 m without walking aid (n = 196)
• nursing home resident or admission (n = 113)
• other reasons (e.g. <65 years, lack of German language skills, transfer to another hospital) (n = 209)
Refused to participate (n = 123)
Randomized (N = 118)
(included in primary analysis)
Allocated to IG (n = 63)
Allocated to CG: (n = 55)
Assessed at 12 weeks: (n = 54)
Discontinued intervention (n = 9)
Death (n = 2)
Serious medical event (n = 7)
Assessed at 12 weeks: (n = 51)
Discontinued intervention (n = 4)
Death (n = 2)
Serious medical event (n = 1)
Motivation (n = 1)
Assessed at 24 weeks (n = 50)
Discontinued intervention (n = 4)
Serious medical event (n = 2)
Motivation (n = 2)
Assessed at 24 weeks months (n = 43)
Discontinued intervention (n = 8)
Death (n = 1)
Serious medical event (n = 1)
Motivation (n = 5)
Not able to contact (n = 1)
Complete cases (n = 89)
(included in complete-case analysis)
Participants with complete cost-data
(n = 49)
Missing cost-data at T3 (n = 1)
Limited concentration (n = 1)
Participants with complete cost-data
(n = 40)
Missing cost-data at T2 (n = 2)
Other reasons (n = 2)
Missing cost-data at T3 (n = 1)
External disturbance of assessment

Table 1. Sample characteristics at baseline (N = 118)

	IG, n = 63		CG, n = 55	
Sociodemographic Variables				
Age in years, mean (SD)	82.2	(5.8)	82.4	(6.2)
Females, n (%)	48	(76)	42	(76)
Living alone, n (%)	35	(56)	25	(46)
Educational level, n (%)				
High	12	(19)	10	(18)
Middle	30	(48)	29	(53)
High	21	(33)	16	(29)
Care Level, n yes (%)	20	(37)[a]	27	(53)[b]
Clinical Parameters				
Number of diseases, mean (SD)	11.3	(3.6)	11.4	(5.3)
Number of medications, mean (SD)	9.4	(3.5)	9.6	(3.9)
Falls within previous year, n (%)				
non-faller	18	(29)	21	(38)
faller (1 fall)	19	(30)	12	(22)
multiple faller (>2 falls)	26	(41)	22	(55)
Cognition				
MMSE score (0-30), mean (SD)	23.3	(2.7)	23.3	(2.1)
Physical function				
SPPB total score (0-12), mean (SD)	5.4	(2.1)	5.0	(2.4)
Health-related quality of life				
EQ-5D-3L index score (0-1), mean (SD)	0.64	(0.28)	0.64	(0.37)
EQ-5D-3L VAS score (0-100), mean (SD)	56.9	(17.2)	53.5	(14.0)
Health care service use costs, €, mean (SD)*	14,456	(10,284)	13,800	(11,695)

Presented are participants' characteristics at baseline including sociodemographic, clinical parameters, cognition, physical function, health-related quality of life and health care service use costs in intervention group and control group. Notes: [a] n = 54 with valid information about care level, [b] n=51 with valid information about care level; MMSE = Mini Mental State Examination, SPPB = Short Physical Performance Battery, EQ-5D VAS score = EQ-5D Visual Analogue Scale score, IG = Intervention Group, CG = Control Group, * health care service use costs before intervention start comprised a 3-month time horizon

Table 2. Resource use in intervention group (IG) and control group (CG) with respective cost units (week:0-24).

