

**Physical activity promotion for individuals with dementia
in nursing homes -
Chances of individualization and digitalization**

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DISSERTATION

von

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PREFACE

This thesis comprised the following manuscripts, which are published in peer-reviewed journals:

MANUSCRIPT I

Bezold, J., Trautwein, S., Barisch-Fritz, B., Scharpf, A., Krell-Roesch, J. & Woll, A. (2021). Effects of a 16-week multimodal exercise program on activities of daily living in institutionalized individuals with dementia. *German Journal of Exercise and Sport Research*, 51, 487-494. <https://doi.org/10.1007/s12662-021-00760-4>.

MANUSCRIPT II

Bezold, J., Krell-Roesch, J., Eckert, T., Jekauc, D. & Woll, A. (2021). Sensor-based fall risk assessment in older adults with or without cognitive impairment: a systematic review. *European Review of Aging and Physical Activity* 18 (1). <https://doi.org/10.1186/s11556-021-00266-w>.

MANUSCRIPT III

Krafft, J., Barisch-Fritz, B., Krell-Roesch, J., Trautwein, S., Scharpf, A. & Woll, A. (2023). A Tablet-based App to Support Nursing Home Staff in Delivering an Individualized Cognitive and Physical Exercise Program for Individuals with Dementia (InCoPE-App): A Mixed-methods Usability Study. *JMIR Aging*, 6, e46480. <https://doi.org/10.2196/46480>.

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SUMMARY

Due to demographic change, the prevalence of age-related diseases like dementia will increase. In 2050, there will be 150 Million individuals with dementia (IWD) worldwide. IWD are affected by cognitive and physical decline, and this results in difficulties in carrying out activities of daily living (ADL) and a higher risk of falling. Therefore, maintaining cognitive and physical functioning, is crucial to improve ADL performance and reduce fall risk among IWD. Since there is no cure for dementia and pharmaceutical treatments have several limitations, physical activity (PA) is one non-pharmacological approach that may improve or even decelerate the progression of these disease-related alterations. The possible interrelations and mechanisms of PA, cognitive and physical performance were examined in previous studies, but the high heterogeneity of IWD with regard to overall health status, age, severity of symptoms etc. may limit the effectiveness of several PA interventions. The consideration of individual prerequisites (i.e. cognitive and physical performance) of IWD may therefore be a possible starting point, that has to be investigated further. Therefore, the first objective of this cumulative dissertation was

to examine the effects of a multimodal (motor-cognitive) exercise program for IWD on ADL performance, and to reveal the needs for and possibilities of individualized PA in IWD.

(Manuscript I)

In the first manuscript, we hypothesized that a multimodal exercise program has effects on ADL performance in IWD compared to conventional treatment in nursing homes. Furthermore, we exploratively investigated if responder groups (positive-, non-, and negative-responder) would differ in their baseline cognitive and physical performance, and if cognitive and physical performance can explain the variance in ADL performance. We conducted a randomized controlled trial involving 319 institutionalized IWD aged >65 years with mild to moderate dementia. The intervention (IG) group participated in a 16-week multimodal exercise program, consisting of imaginary journeys that combine cognitive and physical exercises (2x/week, 60min, guided by trained instructors). The control group (CG) maintained its normal daily routine. Before and after the intervention, ADL performance, and cognitive and physical performance were tested. For ADL performance, the Barthel Index, the 7-item Physical Performance Test, and the Erlangen Test of Activities of Daily Living were used. Differences in baseline cognitive and motor performance between the responder-groups were examined using one-factor ANOVA. To examine the effects of the intervention, we calculated an ANOVA with repeated measurements. To investigate if cognitive and motor performance can explain the

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variance in ADL performance, we calculated a regression analysis. The IG did not improve ADL performance over the 16-weeks compared to the CG (ANOVA: $p > 0.05$, $\eta^2 = 0.004 - 0.019$). The responder-analysis showed that between 20-32% of participants were positive-responders with regard to ADL performance, and that these positive-responders had lower baseline physical performance compared to non-responders ($p < 0.05$). Regression analysis revealed that up to 51.4% of ADL performance was explained by cognitive and physical performance. Even though the multimodal exercise program had no overall effect on ADL performance, our study provided evidence of an effectiveness of PA depending on individual prerequisites of IWD. These results are highly relevant for an adequate design of future PA interventions.

To date, successful and long-term implementation of PA interventions for IWD in nursing homes is challenging, as time and expertise of nursing home staff regarding PA are often limited. With the beginning of the COVID-19 pandemic and the accompanying safety measures, external PA instructors were not allowed to enter nursing homes. Consequently, many nursing homes discontinued PA programs, further exacerbating inactivity among nursing home residents. To ensure that IWD in nursing homes stay engaged in PA interventions, new solutions are needed that allow for a more objective and feasible monitoring of individual health-related factors (e.g., fall risk) and a low-threshold implementation of PA (e.g., individualized PA intervention). To this end, new approaches applying digital health (e.g. body-worn sensors, mobile applications) are promising and need to be investigated. So far, digital health solutions in care settings are increasingly developed and implemented, but current research is sparse in the target group of IWD. Therefore, this thesis focuses on two possible ways of using digital health solutions for IWD: 1) 1) The detection of fall-associated factors with the help of body-worn sensors in order to prevent risk of falling and subsequent inactivity and 2) the implementation of an individualized PA program with the help of a digital application. For this reason, the second objective of this thesis was

to review current research on objective assessment of fall risk using body-worn sensors in persons with and without cognitive impairment.

(Manuscript 2)

In Manuscript 2, we hypothesized that wearable sensors provide accurate data on motor performance (e.g., balance, gait) to distinguish between fallers and non-fallers or between high-risk and low-risk of falling in older adults. Furthermore, we wanted to give practical recommendations on the use of sensors in fall risk assessment especially in individuals with cognitive impairment, like dementia. Therefore, a systematic literature search was conducted in

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July 2019 (updated in July 2020). We included 28 studies carried out in a community-based or a geriatric setting that examined fall risk factors in older adults (>60 years) with or without cognitive impairment using body-worn sensors. Overall, sensor-based data were able to distinguish between fallers and non-fallers, or between high-risk or low-risk of falling. The best classification model was found for daily-life data of three consecutive days (accuracy=90.6%, sensitivity=91.7%, and specificity=89.2%). Sensor-based data from laboratory assessment were not as precise (best in-lab data model: accuracy=89.4%, sensitivity=92.7%, specificity=84.9%). Only four studies focused on individuals with cognitive impairment, while 19 studies explicitly excluded them. Collecting sensor data throughout daily life was considered feasible in individuals with cognitive impairment, and should be preferred to in-lab data. Furthermore, a non-obtrusive location (e.g., lower back) should be chosen to ensure that participants are not disturbed by the device. Wearable sensors appear to be feasible in objectively assessing individual fall risk in older adults with or without cognitive impairment. The accuracy of classification may vary depending on various factors (e.g., sensor location, type of assessment). Sensor-based data may be used to tailor PA to the individual's need in future studies.

Besides sensor-based individual assessment, mobile applications may be a possible and future-oriented solution to implement PA interventions for IWD through nursing home staff. The tablet-based InCoPE-App (= Individualized Cognitive and Physical Exercise) was designed by our research team in cooperation with software developers, to realize the low-threshold implementation of individualized PA interventions for IWD in nursing homes. The peculiarity of the InCoPE-App is its integrated algorithm that generates an individualized PA intervention based on the results of cognitive and physical performance testing. Following user experience methods, the integration of end-users (i.e., nursing home staff) in the app development processes is crucial for a long-term compliance with the application. Involving the end-users in the development process unravels relevant usability issues that must be considered to ensure sustainable use of the InCoPE-App. In nursing homes, where time and experience are sparse, future applications need to consider end-users' wants and needs. Therefore, the third objective of this dissertation was

to examine the usability of the InCoPE-App perceived by nursing home staff and to identify potential for improvement (Manuscript 3).

In Manuscript 3, a mixed-methods approach was chosen, including the use of the System-Usability-Scale (SUS), as well as guided "Think Aloud" interviews. The SUS sum score ranges from 0 to 100, with higher scores representing better usability (Brooke, 1996). The

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interviews of the “Think Aloud” sessions were transcribed verbatim. Afterwards, the protocols were coded to identify upcoming usability problems which will be further ranked by frequency and urgency. 14 employees in nursing homes were included (13 female, mean age=53.7, SD=10.2). The mean SUS score was 72.3 (SD=18.2) indicating “good” usability and marginal usability problems. The main usability issues found by the “Think Aloud” approach were in the areas of navigation logic and comprehensibility of app content. Derived from these results, the InCoPE-App can be seen as a usable application that enables nursing home staff to deliver and implement individualized PA interventions for IWD in nursing homes. We found that even in persons aged ≥ 50 years who may have low digital literacy, the InCoPE-App can be used with little training. According to the results of the end-user review, but beyond of the scope of this thesis, the prototype of the InCoPE-App was revised and then tested in an 18-weeks field study.

In sum, this thesis contributes to a highly relevant and critically important research field in light of an aging society and the increasing prevalence of dementia. As dementia is a non-curable disease that poses a significant challenge for individuals, caregivers, and health care systems, there is an urgent need for studies focusing on easy, low-threshold and feasible solutions for the implementation of PA interventions, particularly in nursing home settings. The results of this thesis confirm the findings of existing literature concerning the heterogeneity of IWD which limits the effectiveness of general PA interventions. However, this thesis goes beyond the conclusion, that individualized PA interventions could be useful, and presents concrete approaches and starting points for further investigations, using ADL performance as an example. Furthermore, with the example of sensor-based fall risk assessment, this thesis shows how individual vulnerabilities can be assessed objectively. Assessing these data with high resolution using body-worn sensors is crucial for the individualization of PA interventions. Moreover, as to date there is no existing mobile health app for PA promotion in nursing homes, the approach of using a tablet-based application that supports nursing home staff, is novel and innovative, and has not been proposed in the literature yet. Therefore, this thesis adds highly relevant information to the research on long-term realization of PA interventions in nursing homes, as they are often the first to be cut down, when time and (wo)manpower is sparse (e.g. due to a pandemic). In future studies, the feasibility of combining sensor-based assessment methods, as presented in Manuscript 2, and the implementation of PA interventions via mobile health apps as presented in Manuscript 3 could be combined. Integrating sensor data into an individualization algorithm would provide more accurate data and may lead to a more suitable PA intervention for the individual. However, especially in the target group of IWD and in the setting of nursing homes, the feasibility and effort of such solution should be carefully examined.

ZUSAMMENFASSUNG

Aufgrund des demografischen Wandels steigt die Prävalenz altersbedingter Erkrankungen, weshalb im Jahr 2050 Hochrechnungen zufolge weltweit ca. 150 Millionen Personen mit einer Demenzerkrankung leben werden. Personen mit Demenz leiden häufig an einer Verschlechterung der kognitiven und körperlichen Leistungsfähigkeit, was zu Problemen in der Ausführung von Alltagsaufgaben sowie zu einem erhöhten Sturzrisiko führt. Aus diesem Grund ist es in dieser Zielgruppe wichtig, die kognitive und körperliche Leistungsfähigkeit zu erhalten, um die Alltagsfähigkeit zu verbessern und das Sturzrisiko zu reduzieren. Da Demenzerkrankungen nicht heilbar sind und medikamentöse Therapien ihre Grenzen haben, gilt der Einsatz von Bewegungsinterventionen bei Personen mit Demenz als nicht-medikamentöser Ansatz, der die krankheitsbegleitenden Symptome bei Demenz verbessern oder zumindest deren Verschlechterung verzögern kann. Die möglichen Zusammenhänge von körperlicher Aktivität, und kognitiver sowie körperlicher Leistungsfähigkeit waren bislang Untersuchungsgegenstand zahlreicher Studien. Jedoch erschwert die Heterogenität von Personen mit Demenz bezüglich des Gesundheitszustands, Alter, Symptomschwere etc., die Effektivität vieler Bewegungsprogramme. Die Berücksichtigung individueller Voraussetzungen bei der Planung von Bewegungsprogrammen kann daher ein möglicher Ansatzpunkt sein, um die Effektivität zu steigern. Dieser Ansatz muss jedoch in Studien genauer untersucht werden. Das erste Ziel der vorliegenden Thesis ist es daher,

die Effekte eines multimodalen (motorisch-kognitiv) Bewegungsprogrammes für Personen mit Demenz auf die Ausführung der Aktivitäten des täglichen Lebens zu untersuchen, und die Notwendigkeit aber auch Möglichkeiten von individualisierter Bewegungsförderung in dieser Zielgruppe zu identifizieren.

(Manuskript I)

Die erste Publikation beschäftigte sich mit der Hypothese, dass die Teilnahme an einem multimodalen Bewegungsprogramm einen positiven Einfluss auf die Ausführung der Aktivitäten des täglichen Lebens (ADL-Leistung) hat im Vergleich zu einer Kontrollgruppe. Darüber hinaus wurde explorativ untersucht, ob verschiedene Responder-Gruppen (Personen die positiv, gar nicht, oder negativ auf das Programm reagieren) sich in ihrer kognitiven und körperlichen Leistungsfähigkeit vor dem Start der Intervention voneinander unterscheiden und ob die kognitive und die körperliche Leistungsfähigkeit einen Teil der Varianz in der ADL-Leistung erklären. Hierfür nahmen 319 Personen im Alter von >65 Jahren mit leichter bis mittelschwerer Demenz in Pflegeeinrichtungen an einer randomisierten, kontrollierten

Interventionsstudie teil. Die Interventionsgruppe durchlief ein 16-wöchigen Interventionsprogramm, das aus in Fantasiereisen integrierten kognitiven und körperlichen Übungen bestand (2x/Woche, je 60min, unter Anleitung von ausgebildeten Trainer*innen). Die Kontrollgruppe behielt ihren normalen Pflegealltag bei. Vor, sowie nach der Intervention absolvierten die Teilnehmenden Tests, welche die ADL-Leistung, die kognitive, sowie die körperliche Leistungsfähigkeit erfassen. Die ADL-Leistung wurde mit Hilfe des „Barthel-Index“, des „7-items Physical Performance Tests“, sowie des „Erlangen Test of Activities of Daily Living“ erhoben. Einfaktoriellen Varianzanalysen kamen zum Einsatz, um Unterschiede zwischen der Interventions- und der Kontrollgruppe zu Beginn der Intervention zu untersuchen. Die Effekte des Bewegungsprogrammes auf die Ausführung der Aktivitäten des täglichen Lebens wurden mit Hilfe von mehrfaktoriellen Varianzanalysen mit Messwiederholung untersucht. Eine multiple Regressionsanalyse sollte herausstellen, ob die kognitive und motorische Leistung einen Teil der Varianz der ADL-Leistung erklärt. Die Ergebnisse zeigen, dass die Interventionsgruppe ihre ADL-Leistung im Vergleich zur Kontrollgruppe nicht verbessern konnte (ANOVA: $p > 0.05$, $\eta^2 = 0.004 - 0.019$). Eine „Responder“-Analyse belegt jedoch, dass zwischen 20-32% der Teilnehmenden der Interventionsgruppe positiv auf das Bewegungsprogramm reagieren. Auffallend war, dass „Positiv-Responder“ eine schlechtere Leistung zu Beginn der Intervention im Vergleich zu „Non-Respondern“ aufwiesen ($p < 0.05$). Mit Hilfe der Regressionsanalysen konnte gezeigt werden, dass bis zu 51.4% der Varianz der ADL-Leistung durch die kognitive und körperliche Leistungsfähigkeit erklärt werden kann. Auch wenn das Bewegungsprogramm keine allgemeinen Effekte auf die ADL-Leistung hatte, zeigt Manuskript I die individuelle Wirksamkeit abhängig von den kognitiven und körperlichen Leistungsvoraussetzungen von Personen mit Demenz. Diese Ergebnisse sind für die Entwicklung von zukünftigen Bewegungsprogrammen hoch relevant.

Neben der Wirksamkeit von Bewegungsinterventionen für Personen mit Demenz in Pflegeeinrichtungen, ist die Umsetzbarkeit ein weiterer wichtiger Faktor für eine langfristige und erfolgreiche Implementierung. Diese ist, aufgrund des Zeitmangels und der oftmals fehlenden Expertise bei Pflegeheimmitarbeitenden bezüglich Bewegungsförderung, jedoch eine Herausforderung. Mit Beginn der COVID-19 Pandemie und den damit einhergehenden Sicherheitsmaßnahmen wurden Bewegungsprogramme, insbesondere von externen Anbietern, nicht weitergeführt, was die Inaktivität der Betroffenen noch einmal verstärkte. Damit Personen mit Demenz in Pflegeeinrichtungen dennoch weiterhin körperlich aktiv bleiben, werden neue Lösungen benötigt, die eine objektive Erfassung von individuellen, gesundheitsbezogenen Faktoren (z.B. Sturzrisiko) erfassen, sowie eine niederschwellige Umsetzung von

Bewegungsinterventionen (z.B. individualisierte Bewegungsprogramme) ermöglichen. Digitale Gesundheitsanwendungen (z.B. am Körper getragene Sensoren, mobile Applikationen) sind hier vielversprechend und müssen in Studien untersucht werden. Die Zahl der entwickelten und implementierten digitalen Gesundheitsanwendungen für das Setting Pflegeeinrichtung nimmt stetig zu, jedoch existiert in der Zielgruppe der Personen mit Demenz bislang wenig Forschung. Die vorliegende Dissertation legt den Fokus auf zwei mögliche Anwendungsbereiche, die in dieser Zielgruppe vielversprechend scheinen: 1) Die Erfassung von sturzassoziierten Faktoren mit Hilfe von am Körper getragenen Sensoren, um Risiken für Stürze und folgender Inaktivität vorzubeugen und 2) die Umsetzung eines individualisierten Bewegungsprogrammes mit Hilfe einer digitalen Anwendung. Aus diesem Grund ist das zweite Ziel der vorliegenden Dissertation

die aktuelle Forschung bezüglich objektiver Sturzrisikoerfassung mit Hilfe von tragbaren Sensoren bei Personen mit und ohne kognitive Beeinträchtigung systematisch zusammenzufassen.

(Manuskript II)

Die zweite Publikation überprüfte die Annahme, dass tragbare Sensoren korrekte Daten zur körperlichen Leistung (z.B. Balance, Gang) liefern, um zwischen sogenannten „Fallern“ (Personen, die bereits gestürzt sind) und „non-Fallern“ (Personen, die noch nie gestürzt sind) oder zwischen Personen mit hohem und niedrigem Sturzrisiko zu unterscheiden. Darüber hinaus war das Ziel, praktische Empfehlungen zur Nutzung von tragbaren Sensoren zu geben, insbesondere für Personen mit kognitiven Beeinträchtigungen (z.B. Demenz). Zu diesem Zwecke wurde eine systematische Literaturrecherche im Juli 2019 (Update im Juli 2020) durchgeführt. Die Analyse schloss 28 Studien im geriatrischen Setting ein, die sensor-basiert das Sturzrisiko bei älteren Personen (>60 Jahre) mit und ohne kognitive Beeinträchtigung erfassten. Die Ergebnisse zeigen, dass die Daten von tragbaren Sensoren sowohl „Faller“ und „Non-Faller“, als auch Personen mit hohem und Personen mit niedrigem Sturzrisiko voneinander unterscheiden können. Das beste Klassifikationsmodell schloss Daten ein, die über drei aufeinanderfolgende Tage im Alltag erfasst wurden (Genauigkeit=90,6%, Sensitivität=91,7% und Spezifität=89,2%). Sensordaten aus kontrollierten Messungen im Labor waren weniger präzise (bestes Datenmodell aus dem Labor: Genauigkeit=89,4%, Sensitivität=92,7%, Spezifität=84,9%). Nur vier der untersuchten Studien schlossen auch Personen mit einer kognitiven Beeinträchtigung ein, während 19 Studien diese Zielgruppe explizit von der Analyse ausschlossen. Es bleibt festzuhalten, dass die Erfassung von Sensordaten im Alltag auch bei Personen mit kognitiver Beeinträchtigung machbar ist, und einer Erfassung im Labor aufgrund von Datenverzerrung durch Störungen von außen (z.B. Testleiter*in) vorgezogen werden sollte. Darüber hinaus sollte bei

Personen mit einer kognitiven Beeinträchtigung im besten Fall ein unauffälliger Trage-Ort am Körper gewählt werden (z.B. unterer Rücken), an welchem der Sensor nicht stört. Insgesamt scheinen am Körper getragene Sensoren zur objektiven Erfassung des individuellen Sturzrisikos gut geeignet zu sein, unabhängig von der kognitiven Einschränkung der betroffenen Person. Die Genauigkeit der Klassifizierung kann in Abhängigkeit von verschiedenen Faktoren (z. B. Standort des Sensors, Art der Bewertung) variieren. Sensorbasierte Daten können in zukünftigen Studien dazu verwendet werden, Interventionsprogramme auf die Bedürfnisse des Individuums anzupassen.

Neben sensor-basierter Erfassung von individuellen Risikofaktoren, können digitale Gesundheitsanwendungen (z.B. Apps) auch dafür eingesetzt werden, um Bewegungsinterventionen für Personen mit Demenz in Pflegeeinrichtungen zu implementieren. Die InCoPE-App (Individualized Cognitive and Physical Exercise) wurde von unserem Forschungsteam in Zusammenarbeit mit einer Software-Firma entwickelt, um niederschwellige, individuelle Bewegungsangebote für Personen mit Demenz in Pflegeeinrichtungen zu realisieren. Die Tablet-basierte InCoPE-App unterstützt dabei die Mitarbeitenden in Pflegeeinrichtungen bei der Planung und Anleitung der Bewegungsprogramme. Die Besonderheit der InCoPE-App ist ihr integrierter Algorithmus, der auf Basis der Ergebnisse von kognitiven und körperlichen Leistungstests individuelle Bewegungsprogramme generiert. In Anlehnung an die „User-Experience“-Methode, ist die Einbindung der zukünftigen Endnutzer*innen (hier: Pflegeheimmitarbeitende) in den Entwicklungsprozess einer solchen App ausschlaggebend für eine langfristige Nutzung. Durch die Einbindung der Endnutzer*innen können Nutzerprobleme aufgedeckt werden, die für eine nachhaltige Implementierung berücksichtigt werden müssen. Insbesondere in Pflegeeinrichtungen, in denen es oft an Zeit und Erfahrung mangelt, sollten mobile Apps die Wünsche und Bedürfnisse der Endnutzer*innen unbedingt berücksichtigen. Daher war das dritte Ziel der vorliegenden Dissertation

die Nutzerfreundlichkeit der InCoPE-App aus Sicht der Mitarbeitenden in Pflegeeinrichtungen zu untersuchen und Verbesserungspotenziale zu identifizieren.

(Manuskript III)

Die dritte Publikation beinhaltete zu diesem Zwecke eine Kombination quantitativer und qualitativer Erhebungsmethoden, welche den Einsatz der „System-Usability-Scale“ sowie die Durchführung von sogenannten „Think-Aloud“ Interviews umfassten. Der Gesamtscore der „System-Usability-Scale“ reicht von 0 bis 100 Punkte, wobei höhere Werte eine bessere Nutzerfreundlichkeit darstellen. Die „Think-Aloud“ Interviews wurden wortwörtlich transkribiert.

Im Anschluss wurden die Protokolle kodiert, um relevante Nutzerprobleme zu identifizieren und anschließend nach Häufigkeit und Dringlichkeit zur Änderung zu sortieren. Insgesamt nahmen 14 Mitarbeitende in Pflegeeinrichtungen (weiblich, $n=13$; Alter $MW=53,7$, $StAbw=10,2$) an der Studie teil. Der mittlere Summenscore der „System-Usability-Scale“ betrug 72,3 ($StAbw=18,2$), was auf eine gute Nutzerfreundlichkeit und kleinere Nutzerprobleme hinweist. Die Hauptprobleme in der Nutzung der InCoPE-App, die sich mit Hilfe der „Think Aloud“ Protokoll identifizieren ließen, lagen in den Bereichen der Navigation und der Verständlichkeit der App-Inhalte. Aus diesen Ergebnissen lässt sich ableiten, dass die InCoPE-App eine nutzerfreundliche Anwendung ist, die es Mitarbeitenden in Pflegeeinrichtungen ermöglicht, individualisierte Bewegungsprogramme für Personen mit Demenz anzubieten. Die Ergebnisse zeigen zudem, dass auch Pflegeheimmitarbeitende, die über 50 Jahre alt waren und möglicherweise über weniger digitale Kompetenzen verfügen, die InCoPE-App mit geringem Schulungsaufwand nutzen konnten. Mit Hilfe dieser Ergebnisse wurde die InCoPE-App außerhalb des Rahmens dieser Dissertation noch einmal überarbeitet und in einer 18-wöchigen Feldstudie eingesetzt.