Cost category	Resource use				Cost units
	IG (n=63)		CG (n=55)		
	Number of users (%)	*Average Occasions per Participant, mean (SD)*	*Number of users (%)*	*Average Occasions per Particpiant mean (SD)*	
Intervention delivery					
Travel	63 (100)	116.1 (80.3) km			0.30 € / km[a]
Home visits[b]	63 (100)	8.4 (1.8) hours			23.57 € / hour[c]
Phone calls	56 (89)	43.8 (27.9) minutes	-		23.57 € / hour[c]
Material	63 (100)	-			22.12 €/pedometer; 5€ / poster and manual
Healthcare service use					
Inpatient treatment	16 (25)	3.0 (6.6) days	13 (24)	4.8 (13.2) days	49.15 – 1408.62 € / day[d]
Outpatient medical treatment	51 (81)	10.1 (8.0) contacts	48 (87)	11.6 (9.9) contacts	21.12 - 82.22 € / contact[d]
Outpatient therapy	43 (68)	9.0 (10.0) contacts	42 (76)	14.2 (22.8) contacts	17.29 – 40.64 € / contact[d]
Assistive devices	32 (51)	1.0 (1.2)	11 (20)	0.7 (0.8)	54.23 – 1019.04 € / unit[e]
Inpatient care	3 (5)	1.6 (8.1) days	4 (7)	5.5 (25.4) days	48.60 – 74.55 € / day[f]
Outpatient Care[g]	37 (59)	49.6 (71.2) hours	41 (75)	53.4 (69.1) hours	0.29 - 0.51€ / minute[i.];5.01€ / contact
Informal care	49 (78)	116.2 (139.9) hours	52 (95)	251.6 (201.4) hours	18.49 € / hour

Notes: Resource use is based on original data. [a]. based on the German tax-deductible rate; b home visits include time spent during home visits, preparation time (10 minutes) and travel time; [c.] including 28% of employee on-costs; [d.] cost units erived from Bock et al. (2015); [e]. Assignment of cost units by Bock et al. (2015) according to the classification system of the statutory health insurance except for expenditures on dentures, which were based on cost units derived from a report of a statutory health insurance (Barmer Zahnreport); [f.] based on weighted means of cost units accross care levels according to Bock et al. (2015); [g.] including resource use of 24-hour assistance, cost unit for 24-hour assistance was derived from the average wage for "care of older adults" (coding Q821) as informal care; [i.] services for assistance on basic activities of daily living are based on 0.51€ / minute, services for assistance on household were based on 0.29€ / minute.

Table 3. Effect of Intervention for main health-related outcomes

	IG, mean	CG, mean	Mean difference IG minus CG, adjusted for baseline value (95% CI)	*P*
SPPB total score (0-12)				
Week 0	5.4	5.0		
Week 12	6.7	4.9	1.8 (1.0 to 2.6)	**<0.001**
Week 24	5.9	4.6	1.3 (0.5 to 2.2)	**0.003**
EQ-5D-3L index score (0-1)				
Week 0	0.64	0.64		
Week 12	0.69	0.62	0.07 (-0.04 to 0.18)	0.203
Week 24	0.63	0.54	0.08 (-0.05 to 0.21)	0.218
QALY (0-1)				
0-24 weeks	0.30	0.26	0.04 (-0.02 to 0.05)	0.259

Presented are effects of intervention including mean difference between groups for health-related outcomes, adjusted for baseline values (T1). Abbreviations: SPPB = Short Physical Performance Battery, QALY = quality adjusted life year, CI = Confidence Interval, IG = Intervention Group, CG = Control Group.

Table 4. Comparison of intervention costs and aggregated health care service use costs (week: 0-24)