Zusammenfassend lässt sich festhalten, dass die vorliegende Dissertation einen Beitrag zu einem hoch relevanten und, im Hinblick auf die alternde Gesellschaft, äußerst wichtigen Forschungsbereich leistet. Da Demenzerkrankungen bislang nicht heilbar sind und damit eine große Herausforderung für Betroffene, Pflegende und auch das Gesundheitssystem darstellen, besteht ein dringender Bedarf an Studien, die eine einfache und niederschwellige Implementierung von praktikablen Lösungen zur Bewegungsförderung anstreben. Insbesondere im Setting Pflegeeinrichtung ist dies von besonderer Bedeutung. Die Ergebnisse dieser Dissertation bestätigen die Annahmen bestehender Literatur, dass unter Personen mit Demenz eine große Heterogenität herrscht, welche die Effektivität von unspezifischen Bewegungsinterventionen einschränkt. Diese Arbeit geht jedoch über die Erkenntnis hinaus, dass individualisierte Ansätze notwendig sind, und stellt konkrete Ansatzpunkte für weitere Untersuchungen vor. Zudem legt die vorliegende Dissertation einen Fokus auf den Einsatz von digitalen Technologien zur möglichen Lösung der genannten Herausforderungen. Am Beispiel der sensorbasierten Sturzrisikoerfassung wird gezeigt, wie individuelle Vulnerabilitäten objektiv bewertet werden können. Dies kann unter anderem für die Individualisierung von Bewegungsinterventionen entscheidend sein. Da es bislang keine mobile App zur Bewegungsförderung von Personen mit Demenz im Setting Pflegeeinrichtung gibt, ist der Ansatz einer Tablet-basierten App zur Unterstützung der Pflegeheimmitarbeitenden neu und innovativ. Die vorliegende Dissertation liefert damit äußerst relevante Informationen für weitere Forschung zur langfristigen Realisierung von

Bewegungsinterventionen in Pflegeeinrichtungen mit Hilfe digitaler Lösungen. Zukünftige Studien könnten die Machbarkeit der Kombination von sensorbasierten Erhebungsmethoden, wie in Manuskript II dargestellt, und der App-gestützten Implementierung von Bewegungsinterventionen (Manuskript III) kombinieren. Die Integration von objektiven Sensordaten in einen Algorithmus könnte zu einer Verbesserung der Individualisierung von Bewegungsprogrammen führen. Insbesondere bei Personen mit Demenz in Pflegeeinrichtungen sollte jedoch die Machbarkeit und der Aufwand der Implementierung einer solchen Lösung sorgfältig überprüft werden.

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LIST OF ABBREVIATIONS

AD	Alzheimer's Disease
ADL	Activities of daily living
DHS	Digital health solutions
InCoPE	Individualized Cognitive and Physical Exercise
IWD	Individuals with dementia
PA	Physical activity
VD	Vascular dementia

1 GENERAL INTRODUCTION

1.1 DEMENTIA – A PUBLIC HEALTH PRIORITY

Dementia is defined as “a syndrome in which there is deterioration in cognitive function beyond what might be expected from usual consequences of biological aging” (World Health Organization, 2022a, n.p.). In persons with dementia, cognitive function in different domains (e.g., memory, language, executive function) is significantly impaired compared to a previously higher cognitive level. Furthermore, cognitive impairments must be severe enough to negatively affect everyday life activities (Hugo & Ganguli, 2014). Due to the elevating cases of the disease, the World Health Organization referred to dementia as a public health priority (World Health Organization & Alzheimer's Disease International, 2012) already 10 years ago. This chapter displays important facts and figures related to dementia (1.1.1). Moreover, it will briefly summarize the symptoms of dementia, prioritizing those that are relevant within the scope of this thesis (1.1.2). Thereupon, current treatment options for dementia will be discussed (1.1.3).

1.1.1 FACTS AND FIGURES

Due to the demographic change, the number of the oldest old and therefore, the prevalence of age-related diseases like dementia increases. According to World Health Organization, there will be 139 million of individuals with dementia (IWD) worldwide in 2050. From 1990 to 2016, there was an increase of 117% of IWD, reflecting the steady growth of numbers (Dementia Forecasting Collaborators, 2022). The prevalence of dementia increases with age (Prince et al., 2015), and is usually higher among women than men due to longer life expectancies in women (Hugo & Ganguli, 2014). Along with Greece and Italy, Germany has the highest dementia prevalence in Europe (Alzheimer Europe, 2019). Dementia is a leading cause of death (World Health Organization, 2022a), and the costs for the health care system are increasing (Hugo & Ganguli, 2014). Moreover, dementia poses a major financial challenge and psychological burden for family caregivers (Aranda et al., 2021). This makes the disease a general societal challenge, and research to examine potential risk and protective factors of dementia is highly important.

There are several modifiable and non-modifiable factors, which are associated with an increased risk of developing dementia. They can be classified into demographic (e. g. age, education), genetic (e. g. Apolipoprotein E4), medical (e. g. cardiovascular disease), psychiatric (e. g. depression), and lifestyle-related factors (e. g. smoking, physical inactivity) (Hugo & Ganguli, 2014). To date, predisposition to dementia is most explored for age, and genetic

disposition (Alzheimer's Society, 2021; Lourida et al., 2019). In contrast, several protective factors also exist, that are associated with decreased prevalence and incidence rates. For example, regular engagement in cognitive stimulating activities appears to have a protective factor on cognition (Hugo & Ganguli, 2014; Krell-Roesch et al., 2019). Furthermore, being physically active also seems to have a positive influence (Krell-Roesch et al., 2021).

Dementia is usually diagnosed by a physician based on subjective concern expressed from patients, family members and/ or caregivers, and objective clinical assessments. At onset of clinical symptoms, affected individuals or their relatives may notice a decrease in cognitive performance, impaired management of everyday life activities, and/ or changes in personality or onset of neuropsychiatric symptoms such as depression or agitation (Hugo & Ganguli, 2014). This subjective concern is further corroborated by neurologic examination and standardized, objective neuropsychological/ cognitive tests administered by a clinician. There are several global cognitive screening scales, which are widely used, such as the Mini Mental State Examination (Folstein et al., 1975) or the Montreal Cognitive Assessment (Nasreddine et al., 2005). Additional information about the underlying dementia type and current stage of the disease can be gathered by neuroimaging techniques, such as computer tomography, magnetic resonance imaging or PET scans (Ahmed et al., 2019).

One distinguishes between primary and secondary dementia. Primary dementia, also called “neurodegenerative dementia”, is characterized by a deterioration of nerve cells in the brain (Bello & Schultz, 2011). Secondary dementias often arise as a consequence of other diseases (e. g. metabolic disorder), traumatic brain injuries, or drug abuse (Bello & Schultz, 2011). For the purpose of this thesis, the main focus will be on primary dementia. The most common forms of primary dementia are Alzheimer’s Disease (AD) and vascular dementia (VD) (Hugo & Ganguli, 2014). In AD, there is an accumulation of amyloid plaques, and a subsequent loss of synapses and neurons in the brain. In most cases, AD is diagnosed at the eighth decade of life, and is associated with a remaining life expectancy after the diseases’ diagnosis of about 10 years (Hugo & Ganguli, 2014). VD, as the second most common type of primary dementia, often results from strokes and transient ischemic attacks that lead to the deterioration of cortical nerve cells due to reduced or no blood circulation for a substantial time (Iadecola, 2013). In order to differentiate between types of dementia, the symptoms, as well as the start and course of the disease are compared. Mixed dementia is also very common and refers to the coexistence of more than one dementia type in a patient, e.g. AD and VD (Iadecola, 2013).

1.1.2 DEMENTIA-RELATED IMPAIRMENTS

Dementia is accompanied by various impairments including but not limited to a decline in cognitive functions and problems in maintaining physical performance. As dementia is a disease of the brain, impairments in different cognitive domains (e.g., memory, attention, executive function, language and visuo-spatial functions) are often the first symptoms to be noticed.

An *impaired memory*, in relation to other persons of the same age and sex, is a defining characteristic in dementia (Stopford et al., 2012). Different forms of memory can be distinguished, e.g. short-term memory, working memory, and long-term memory (Calabrese & Förstl, 2009). In the early stages of AD, affected individuals often have problems with remembering new information. This condition worsens in later stages of the disease. In severe AD, even long-term memory is affected (Förstl et al., 2009). In contrast, individuals with VD typically show a well-preserved long-term memory (Haberl & Schreiber, 2009).

Attentional deficits in IWD can be observed even in early stages of the disease, and patients are often easily distractible or unable to concentrate while carrying out activities of daily living (Perry & Hodges, 1999). With regard to sustained attention (i. e., focus on one task for uninterrupted time periods), research has shown a difference between persons with AD (who have sustained attention impairment in later stages of the disease) compared to individuals with VD (who have sustained attention impairment in early stages of the disease) (McGuinness et al., 2010). Divided attention (i. e., attention on more than one stimulus) can be investigated within dual task paradigms. Studies have shown that IWD have problems in performing dual tasks (e.g. walking while talking), that may also affect gait parameters (e.g. shorter steps, reduced gait speed) and postural stability (Mirahadi et al., 2018).

Executive function is an umbrella term for cognitive processes which are important for controlling and directing actions and thoughts in everyday life (Martyr & Clare, 2012; Perry & Hodges, 1999). There is evidence, that even in early or pre-stages of dementia, impairments in executive function are present (Grober et al., 2008) and may affect daily tasks (e.g. choosing appropriate clothes, cooking a meal) which can suddenly cause problems for IWD (Perry & Hodges, 1999).

Language impairments can also be observed at early stages of dementia (Mendez et al., 2003; Rousseaux et al., 2010). In most cases, naming things or finding the right words are difficult for affected individuals (Kempler & Goral, 2008; Klimova & Semradova, 2016).

Additionally, a reduction of phrase length occurs (Rousseaux et al., 2010). In later stages of the disease, language impairments are characterized by non-fluent communication, difficulties in understanding spoken and written language accompanied with a breakdown of comprehension and decreased complexity of spoken words (Klimova & Kuca, 2016; Klimova & Semradova, 2016).

Visuo-spatial function describes the usage of vision in the perception and location of objects in a certain environment (Pal et al., 2016). In AD, visuo-spatial function is often impaired in early stages of the disease, and declines along with deterioration of other cognitive functions over time (Pal et al., 2016). Impairments in visuo-spatial function are indicated by reading difficulties, problems in differentiating shapes and colors, or perceiving visual contrasts (Quental et al., 2013).

With the progression of dementia from earlier to later disease stages, cognitive impairments are accompanied by decline in physical performance, as physical performance often requires a complex coordination of multiple body systems. The following physical impairments can be observed frequently in IWD.

Gait and related mobility impairments are present in over 50% of IWD (Allali & Verghese, 2017) and include reduced gait speed and a higher variability in stride length (Modarresi et al., 2019). Moreover, decreased step and stride length, as well as increase single stance time and double support time (Ries et al., 2015) can be observed. Gait also becomes more impaired with increased severity of cognitive impairment (Modarresi et al., 2019). Gait impairments are more pronounced in individuals with non-AD types (Ries et al., 2015).

Balance and postural stability are often impaired in IWD, as balance strongly requires an optimal use of cognitive abilities, especially of executive function, amongst others (Ries et al., 2015). Therefore, cognitive decline in dementia may impair balance, which is expressed in a greater sway and a larger sway velocity (Mc Ardle, Pratt, et al., 2021). Consequently, impaired balance in IWD is associated with an increased risk of falling (H.-J. Park et al., 2020).

A decline in upper and lower limb strength is also frequently present in IWD (Blankevoort et al., 2013; Filardi et al., 2022). For example, handgrip strength (which is often used as an indicator of motor fitness in studies among older adults) is associated with decreased performance in memory, attention and executive function, and therefore, is proposed as a tool to assess and monitor cognitive decline in older adults (Filardi et al., 2022). Moreover, studies

have shown a significant lower handgrip strength in IWD compared to healthy controls (Filardi et al., 2022).

The interplay of cognitive and physical impairments additionally leads to problems in *performing ADL*, which is one of the most prevalent characteristics of dementia (Giebel et al., 2015). In early disease stages, instrumental ADL are mainly affected, which are more complex and demand higher executive function. They are especially important for maintaining an independent daily life (i. e., shopping, cooking, or finance) (Giebel et al., 2015). As the disease progresses, basic ADL are increasingly affected, which involve basic needs and activities such as personal hygiene, food intake, and mobility (Giebel et al., 2015). Once basic ADL are impaired, then the affected individual is completely dependent on assistive support in daily life. Finally, both cognitive and motor symptoms in dementia, are related to *risk of falling* in IWD. 60% of IWD experience a fall at least once per year (Harvey et al., 2016), and fall twice as often as their cognitively intact peers (Peek et al., 2020). This poses a special challenge in the care of dementia, as a higher fall risk and higher number of falls are related to fractures, hospitalization, and higher mortality (Fernando et al., 2017; Joshi et al., 2020).

Of note, there is a high interindividual heterogeneity of accompanying symptoms in dementia, including but not limited to cognitive and physical functions (Verdi et al., 2021). This is mainly caused by the different causes and forms that may underly the disease (Ryan et al., 2018). Nevertheless, a certain part of the interindividual heterogeneity remains unexplained, complicating the treatment of the disease.

1.1.3 TREATMENT POSSIBILITIES

To date, there is no cure for dementia. Existing treatments can be divided into pharmacological and non-pharmacological interventions. Pharmacological interventions are aimed at relieving symptoms (e.g. behavioral changes) or delaying the process of cognitive deterioration (Kuang et al., 2021; Sopina & Sørensen, 2018), rather than addressing or acting on the cause of the disease (Beshir et al, 2022). Commonly used drugs are cholinesterase inhibitors or receptor antagonists. Cholinesterase inhibitors are thought to help restore cholinergic neurotransmission, thereby decreasing learning and memory impairments in dementia (Kasper & Volz, 2014). Receptor antagonists protect neurons in the brain from chronic glutamate overstimulation (Hausner & Frölich, 2019). Moreover, combined drug therapy is often used (Kabir et al., 2020). The first drug that is supposed to be disease-modifying is Aducanumab (Beshir et al., 2022), and first studies have shown a modest effect on general cognitive decline in mild cognitive impairment or early stages of AD but not on memory function in AD (Beshir et al., 2022).

Aducanumab was approved by the US Food and Drug Administration in 2021. In Germany, however, the European Medicines Agency has not (yet) approved the drug due to the low level of evidence (European Medicines Agency, 2022). Besides the questionable effectiveness of drug therapies in dementia, the negative side effects (e. g., dizziness, fatigue, or cardiac arrhythmias) and the high costs must be considered (Förstl, 2009; Jönsson et al., 2023; Sopina & Sørensen, 2018).

A wide range of non-pharmacological interventions for dementia exists, including but not limited to cognitive training, cognitive rehabilitation, cognitive stimulation therapy, physical exercise/ activity, nutritional and sleep treatments, meditation, reminiscence therapy, or music therapy (Sikkes et al., 2021). In particular, cognitive interventions have been studied extensively, albeit results are conflicting (Tisher & Salardini, 2019). A recent review showed positive effects on dementia symptoms, especially when cognitive interventions are combined with physical activity (Wollesen et al., 2020). Physical activity alone has also been studied as a non-pharmacological treatment in dementia care. Basically, physical activity in old age can operate as a neuroprotector and preserve cognitive function (Sujkowski et al., 2022). Prospective studies have shown that light or vigorous physical activity in mid-life is associated with a lower risk of incident mild cognitive impairment (Krell-Roesch et al., 2016). Moreover, moderate physical activity in persons with mild cognitive impairment can reduce the risk to develop dementia (Krell-Roesch et al., 2018). Physical activity interventions are also being examined in a growing number of studies as a rehabilitation therapy, and are hypothesized to influence the progression and symptoms of the disease. Of note, physical activity is particularly promising, as it may affect not only cognitive function, but also ADL and physical functioning, and may have only little to no side effects. A detailed description on the effectiveness of physical activity in IWD is provided in Chapter 1.2.2.

Despite of all the aforementioned ways of treating dementia disease, it must be noted that the multitude of disease-related symptoms, as described in Chapter 1.1.2 lead to a high heterogeneity among IWD. The magnitude of impairments is highly individual which may influence the effectiveness of PA interventions. Despite the knowledge about the heterogeneity in IWD, studies often fail to capture and consider this heterogeneity (Verdi et al., 2021).

Text box 1-1: Summary of chapter 1.1

Dementia is a disease of the brain in old age with increasing prevalence due to demographic change. The most common forms of primary dementia are Alzheimer's disease and vascular dementia. The main hallmark of dementia is impaired cognitive functions. In addition, physical performance, as well as activities of daily living and quality of life are impaired over the course of the disease. Moreover, persons with dementia have a higher risk of falling compared to their cognitively intact peers. All these factors may lead to a higher cost for the health care system in general, as well as higher care burden. To date, dementia is not curable. Pharmacological treatment can only reduce severity of symptoms, but is associated with side effects and high costs. Non-pharmacological interventions are therefore of great importance. In particular, physical activity seems promising, as it may have a beneficial impact on various symptoms, including but not limited to cognitive and motor performance declines.

1.2 PHYSICAL ACTIVITY FOR INDIVIDUALS WITH DEMENTIA

As mentioned in chapter 1.1.3, there are many treatment options for dementia, and non-pharmacological interventions are more cost-effective than drug-based treatment. PA in particular seems to be a promising approach to be implemented in different settings such as nursing homes to benefit IWD, as it may have an effect on various symptoms. For example, in contrast, cognitive interventions only address cognitive function. The potential contribution of physical activity to the maintenance of important functions (e.g. physical function, cognition, activities of daily living), may positively affect independency in IWD, in general. This, in turn, may be associated with reduced care burden among nursing home staff. In the following sections, existing recommendations of PA for IWD are presented (1.2.1). Furthermore, current research on the effectiveness of PA on selected outcomes in IWD will be briefly summarized (1.2.2), followed by a description of PA implementation in nursing homes (1.2.3). In chapter 1.2.4, existing research gaps in the field of PA promotion and effectiveness in IWD are presented.

1.2.1 RECOMMENDATIONS

Recommendations on PA exist for healthy older adults, as well as for older adults with impairments, e.g. dementia. For the most parts, recommendations for these two groups are overlapping. The guidelines of the World Health Organization are focusing on older adults aged > 65 years. The World Health Organization recommends aerobic exercise training to an extend of 150 to 300 minutes per week at moderate to high intensity. In addition, a multimodal training of strength and balance at least three times per week, as well as reducing sedentary behavior to a minimum, is suggested (World Health Organization, 2022b). For IWD, the American College of Sports Medicine suggests to integrate PA as much as possible into daily life. Moreover, a 30 to 60 minutes aerobic training carried out five times per week is recommended, in addition to a moderate to intense strength training with small training devices carried out two times per week. It is also recommended to combine different activities within one training session, e.g. mobility and balance exercises (Liguori et al., 2022). When comparing the recommendations for healthy older adults to those for IWD, it is striking, that there is no difference in terms of training volume. It is questionable to which extent these recommendations can be translated into the daily life in nursing homes. Therefore, specific suggestions also exist for nursing home residents. They include increasing PA in everyday life (e. g. reducing sedentary breaks, increasing active daily tasks), and multicomponent training (i. e., balance, strength, mobility) but differ in terms of training volume and frequency. Here, it is recommended to engage in physical exercise at least two times per week for a duration between 35 and 45 minutes at a moderate intensity and

without complete exhaustion (Souto Barreto et al., 2016). Regardless of the different recommendations for IWD and nursing home residents in general with regard to training volume, multimodal exercise programs or programs including aerobic exercises seem to be most effective.

1.2.2 EFFECTIVENESS ON SELECTED OUTCOMES

A growing body of research has examined the effects of PA on cognition, physical performance, activities of daily living, and falls. A short, non-systematic research on PubMed yielded 39 systematic reviews and / or meta-analyses from the last 10 years (Table 1.1) with main focus on cognitive outcomes (State: Spring/Summer 2023).

Table 1.1: Systematic Reviews and Meta-Analyses on the effects of physical exercise in dementia (from 2013-2023)

Outcome	n	Systematic Reviews / Meta-Analyses
<i>Cognition</i>	27	Ali et al., 2022; Almeida et al., 2020; Andrade et al., 2022; Balbim et al., 2022; Borges-Machado et al., 2021; Brett et al., 2016; Cámara-Calmaestra et al., 2022; Cammisuli et al., 2017; Cardona et al., 2021; Demurtas et al., 2020; Du et al., 2018; Forbes et al., 2015, 2015b; Groot et al., 2016; Guitar et al., 2018; Huang et al., 2022; Karssemeijer et al., 2017; Kuang et al., 2021; Law et al., 2020; H. S. Lee et al., 2016; J.-H. Liang et al., 2018; Y.-J. Liang et al., 2022; López-Ortiz et al., 2023; Öhman et al., 2014; Steichele et al., 2022; Venegas-Sanabria et al., 2022; S. Zhang et al., 2022; Zhu et al., 2020
<i>Physical performance</i>	11	Ali et al., 2022; Almeida et al., 2020; Borges-Machado et al., 2021; Brett et al., 2016; Cámara-Calmaestra et al., 2022; Lam et al., 2018; H. S. Lee et al., 2016; López-Ortiz et al., 2021; Racey et al., 2021; Rao et al., 2014; Yeh et al., 2021
<i>Activities of daily living</i>	8	Borges-Machado et al., 2021; Forbes et al., 2015; Karssemeijer et al., 2017; H. S. Lee et al., 2016; Rao et al., 2014; Steichele et al., 2022; S. Zhou et al., 2022; Zhu et al., 2020
<i>Falls</i>	7	Burton et al., 2015; Chan et al., 2015; Demurtas et al., 2020; Gulka et al., 2020; Li, Harmer, Eckstrom, et al., 2021; Y.-J. Liang et al., 2022; Racey et al., 2021

n= number

To summarize the multitude of existing reviews and meta-analyses, three umbrella reviews have also been published. As shown in Table 1.2, they provide results for the effectiveness of physical exercise on selected outcomes in IWD and with regard to type, frequency and duration of PA, albeit the evidence remains rather low (Andrade et al., 2022; Begde et al., 2022;

López-Ortiz et al., 2023). Significant effects were reported for global cognition, but not for domain-specific cognitive functions such as memory, executive function, attention, or language (Andrade et al., 2022; López-Ortiz et al., 2023). With regard to the effectiveness of PA on physical performance outcomes, small to large effects were reported for gait and balance, with only high evidence for the latter (Andrade et al., 2022; Begde et al., 2022). For strength or mobility outcomes, no results were reported. With regard to activities of daily living, small to large effects were found (Andrade et al., 2022; Begde et al., 2022). Finally, in all three umbrella reviews, no results were reported on falls or fall risk.

Table 1.2: Main results of the latest umbrella reviews on the effects of PA in IWD

	López-Ortiz et al., 2023 ²		Andrade et al., 2022 ²		Bedge et al., 2022 ¹		Recommended types, frequency and duration of exercise
	Effect	Evidence	Effect	Evidence	Effect	Evidence	
<i>Global Cognition</i>	small to large	low to unclear	medium	-	n/a	-	multimodal exercise at least 30min, 3 days/week
<i>Gait</i>	n/a	-	small	-	small to large	low	functional exercise training at least 60min
<i>Balance</i>	n/a	-	n/a	-	small to large	high	exergaming or high-intensity functional exercises at least 60min, 5 days/week
<i>ADL</i>	n/a	-	large	-	small to large	-	multimodal exercise, combination of cognitive and physical training 45-60min, 3-5 days/week

¹included reviews with different types of primary dementia and mild cognitive impairment; ²only included reviews with Alzheimer's disease; n/a= not applicable; PA= physical activity, IWD= individuals with dementia

Even though these recent umbrella reviews did not include research concerning strength, mobility, and falls, these outcomes have already been investigated in past studies. A systematic review by Lam et al. (2018) concludes that there is strong evidence that PA improves mobility and strength in individuals with mild to moderate dementia, but results for falls remain inconclusive. This was also confirmed by another systematic review, that investigated the

effects of PA on number of falls, and reported conflicting or inconclusive results (Burton et al., 2015).