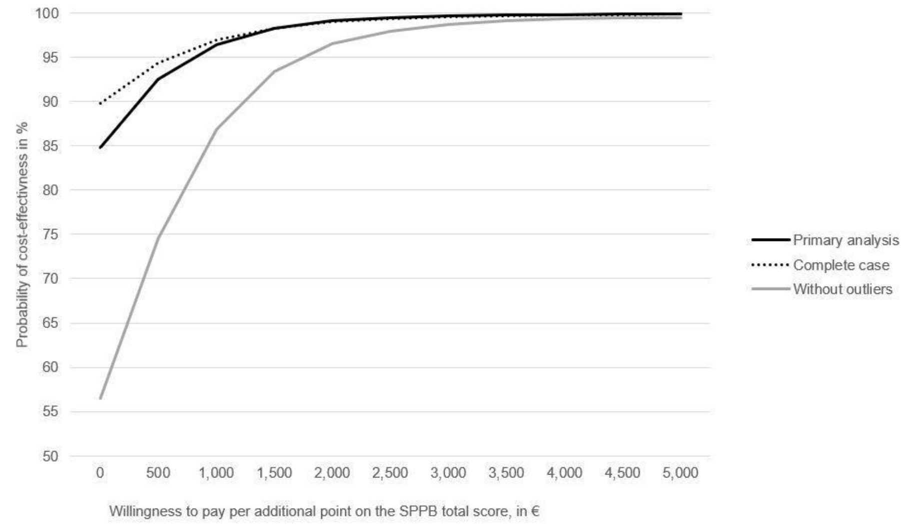
	IG, mean	CG, mean	Mean Difference, IG minusCG (95% CI)		*P*
Intervention Costs, €					
Travel Costs	34				
Home Visits	204				
Phone Costs	18	0.00	-		
Material Costs	27				
Total Intervention Costs	284				
Health Care Service Costs, €					
Inpatient Treatment	1,940	2,873	-932	(-2,854 to 989)	0.990
Outpatient Treatment	302	373	-71	(-192 to 50)	0.239
Outpatient Therapy	180	282	-103	(-354 to 149)	0.408
Assistive Devices	262	157	104	(-26 to 235)	0.111
Inpatient Care	108	186	-78	(-257 to 101)	0.860
Outpatient Care	2,332	2,325	7	(-1,073 to 1,086)	0.991
Informal Care	2,536	3,279	-743	(-2,264 to 777)	0.331
Total Health Care Service Costs	7,658	9,475	-1,817	(-4,729 to 1096)	0.213
Total Costs, €	7,942	9,475	-1,533	(-4,447 to 1381)	0.295

Presented is the comparsions of Intervention Costs and aggregated health care service use costs over 24 weeks between the intervention group and control group, using differences were tested by use of generalized linear modeling with a gamma distribution and log-link, unadjusted for baseline costs. Notes: CI = Confidence Interval, IG = Intervention Group, CG = Control Group

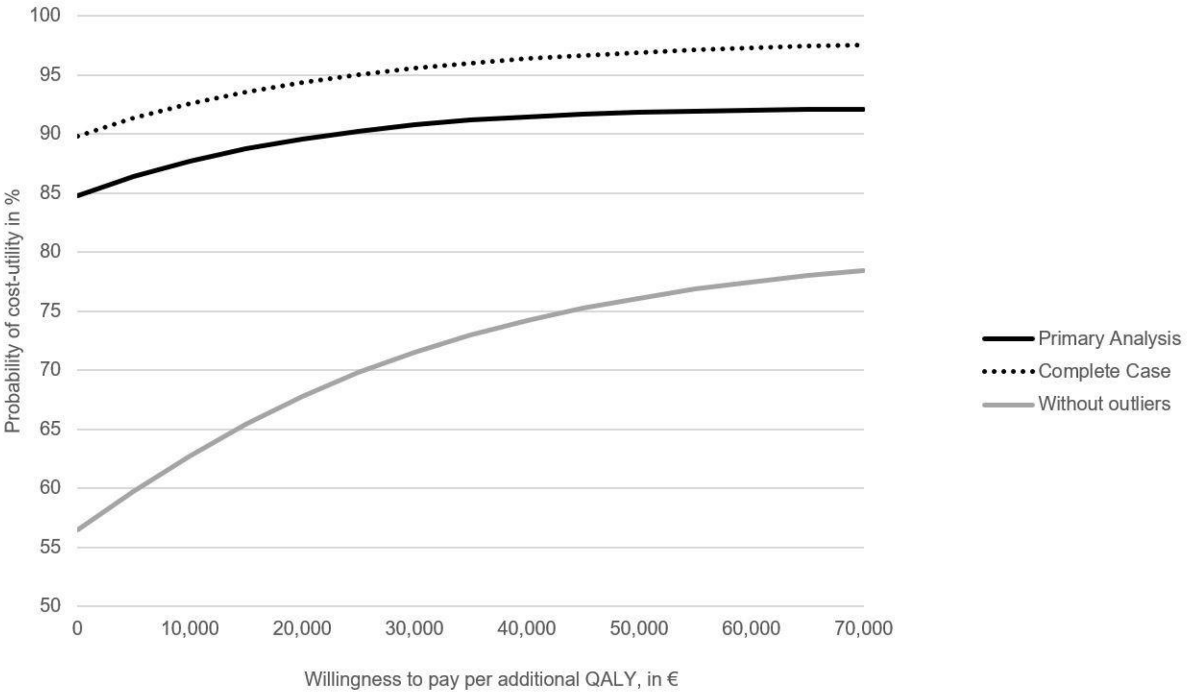
Table 5. Net monetary benefit (NMB) in IG and CG and incremental net monetary benefit of the exercise intervention (IG minus CG)