With regard to the type of exercise, there is evidence that particularly multimodal exercise, i.e., combined cognitive and physical training, may be most effective to impact both cognition and activities of daily living. Examined durations and frequency of exercise sessions in studies ranged from 30 to 60 minutes on at least three to a maximum of five days per week (Begde et al., 2022). There appears to be a beneficial impact on gait and balance after a more specific training, i. e., functional exercise training, with a higher session duration of 60 minutes (Begde et al., 2022). For improvement of strength and mobility, Lam et al. (2018) recommend multimodal exercise with 60 minutes carried out at 2 to 3 times per week. Similarly, for fall prevention, multimodal interventions, including strength, balance and mobility training seem to be promising. Moreover, progression of exercise intensity over time is recommended (Burton et al., 2015).

1.2.3 IMPLEMENTATION OF PHYSICAL ACTIVITY IN NURSING HOMES

There are various efforts in place to ensure that PA is implemented and that recommendations and guidelines for PA are met in nursing home settings. In Germany, the legal basis is the §5 SGB XI (GKV-Spitzenverband et al., 2022) which specifies that offerings to maintain cognitive function and physical performance should be implemented. Despite these existing recommendations for PA for IWD and/ or individuals living in nursing homes, the reality is usually different (Frahsa et al., 2020). The specific living environment in nursing homes (Tak et al., 2015) and the daily structure, which is mainly determined by meal times and schedules, has a significant impact on both quantity and quality of PA in nursing home residents. Unfortunately, nursing home residents spend most of their time being inactive in their private rooms, and often only move in order to get to dining areas (Jansen et al., 2017). In addition, IWD are less likely to participate in regular PA than their cognitively unimpaired peers (Lam et al., 2018). It is thus not surprising that studies showed that IWD are mostly physically inactive, and spend most of their day (72%) sitting or lying compared to healthy peers (van Alphen, Volkers, et al., 2016). This passive lifestyle may, in turn, lead to a worsening of dementia symptoms, especially in physical function, that is beyond and above the anticipated age-related decline (Vikström et al., 2021).

Implementation of PA in nursing homes is also complicated by several barriers on both administrators' and implementors' sides. In particular, administrators in nursing homes face the challenge that integration of PA into the regular care requires substantial time and staff

resources (Benjamin et al., 2011). There is also the belief that staff would need appropriate training to effectively and safely guide and administer physical activity programs. Another concern often raised by administrators is, that due to the multimorbidity of nursing home residents, they do not only need support while participating in exercise programs, but also even to get to rooms within the nursing home where the PA program takes place which requires additional staff resources (Benjamin et al., 2011). Most nursing home staff in Germany have no official training to guide PA offers (Frahsa et al., 2020). Nevertheless, it is generally recommended, that nursing home staff is specialized in dementia care (Groot Kormelinck et al., 2021) and that PA for older adults with cognitive impairment is supervised by professional staff or, at least, a properly trained caregiver (Groot Kormelinck et al., 2021). However, a study by van Alphen, Volkers, et al. (2016) showed that a common barrier of implementing PA in nursing homes are difficulties in guidance and organization of PA programs by caregivers. Another study reported problems with the implementation of new knowledge or skills, and resulting changes to the work routines in nursing homes (Nolan et al., 2008). Moreover, implementors of PA in nursing homes are often not familiar with the guidelines of the World Health Organization, and argue that implementation of PA is difficult or impossible due to a lack of time and staff resources (Baert et al., 2015). Studies have also shown that implementors of PA programs (e. g. physiotherapists or nursing home staff itself) often fear to put too much pressure on participants who may not wish to be physically active (Baert et al., 2015; Vikström et al., 2021). Moreover, some express difficulties in implementing PA particularly for persons with cognitive impairment (Baert et al., 2015), or feel they lack specific guidance and skills to do so (Vikström et al., 2021).

Another main problem of PA programs in nursing homes is the generally low attendance to these programs. As many residents in nursing homes have medical comorbidities, including several physical and cognitive impairments (see chapter 1.1.2), their low willingness and motivation to participate in physical exercise poses a difficult challenge (Lam et al., 2018). A recent meta-analysis showed that the mean attendance of nursing home residents in 23 PA trials ranged from 33 to 99%, with only three trials reporting potential reasons for low attendance (e.g., disease, disagreement/ unwillingness to continue, behavior disorders, health-related problems, ADL disabilities). In addition, being female and having severe dementia was found to be associated with low attendance rates in studies before (Lam et al., 2018). Studies also reported that IWD in nursing homes are more motivated to engage in and maintain PA if they can participate in preferred PA options (van Alphen, Volkers, et al., 2016).

1.2.4 RESEARCH GAPS

As shown in chapters 1.2.2 and 1.2.3, there are several challenges that must be addressed when designing and implementing PA programs in nursing home settings. For example, the PA programs should meet the needs of IWD and be effective with regard to cognitive and motor performance outcomes, but also be feasible to be carried out in care settings (i.e. nursing homes) (Gebhard & Mir, 2021). Furthermore, the evidence of the effectiveness of PA programs in nursing homes is still limited, also due to the fact that past studies examined a vast variety of interventions (e. g. aerobic exercise, multimodal exercise, combination of physical and cognitive exercise) assessments for different outcome parameters (e. g. Mini Mental State Examination vs. Montreal Cognitive Assessment for global cognition). Moreover, past studies have often used inappropriate or non-standardized assessments that lack sound psychometric properties (Trautwein, Barisch-Fritz, et al., 2019). Therefore, it remains difficult to compare study results, and derive clear recommendations from previous research (López-Ortiz et al., 2023; López-Ortiz et al., 2021).

Moreover, to date, it is not conclusively clarified which intervention content is beneficial for which outcomes, and for which type of dementia; however, multimodal exercise appears to be most promising (Begde et al., 2022). Nevertheless, recommendations regarding content, duration and frequency of physical exercise differ, mainly because there is still a lack of detailed information on exercise protocols reported in studies (e. g. training intensity, rules for progression of intensity) (Lam et al., 2018).

Besides the problem, that there is still no consistent recommendation for type, intensity and duration for PA for IWD, in most cases the phenomenon of heterogeneity in this target group is not considered, leading to “general” exercise programs that do not take into account intraindividual impairments or needs of participants with dementia. Studies on dementia prevention have shown that a “one-size-fits-all” approach is less effective, since participants may either be “responders” and “non-responders” to the PA program and this may determine whether effects on physiological outcomes will be observed (Müllers et al., 2019).

Finally, on an organizational level, PA programs are often not included into nursing home decision programs (Frahsa et al., 2020), and nursing home staff often feels not well trained to guide and administer such interventions (Baert et al., 2015). Therefore, there is a need for low-threshold PA programs that are easy to implement in nursing homes, and do not require extensive training or skill sets of nursing home staff. Otherwise, long-term implementation of PA in nursing homes’ daily routines is less likely.

Text box 1-2: Summary of Chapter 1.2

For IWD, similar PA recommendations exist as for cognitively unimpaired older adults. Nevertheless, especially in nursing homes, IWD are physically inactive most of the day, and the usefulness of such general recommendations remains debatable. However, research has shown that PA has promising effects on IWD in terms of cognitive function, physical performance, activities of daily living, and fall prevention, but evidence of recent studies is still limited and quality of studies is varying. Therefore, high-quality studies are necessary that include a sufficiently large sample size, and a multi-component PA intervention program, and that use highly standardized assessments which have already been used and preferably validated in IWD. In addition, the specific circumstances and characteristics of the nursing home setting must be carefully considered when designing and implementing PA programs for IWD, particularly when aiming at a long-term implementation. Finally, the question remains, as to whether a “one-size-fits-all” approach is effective in this highly heterogeneous target group of IWD, or whether individualized programs targeting specific preferences and needs of IWD may be more promising.

1.3 EXCURSUS: COVID-19 IN NURSING HOMES – A PARTICULAR CHALLENGE

The COVID-19 pandemic posed a special challenge in many areas of life and still has an impact on several target groups and settings. Nursing homes were considered “hotspots” or “ground zero” during the pandemic, as they accommodate highly vulnerable target groups of older adults, many of which have impairments and medical comorbidities (Barnett & Grabowski, 2020). Therefore, particularly during the first time of the pandemic, several restrictions were introduced for nursing homes, its staff, and residents. According to Frahsa et al. (2020) who described how nursing homes responded to pandemic related changes during the first lockdown between March and June 2020, three stages could be observed: During a first stage, when access of external persons was prohibited, many nursing homes tried to adapt their daily routines to pandemic-related regulations. For example, group activities were organized outside of the nursing home facilities, in order to insure proper distance between participants. During a second stage, nursing home staff were required to take over activities that had been externally provided prior to the COVID-19 pandemic, such as physical activity which had often been administered by exercise instructors. Despite these efforts, residents’ physical activity levels decreased. Finally, during a third stage, when external visitors were permitted again, nursing home staff was additionally faced with organizational and logistical challenges, e. g., screening of visitors for COVID-19 symptoms (Frahsa et al., 2020). As a consequence of the pandemic-related restrictions and the increased organizational work load for nursing home staff, residents faced severe social isolation that was also linked to decreased physical activity within the nursing home or less participation in special PA programs (Geissler et al., 2021). A recent study reported a statistically significant functional and cognitive decline in 20.2% and 25.9%, respectively, of a sample of 435 nursing homes residents during the COVID-19 pandemic as compared to before (Pérez-Rodríguez et al., 2021). Especially IWD in nursing homes were additionally affected by the restrictions and the COVID-19 pandemic led to an overall decline in PA in this target group (Abasıyanık et al., 2022; Chen et al., 2021; Yamada et al., 2020). This decrease in PA was also found to be correlated with a decline in cognitive function during one year under pandemic conditions (Chen et al., 2021). In addition, this association was also confirmed by subjective impressions of nursing home staff (Geissler et al., 2021). Furthermore, some studies reported a decline in activities of daily living (Borges-Machado et al., 2021; Chen et al., 2021), physical condition and walking abilities (Frahsa et al., 2020) during COVID-19. Moreover, since 98% of IWD suffer from neuropsychiatric symptoms (e.g. depression) (Vik-Mo et al.,

2020), the COVID-19 may have exacerbated symptoms and thus, may have severely impacted quality of life (Pérez-Rodríguez et al., 2021; Velayudhan et al., 2020).

Consequently, especially in times of the COVID-19 pandemic, being physically active was crucial as PA has a wide range of positive effect on body systems and may, amongst others, contribute to a better immune system and decrease the risk of a COVID-19 infection (da Silveira et al., 2021). Particularly, since both advanced age and presence of comorbidities are considered risk factors for COVID-19 infections and related mortality (Fallon et al., 2020), PA promotion may have even become more important in older adults. However, many PA recommendations to maintain an active lifestyle during the pandemic did not consider vulnerable populations and settings (Bentlage et al., 2020). For example, in nursing homes, where PA promotion is often considered as a by-sided activity, PA was often one of the first activities that was halted or cut down during the pandemic (Frahsa et al., 2020). As a consequence, at the beginning of the COVID-19 pandemic, group activities were mostly cancelled (Frahsa et al., 2020; Geissler et al., 2021). Some nursing homes tried to maintain modified PA offers, e.g. individual training, training only in small groups or in rooms with enough space to keep physical distance. For the majority of nursing homes, maintaining PA programs during COVID-19 was associated with additional work load, e. g., nursing home staff were required to sanitize exercise equipment after use (Geissler et al., 2021). According to Frahsa et al. (Frahsa et al., 2022), the problem of PA programs not being fully integrated into the organizational structure and culture in nursing homes, was therefore further exacerbated by the COVID-19 pandemic.

In conclusion, the COVID-19 pandemic once again highlighted the importance of PA programs and interventions for nursing home residents in order to maintain or delay further decline in both cognitive and physical functioning. This may be associated with a more independent daily life and higher quality of life. In turn, the workload for nursing home staff may be reduced if residents experience benefits from PA on cognitive and physical levels (Kleschnitzki et al., 2022). The pandemic has also clearly shown that there is a lack of, and an urgent need for, low-threshold solutions to promote PA in nursing homes. Digital health technologies may play a key role to this end (Kleschnitzki et al., 2022).