WTP threshold per additional SPPB value in €	Net monetary benefit (NMB)		Incremental NMB, IG minus CG, mean (95% CI)	*P*
	IG, mean, (95% CI)	CG, mean (95% CI)		
0	-7,941 (-9,999 to -5,883)	-9,476 (-11650 to -7,302)	1,534 (-1381 to 4,449)	0.305
500	-7,615 (-968 to -5,541)	-9,781 (-11,955 to -7,607)	2,165 (-767 to 5,097)	0.151
1,000	-7,289 (-9,425 to -5,153)	-10,087 (-12,310 to -7,864)	2,798 (-211 to 5,807)	0.071
2,000	-6,636 (-9,019 to -4,253)	-10,699 (-13,157 to -8,241)	4,063 (745 to 7,381)	**0.018**
3,000	-5,982 (-8,736 to -3,228)	-11,310 (-14,144 to -8,476)	5,328 (1,537 to 9,119)	**0.007**
5,000	-4,676 (-8,380 to -972)	-12,534 (-16,366 to -8,702)	7,858 (2,829 to 2,887)	**0.003**
WTP threshold per additional QALY in €	**Net monetary benefit (NMB)**		**Incremental NMB, IG minus CG, mean (95% CI)**	***P***
	IG, mean (95% CI)	CG, mean (95% CI)		
0	-7,942 (-10,000 to -5,884)	-9,475 (-11,649 to -7,301)	1,533 (-1,382 to 4,448)	0.305
2,000	-7,280 (-9,350 to -5,210)	-8,866 (-11,053 to -6679)	1,586 (-1,344,2 to 4,516)	0.291
5,000	-6,288 (-8,377 to -4,199)	-7,953 (-10,164 to -5,742)	1,666 (-1,296 to 4,628)	0.273
10,000	-4,633 (-6767 to -2,499)	-6,432 (-8,690 to -4,174)	1,798 (-1,226 to 4,822)	0.246
20,000	-1,325 (-3,579 to 929)	-3,388 (-5,773 to -1,003)	2,063 (-1,132 to 5,258)	0.208
30,000	1,984 (-425 – 4,393)	-345 (-2,897 to 2,207)	2,328 (-1,092 to 5748)	0.185
50,000	8,601 (5,796 to 11,406)	5,742 (2,775 – 8,709)	2,859 (-1,134 to 6852)	0.163

Presented are NMB values for IG and CG and incremental NMB, expressed as the difference of NMB values between IG and CG. NMB values and CI are based on linear regression models, *P*-value is based on a generalized linear model with Gamma distribution and log-link. Notes: QALY = quality adjusted life year, SPPB = Short Physical Performance Battery, WTP = willingness to pay, CI = Confidence Interval



100
95
90
85
80
75
70
65
60
55
50
Probability of cost-effectivness in %
0
500
1,000
1,500
2,000
2,500
3,000
3,500
4,000
4,500
5,000
Willingness to pay per additional point on the SPPB total score, in €
Primary analysis
Complete case
Without outliers



100
95
90
85
80
75
70
65
60
55
50
Probability of cost-utility in %
0
10,000
20,000
30,000
40,000
50,000
60,000
70,000
Willingness to pay per additional QALY, in €
Primary Analysis
Complete Case
Without outliers