1.4 DIGITAL HEALTH IN DEMENTIA CARE

Over the last decades, digital health has made its way into many areas of health care settings. In various medical fields such as rheumatology (Solomon & Rudin, 2020), diabetes mellitus (Shan et al., 2019) or mental illness (Batra et al., 2017), different kinds of digital health technologies have been developed and evaluated in the past. Due to its many possibilities, digital health also received increasing attention in the field of dementia and in the setting of nursing homes. This chapter defines the term “Digital health” (1.4.11.4.1), and discusses existing solutions and recent developments of digital health in dementia care (1.4.2). Finally, challenges and existing research gaps will be displayed 1.4.3).

1.4.1 DEFINITION OF “DIGITAL HEALTH”

“Digital health refers to the use of information and communication technologies in medicine and other health professions to manage illnesses and health risks and to promote wellness” (Ronquillo et al., 2022, p. 1). To this end, digital health solutions (DHS) include but are not limited to mobile health, wearable devices, telehealth and telemedicine, health information technologies and personalized medicine (U.S. Food and Drug Administration, 2020). In its “Global Strategy on Digital Health 2020-2025”, the World Health Organization stated that digital health may be beneficial in making health services accessible for all people on a global scale, and therefore, digital health may improve cost-effectiveness and efficiency of care (World Health Organization, 2021). Nevertheless, no precise definition of digital health is existing. Therefore, a work Fatehi et al. (2020) tried to develop a consensus definition of published digital health definitions using a quantitative analysis and term mapping. They concluded that digital health refers to the proper use of technologies to improve health and wellbeing of individuals, and to enhance care of patients with intelligent processes of health-related data (Fatehi et al., 2020).

1.4.2 RECENT DEVELOPMENTS

In the care of older adults, over the last decade, several health technologies have been developed and implemented, with different complexity levels, ranging from simple documentation tools to robots which can be used to support care. In addition to economic benefits, DHS may reduce caretakers’ burden and enable better communication between health care professionals (Johnston et al., 2022). Since 2015, an increase of research studies on digital health technologies can be observed (Sohn et al., 2023). The outbreak of the COVID-19 pandemic further accelerated the development and use of health technologies (C. Lee, 2022), even in dementia care (Pothak, 2022). Furthermore, the paradigm shift from treatment-oriented care to

personalised medicine that considers individual characteristics of the patient, benefits from the development. The use of artificial intelligence and big data in health technologies allows for providing such personal care (Sohn et al., 2023). Digital health technology solutions that have been developed and evaluated thus far can be divided into diagnosis and prediction, monitoring, and interventions tools (Sohn et al., 2023).

As *diagnosis and prediction tools*, DHS hold the great promise to address weaknesses of objective and subjective clinical assessments. For example, body-worn sensors offer a great potential even in older persons in geriatric care settings (Jansen et al., 2022). They may be used to diagnose and identify (early) signs of functional decline and diseases (Jansen et al., 2022). For example, the evaluation of balance and balance alterations with accelerometry in older adults was found to be valid and reliable in laboratory settings (Leirós-Rodríguez et al., 2019). Furthermore, sensor-measured balance parameters were considered useful to identify IWD at risk of falls (Hauer et al., 2020). Another study showed a high value of body-worn sensors in measuring gait parameters (i.e., gait speed, step length and time, cadence) in geriatric patients who used a rollator while walking (Werner et al., 2020).

One popular example for *monitoring tools* is the electronic patient record, which was implemented into many nursing homes in order to simplify documentation processes such as care planning and assessment (Shiells et al., 2020). Electronic patient records generally contain different patient-related data (e.g., demographic variables, vital statistics, medical intake, frailty, quality of life) (Cowie et al., 2017). The electronic patient record may be beneficial in improving quality of documentation, and may therefore reduce administrative burdens of caregivers (Shiells et al., 2020). Furthermore, if and when the electronic patient record is compatible with other systems, it has the potential to share data across health care providers (Gheorghiu & Hagens, 2016). Another example for monitoring tools in dementia care are technologies such as sensor mats or movement sensors which are supposed to guarantee the safety of IWD. They typically set off an alarm, when IWD stand up and move (Tsertsidis, 2021). When used properly, these technologies may reduce the need for regular check-ups by nursing home staff during the night, and may therefore decrease caregivers' work load (Lorenz et al., 2019). Moreover, they may improve the detection of falls (Potter et al., 2017).

A third possibility is to use digital health technologies as *intervention tools*. Here, the possibilities are also manifold. For example, (pet) robots have been used in a therapeutic context for IWD, and studies have shown that a social robot which provides music, reminiscence and cognitive games in therapeutic sessions had a positive effect on behaviour and mood, as well

as on physical activity level change in IWD in nursing homes (Cruz-Sandoval et al., 2020; Lorenz et al., 2019; Tsertsidis, 2021). Furthermore, social interactions were encouraged (Pu et al., 2019; Sohn et al., 2023). There appears to be a high acceptance of robots as communication companions among IWD, and this may consequently reduce caregivers' burden (Sohn et al., 2023). (Di Lorito et al., 2022) and colleagues provide an overview of digital health interventions for IWD or individuals with MCI on PA and fall prevention, among other outcomes. They identified a total of 19 interventions, of which the majority included exergaming (i.e., video games including exercise such as Nintendo Wii-Fit). Moreover, five of the included studies used virtual-reality based interventions. Only three interventions were delivered via a smartphone or a tablet (Kwan et al., 2020; Laver et al., 2020; Li, Harmer, Voit, & Chou, 2021). One of them investigated the effects of a brisk walking mHealth intervention on PA behaviour in individuals with MCI living in the community. The authors concluded that participants of the intervention group significantly increased their walking time and time spent engaging in moderate to vigorous PA (Kwan et al., 2020). A study by Li, Harmer, Voit, and Chou (2021) implemented an online virtual fall prevention program (i.e., Tai Ji Quan) in older adults with MCI, and found better fall risk related performance (e.g., balance, and mobility) in the Tai Ji Quan intervention group compared to a stretching group.

1.4.3 CHALLENGES AND RESEARCH GAPS

The recent development of DHS was further accelerated by the COVID-19 pandemic (van Hattem et al., 2021). As the pandemic has also impacted dementia care in nursing homes (see Chapter 1.3), it highlighted the importance of DHS even in this setting, e.g. in order to reduce physical contact among a highly vulnerable target group (Giebel, 2023; Sohn et al., 2023). Despite, or perhaps because of, this rapid development of DHS in the past years, there are some existing challenges and research gaps, leaving room for improvement.

One main challenge of recent DHS is, that they are often tested in laboratory, but not under field conditions. For example, although body-worn sensors were found to be useful to detect balance impairments and fall risk factors in older adults (see Chapter 1.4.2), these results were mainly valid for laboratory but not for real-life or clinical conditions (Leirós-Rodríguez et al., 2019). As a consequence, to date, there is little evidence for the practical application of these solutions (Lorenz et al., 2019). Moreover, the feasibility of body-worn sensors as well as accuracy of data for fall risk evaluation, especially in IWD, is lacking (Bezold, Krell-Roesch, et al., 2021). Nevertheless, the transferability of DHS seems to be inevitable when it comes to the long-term and sustainable implementation in nursing homes.

For mobile health applications, an iterative development process is necessary and recommended (Shackel, 2009), but rarely finds consideration. In particular, the end-users as well as the target setting should be considered during the development process at different time points (Farao et al., 2020). To date, end-users are often not involved into the development process, especially of digital solutions to support IWD (Holthe et al., 2022). However, according to a user-centric development approach, this is necessary to improve the acceptance and usability of such solutions (Farao et al., 2020). When it comes to the setting of nursing homes, the views, concerns and wishes, especially of nursing home staff, should be considered in the development process of DHS (Tsertsidis, 2021). Including nursing home staff in the development process makes them feel valuable and appreciated, which, in turn, could have a positive impact on acceptance and later use (Tsertsidis, 2021). Currently, however, the literature regarding the use of digital health tools to assist health care professionals is scarce and heterogeneous (Choukou et al., 2023). In many cases, the design process of DHS is focused on technical aspects of the final product (i.e., techno-centric product perspective) and does not capture the needs of the complex environment in nursing homes (Tsertsidis, 2021). Often, the additional workload through digital solutions for caregivers is not considered, although there is already a lack of personnel and time resources in nursing homes (Johnston et al., 2022; Lazar et al., 2018). Even though DHS should be mainly designed to support or facilitate processes, they are often perceived as time-consuming or increasing caregivers' burden as the handling with a solution must first be learned anew (Hench et al., 2023). For example, nursing home staff reported electronic patient reports to be hindering some practices, especially when caring for IWD who have more complex needs compared to others (Shiells et al., 2020). Moreover, mobile applications that were developed for direct use of IWD, resulted in an increased caregiver burden as IWD did not accept the application or experienced difficulties when using them (Sohn et al., 2023). Therefore, the feasibility and effectiveness of a direct use of mobile applications by IWD is questionable.

Finally, despite the fact of emerging DHS in the past years, digital health technology in the care of older persons with or without cognitive impairments is understudied, and the existing solutions are heterogeneous, which further complicates a comparison with regard to effectiveness (Choukou et al., 2023). Moreover, best practice standards for the development and implementation of DHS in general (Solomon & Rudin, 2020), but in particular in a nursing home setting (Pothak, 2022) have not been developed yet. To date, there is little evidence for the practical application as well as accessibility, acceptability, and sustainability of these solutions (Di Lorito et al., 2022; Lorenz et al., 2019) in nursing home settings. Therefore, more studies

examining the usability and acceptability of these DHS in nursing home settings are needed (Choukou et al., 2023).

Text box 1-3: Summary of chapter 1.4.3

DHS can support dementia care as diagnosis and prediction (e.g. detection of fall risk factors), monitoring (e.g. electronic patient records) or interventions (e.g. mobile applications for PA promotion) tools. Nevertheless, the rapid development over the last years led to a large number of DHS, but most have not been tested under real world conditions, or do not take into account the end-users or the target setting. However, this is what seems to be essential, in particular in dementia care. One promising application possibility of DHS in dementia care are body-worn sensors for fall risk evaluation, but research in this area is sparse. Another possibility are mobile health applications for PA promotion in IWD. But, as a direct use of such applications by IWD must be questioned, applications supporting nursing home staff in generating, guiding and administering PA should be developed. In order to support the long-term and sustainable use of all DHS in dementia care, the usability and acceptability of these solutions should always be critically examined and considered.

2 SCOPE OF THE THESIS

This thesis was conducted based on two consecutive projects (“Physical Activity against dementia [original title: “Bewegung gegen Demenz”] and “InCoPE – Individualized Cognitive and Physical Exercise”) and aims to address research gaps and challenges of

- a) designing effective PA interventions for IWD in nursing homes,
- b) and eliciting and discussing possibilities of digital health solutions in this field.

In this chapter, the two research projects are briefly described (2.1), followed by a prescription of the overarching aims and research questions (2.2) addressed by this thesis.

2.1 RESEARCH PROJECTS

Within the “*Physical activity against dementia*” project, a large randomized controlled trial was conducted between 2014 and 2018 in 36 nursing homes in South-West Germany. The aim of the study was to design, implement and evaluate a 16-week multimodal dementia-specific exercise program for individuals with mild to moderate dementia in nursing homes. The intervention program was carried out two times per week for 60 minutes, and consisted of imaginary journeys which included a combination of cognitive and physical exercises. Its effectiveness was evaluated on the outcomes of cognitive function, motor performance and activities of daily living. One main finding was that the heterogeneity of IWD is hindering the effectiveness of an “overall” exercise program. For a detailed project description and results on motor performance, the reader is referred to the published study protocol and two original articles (Barisch-Fritz et al., 2021; Trautwein et al., 2020; Trautwein et al., 2017).

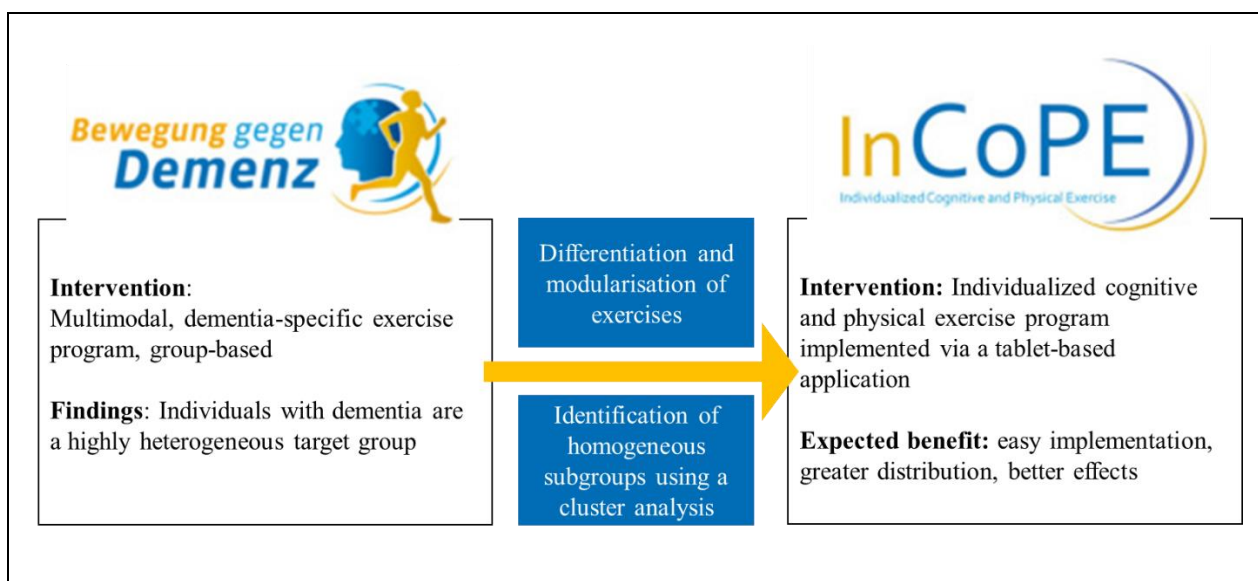


Figure 2.1: Linking the two research projects relevant for this dissertation

Based on the results of “*Physical activity against dementia*”, the second project “*InCoPE*” was developed. The study focused on an individualized and digital approach. The main aim was to scientifically develop the InCoPE-App, a tablet-based application which enables nursing home staff to test cognitive and physical function in IWD and, based thereon, individually train IWD by delivering exercises guided by the app. The individualization of the physical exercise program was derived from cluster-data of the “*Physical activity against dementia*” trial. In addition to the development of the app, the usability as well as effectiveness of the individualized exercise programs were evaluated within this research project (Barisch-Fritz, Bezold, Scharpf, et al., 2022a, 2022b). The evaluation of the data from the InCoPE project is still ongoing. The associations between the two projects are shown in Figure 2.1.

2.2 AIMS AND RESEARCH QUESTIONS

The core structure of this dissertation is presented in Figure 2.2. The first aim of was to address the research gaps identified in Chapter 1.2.4, i.e., the need for implementing and evaluating PA programs/ interventions for IWD within a high-quality randomized controlled trial, and to examine whether a general (not individualized) exercise program can meet the needs of IWD who are considered a heterogeneous target group. The main outcome for the evaluation of the effectiveness was activities of daily living. This leads to the following two subordinate research questions which were addressed in Manuscript 1 (Chapter 3):

Q1: What are the effects of a multi-modal, dementia-specific exercise program on activities of daily living in IWD?

Q2: Are there individual responses to the exercise program?

Implementing PA for IWD in nursing homes is challenging, as time and expertise of nursing home staff are often limited (Chapter 1.2.3). This circumstance was further exacerbated by the COVID-19 pandemic (Chapter 1.3). New solutions are thus needed that allow for an objective and feasible monitoring of individual health-related factors (e.g. fall risk), and a low-threshold implementation of PA programs for IWD in nursing homes. To this end, novel technological approaches applying digital health (e.g. body-worn sensors, mobile applications) are promising and need to be investigated. So far, digital health solutions in care settings are increasingly being developed and implemented, but current research is sparse with regard to the target group of IWD (Chapter 1.4.3). Therefore, the second aim of this dissertation was to review current research on objective assessment of fall risk factors using body-worn sensors. The following two research questions were addressed in Manuscript 2 (Chapter 4):

Q3: *Can body-worn sensors provide accurate data on motor performance that may be used to assess risk of falling?*

Q4: *Which practical recommendations can be given for the application of sensor-based fall risk assessment in individuals with cognitive impairment?*

To overcome the barriers of implementing PA for IWD in nursing homes, even in times of a pandemic, the third aim of this thesis was to evaluate the usability of the InCoPE-App, which addresses the need for individualized PA and represents a first approach for long-term and low-threshold PA promotion in nursing homes by empowering nursing home staff to deliver an individualized PA program guided by the app. To this end, Manuscript 3 (Chapter 5) addressed two research questions:

Q5: *How is the usability of the InCoPE-App perceived by the intended end-users, i.e., nursing home staff?*

Q6: *Which parts of the InCoPE-App should be further developed for the evaluation and implementation in nursing homes?*

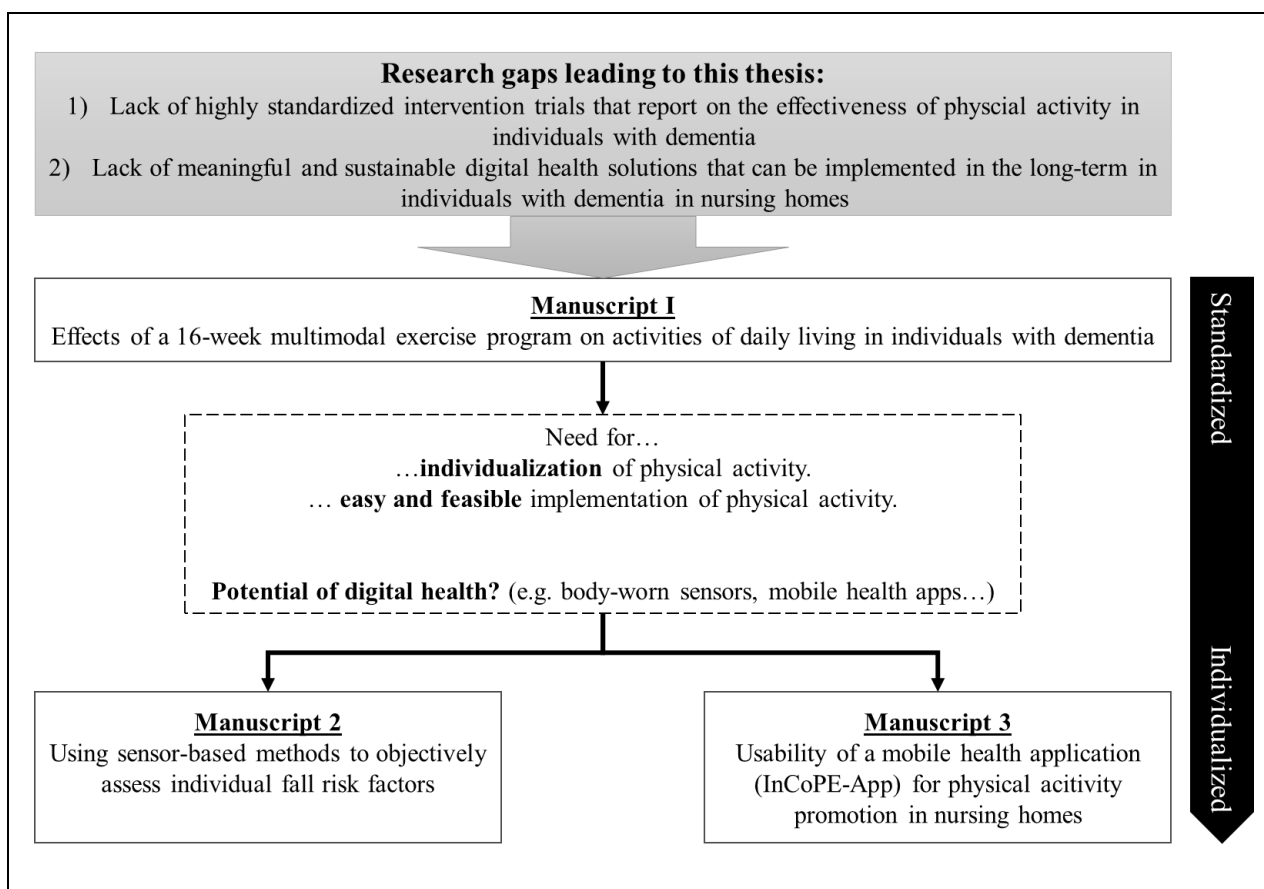


Figure 2.2: Core structure of the thesis

3 MANUSCRIPT 1: EFFECTIVENESS OF A MULTIMODAL, DEMENTIA-SPECIFIC EXERCISE PROGRAM ON ACTIVITIES OF DAILY LIVING IN INDIVIDUALS WITH DEMENTIA

Slightly modified version of the published paper.

Published in: German Journal of Exercise and Sport Research

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Reference:

Bezold, J., Trautwein, S., Barisch-Fritz, B., Scharpf, A., Krell-Rösch, J. & Woll, A. (2021). Effects of a 16-week multimodal exercise program on activities of daily living in institutionalized individuals with dementia. *German Journal of Exercise and Sport Research*, 51, 487-494. <https://doi.org/10.1007/s12662-021-00760-4>

Effects of a 16-week multimodal exercise program on performance of activities of daily living in institutionalized individuals with dementia: a multicenter randomized controlled trial.

3.1.1 ABSTRACT

We aimed to examine the effects of a 16-week multimodal exercise program on activities of daily living in individuals with dementia. Furthermore, we investigated the participants' individual response to the exercise program and whether baseline cognitive and motor performance explain activities of daily living performance.

We conducted a multicentre randomized controlled trial involving 319 participants aged ≥ 65 years with mild to moderate dementia. Activities of daily living were assessed at baseline and after the 16-week intervention using the Barthel Index, the Erlangen Test of Activities of Daily Living and the 7-item Physical Performance Test. We additionally assessed cognitive and motor performance using standardized and validated assessments. Intervention effects were examined through two-factor analysis of variance with repeated measurements applying a per protocol and an intention-to-treat analysis. We compared baseline cognitive and motor performance between positive-responders, non-responders, and negative-responders and examined cognitive and motor performance as potential cofounders of activities of daily living by conducting multiple regression analyses.

There were no significant time*group effects on activities of daily living. Between 20% and 32% of participants responded positively to the intervention, i.e. improved activities of daily living performance from baseline to follow-up. Positive-responders had worse baseline motor performance compared to non-responders. Cognitive and motor performance explained up to 51.4% of variance in activities of daily living.

The multimodal exercise program had no significant overall effect on activities of daily living in individuals with dementia. This may be related to insufficient exercise intensity. However, our results indicate that the response to the exercise program depends on individual prerequisites which should thus be considered in further research on individual exercise approaches.

Keywords: Activities of daily living, dementia, physical exercise, nursing home, intervention study

3.1.2 BACKGROUND

To date, more than 50 million people worldwide are living with dementia, and by the end of 2050, nearly 152 million individuals with dementia (IWD) are expected implying increasing human, economic, and social costs (Patterson, 2018). As a result of the disease specific decrease in cognitive function and motor performance, dementia is a main reason for the loss of autonomy, and the accelerated need for help and institutionalization in ageing (Bürge et al., 2017; World Health Organization & Alzheimer's Disease International, 2012). Furthermore, the cognitive and physical deteriorations translate into hierarchical decline of activities of daily living (ADL) with progressing dementia (Johansen et al., 2020; Mlinac & Feng, 2016). Instrumental ADL require higher cognitive demands (e.g. handling finances, going shopping) and are usually impaired at early dementia stages (Boyd et al., 2018; Martyr & Clare, 2012). With the progression of the disease, additional problems with the performance of basic ADL (e.g. bathing, toileting, eating) arise (Boyd et al., 2018; Martyr & Clare, 2012). These impairments lead to an elevated dependency in daily life, a reduction of quality of life (Giebel et al., 2015), and are related to a higher risk of falling in IWD (Henry-Sánchez et al., 2012).

Between 50 and 80% of individuals in nursing homes are suffering from dementia, implying a higher care burden in terms of time and costs as compared to nursing home residents free of dementia. Studies found a relationship between deficits in ADL performance of individuals in nursing homes with perceived formal caregiver burden (Miyamoto et al., 2010; M. Sun et al., 2018). Moreover, an increase of total resource use (hours per week) in nursing homes is associated with ADL dependence of nursing home residents (Sköldunger et al., 2019). Thus, there is a need for interventions which address improving or maintaining ADL performance in IWD in nursing homes.

High development costs and negative side effects of drug therapies in dementia care lead to an increased demand of non-pharmacological approaches like physical exercise (PE) interventions (Sopina & Sørensen, 2018). The benefits of PE on cognition (e. g. executive function, memory), motor performance (e. g. strength, balance, gait performance), and ADL have been increasingly documented in the last few years . Studies showed that PE interventions may improve or even slow down the progression of ADL deterioration in IWD living in nursing homes (Bossers et al., 2016; Bürge et al., 2017; Toots et al., 2016). Nevertheless, the results of the studies warrant caution of overinterpretation. Intervention periods ranging from seven weeks up to one-year, different settings (nursing homes, home care), different content or focus

of PE interventions (only PE vs. combination of PE with cognitive training or social intervention), various training conditions (e.g. group vs. individuals training), and the implementation of different training parameters in terms of exercise duration and frequency, may complicate the comparison of study results (Forbes et al., 2015).

The primary aim of the present study was to investigate the effect of a 16-week multimodal exercise program (MEP) on ADL performance in IWD within a multicenter randomized controlled trial. To this end, we developed a dementia-specific MEP based on theoretical recommendations and a pilot study (Thurm et al., 2011). The intervention program combines both motor and cognitively stimulating exercises aiming at a higher efficacy on cognitive function, motor performance and ADL performance in IWD. Moreover, the MEP was developed for a sustainable implementation in nursing homes subsequent to the trial. We hypothesized that participants of the intervention group (IG) who underwent the MEP would change their ADL performance compared to participants of a control group (CG) who only received conventional treatment.

Considering the heterogenous results of previous studies on the effects of PE interventions on ADL performance, our secondary aim was to explore the individual responses to our MEP with regard to ADL performance between positive-, negative-, and non-responders (positive-R, negative-R, and non-R). We hypothesized that responder groups would differ in terms of cognitive function and motor performance at baseline. In order to examine the complex interplay of ADL performance, we investigated motor and cognitive functions that may explain ADL performance. We hypothesized that various motor and cognitive assessments may explain the variability in ADL performance, and that these results may provide valuable implications for the design of further intervention studies.

3.1.3 METHODS

This multicenter randomized controlled trial, was developed and carried out by our research group at Karlsruhe in Germany. A 16-week MEP for individuals with mild to moderate dementia was implemented in 36 nursing homes in Southwestern Germany. The MEP was developed based on a pilot study (Thurm et al., 2011) and a literature review (Scharpf et al., 2013). The intervention program combines both motor und cognitively stimulating exercises as well as the ritualization of the program sequences. Ethical approval for the study was provided by Karlsruhe Institute for Technology. The study was retrospectively registered in the German National Register of Clinical Trials (DRKS00010538). The following sections provide an

abbreviated summary of the study methodology. A more detailed methodological study description, especially with regard to the MEP, can be found in the published study protocol (Trautwein et al., 2017). The effects of the MEP on gait and motor performance have been published recently (Barisch-Fritz et al., 2021; Trautwein et al., 2020), while the focus of this paper is on the effects on ADL performance.

STUDY DESIGN AND PARTICIPANTS

The multicentred randomized controlled trial included baseline and post-intervention assessments of cognition function, motor performance and ADL. Participants were allocated to the IG or CG using minimization software (MiniPy, Version 0.3). A power analysis with G*Power 3, (Version 3.1.9.2, two-factor analysis of variance with repeated measurements, two groups, and two measurements, $\alpha = 0.05$, $\beta = 0.80$, $\eta^2 = 0.01$) resulted in a total sample size of 200 participants (Faul et al., 2007). We expected that 35% of participants would drop out of the study or have missing data. Thus, 270 participants for the total sample are required. As attendance and adherence to exercise interventions are not well documented in previous studies (Forbes et al., 2015), and a higher dropout rate was assumed in the IG (e.g. due to motivational problems), the sample of the IG was doubled. Hence, we aimed at a total sample size of 405 participants. Participants were identified by healthcare professionals in the nursing homes. Prior to baseline assessments, informed consent was signed by potential participants themselves or their legal guardian. Inclusion criteria were (1) diagnosis of primary dementia or “suspected dementia” (i.e. without a confirmed diagnosis or awaiting further clinical evaluation) verified by general practitioners and/or based on ICD-10 criteria, (2) Mini Mental State Examination (MMSE) with mild to moderate status (MMSE: 10-24), (3) age >65 years, (4) being able to walk for approximately 10 meters and (5) clearance by a general practitioner. Participants with secondary dementia, other severe cognitive impairments, neurological or severely acute diseases, severe motor impairments and/or no informed consent were excluded.

INTERVENTION

The 16-week dementia-specific MEP was implemented, with two sessions per week, each lasting 60 minutes. Every training session was designed as an imaginary journey with a ritualized arrival and departure element aiming to give participants orientation and familiarization. The mere exercise time included a combination of motor and cognitive tasks and took about 45 minutes. In detail, strength, balance, endurance and flexibility tasks were performed at various durations and with medium to submaximal intensity. Small training devices, such as dumbbells (1 - 4,4lbs), sandbags (~1lbs), skipping ropes or pool noodles were integrated into

the exercises. Furthermore, different cognitive tasks were embedded in the MEP to stimulate cognitive functions, i.e. memory (e.g. remembering the destination of the last imaginary journey), attention (e.g. remembering a certain sequence of numbers), language (e.g. naming animals) and executive function (e.g. learning to perform according to visual or acoustic signals). Throughout the 16-week MEP, a progression of intensity of motor and cognitive exercises were planned and carried out, e.g. by increasing difficulty level or the number of exercise repetitions. Exercise intensity followed a predefined progression plan throughout the intervention period and was supervised by experienced instructors. Examples of different motor and cognitive tasks and their progression are presented in the appendix (Supplementary Table 3.1). In order to achieve a high degree of standardization, all instructors received a detailed manual of the MEP and underwent a special training program concerning the content of the MEP as well as the characteristics of the study sample. Furthermore, only instructors with theoretical and practical knowledge in sport science guided the MEP during the intervention study.

OUTCOMES

ADL (primary outcome measure) were assessed by a proxy-based questionnaire, the Barthel Index (BI; (Mahoney & Barthel, 1965) and two performance-based assessments, i.e., the Erlangen Test of Activities of Daily Living (E-ADL; (Graessel et al., 2009)) and the 7-item Physical Performance Test (PPT-7; (Reuben & Siu, 1990)). The BI is a widely used questionnaire in geriatric care to assess functioning of older individuals in daily life. Usually, it is completed by caregivers and contains ten items: feeding, moving from a wheelchair to bed and return, personal toilet, getting on and off toilet, bathing, walking on level surface, ascend and descend stairs, dressing, controlling bowels and controlling bladder. The BI sum score ranges from 0 (totally dependent) to 100 (independent) (Mahoney & Barthel, 1965). The PPT-7 contains seven activities of everyday life: 50-foot walk, putting on and removing a jacket, simulated eating, writing a sentence, putting a book into a shelf, a 360° turn, and picking up a penny from the floor. The maximum attainable score of the PPT-7 is 28, with a higher score indicating a better ADL performance (Reuben & Siu, 1990). The PPT-7 was found to be feasible and reliable in IWD (Farrell et al., 2010). The E-ADL is the only ADL assessment that was specifically developed for IWD. It is performance-based and comprises five typical routines of daily life: cutting a bread, pouring a drink, opening a cupboard, washing hands and tying a bow. The total score of the E-ADL ranges from 0-30, with a higher score representing better results. The E-ADL has good validity and test-retest reliability in IWD (Graessel et al., 2009).

For the explorative analysis of responder groups and underlying functions of ADL performance, we defined cognitive function and motor performance as secondary outcomes. We assessed overall cognition with the Mini Mental State Examination (MMSE) (Folstein et al., 1975), learning and memory with Digit Span forward and backward (Wilde et al., 2004), processing speed with the Trail Making Test Part A (TMT-A) (Reitan, 1958), and visual spatial function with the Clock Drawing Test (CDT) (Shulman et al., 1986). To assess motor performance, we used the modified 30-second chair stand test (30s CST) for lower limb strength (Blankevoort et al., 2010), the Short Physical Performance Battery (SPPB) (Guralnik et al., 1994) for lower limb function, Frailty and Injuries: Cooperative Studies of Intervention Techniques (FICSIT-4) for balance (Rossiter-Fornoff et al., 1995), and Timed-Up and Go (TUG) (Podsiadlo & Richardson, 1991) as well as a 6-meter walk test (6MWT) (Graham et al., 2008) for mobility. The reader is referred to the study protocol (Trautwein et al., 2017) for a more detailed description of all motor and cognitive assessments. Feasibility of the motor assessments were discussed with an international expert panel before the conduct of this study. Furthermore, a standardized testing procedure was developed by the expert panel (Trautwein, Barisch-Fritz, et al., 2019). Subsequently, the applied test battery has been checked for feasibility in IWD.

STATISTICAL ANALYSIS

Statistical analysis was done with SPSS 27.0 (IBM Corporation, Armonk, USA) for Windows with alpha set a priori at 0.05 for all tests. To investigate the effect of the MEP on ADL performance between IG and CG, we using two different approaches (per protocol, intention to treat). This approach was also addressed but not further specified within the study protocol (Trautwein et al., 2017). First, a per protocol analysis was performed including all participants with sufficient attendance to the MEP (only IG: $\geq 75\%$, at least 24 of 32 trainings sessions) and a complete assessment (IG and CG: baseline, post) of at least one ADL assessment. In IWD, attendance to PE interventions and possible barriers (e.g. illness, previous exercise experience) vary widely (van der Wardt et al., 2017). A minimum of 75% for the per protocol analysis was defined on the basis of mean attendance rates of previously published studies with similar intervention period, duration and frequency of training sessions, as well as sample sizes (Telenius et al., 2013; Toots et al., 2016). Second, we imputed missing data of the primary outcomes for an intention-to-treat analysis using multiple imputation (fully conditional specification imputation method, ten imputations, ten iterations). Data of deceased participants was not imputed. ADL performance was considered as primary outcome and motor performance

and cognitive function were considered as predictors. Furthermore, to ensure plausibility of data, other constraints like minimum and maximum values in each variable according to observed ranges, rounding according to original data, 100 maximal case draws and ten maximal parameter draws were defined. We considered pooled results as provided by SPSS. If SPSS did not support this pooling procedure for several statistical analyses, we reported ranges observed throughout the imputations.

Before carrying out statistical analyses, required assumptions were tested. Differences in baseline characteristics between IG and CG were calculated using unpaired T-Tests, Chi-square tests and Mann-Whitney-U Tests. Normally distributed data are presented as means (M) and standard deviations (SD). To investigate group-, time- and interaction effects of the MEP, two-way repeated measures analysis of variance (ANOVA) and paired T-Tests were calculated for primary outcomes. The calculated effect sizes are Cohen's d for paired and unpaired T-Tests and η_p^2 for two-way repeated measures ANOVA.

Furthermore, we applied an explorative approach for the secondary aim, i.e. the responder-analysis. Previous studies often focused on main effects and group differences, however the need to consider individual responses to exercise programs in IWD is currently discussed (Yu et al., 2021). We decided against a simple "responder" and "non-responder" division as proposed in a previously published article (Müllers et al., 2019), and additionally defined a group with maintaining ADL performance, which may be considered as partial success of physical exercise in IWD. To this end, we divided the IG of the per protocol sample into three groups based on distribution-based methods (i.e. information about the standard measurement error of the assessments within the per protocol analysis): positive-R (positive change of 10% and more in ADL performance), negative-R (negative change of 10% and more in ADL performance), and non-R (change between positive and negative 10% in ADL performance). We compared baseline cognitive function and motor performance between these responder groups using Kruskal-Wallis-Test, and one-factor ANOVA. Dunn-Bonferroni-Tests and Tukey-Kramer post-hoc tests were used for post-hoc analysis. For the analysis of underlying mechanisms of ADL performance, multiple regression analysis with stepwise selection were used with BI, E-ADL, and PPT-7 as dependant variables, and the already mentioned motor and cognitive assessments as independent variables. The calculated effect size was f^2 .

3.1.4 RESULTS

SAMPLE

600 IWD were screened for eligibility of study participation between March 2015 and March 2017, and 319 persons were considered as suitable for the study. 201 participants were randomly allocated to the IG and 118 participants to the CG after baseline assessment. Please refer to Figure 3.1 for a flow chart of participants. Dropout rate in both IG and CG was 8%.

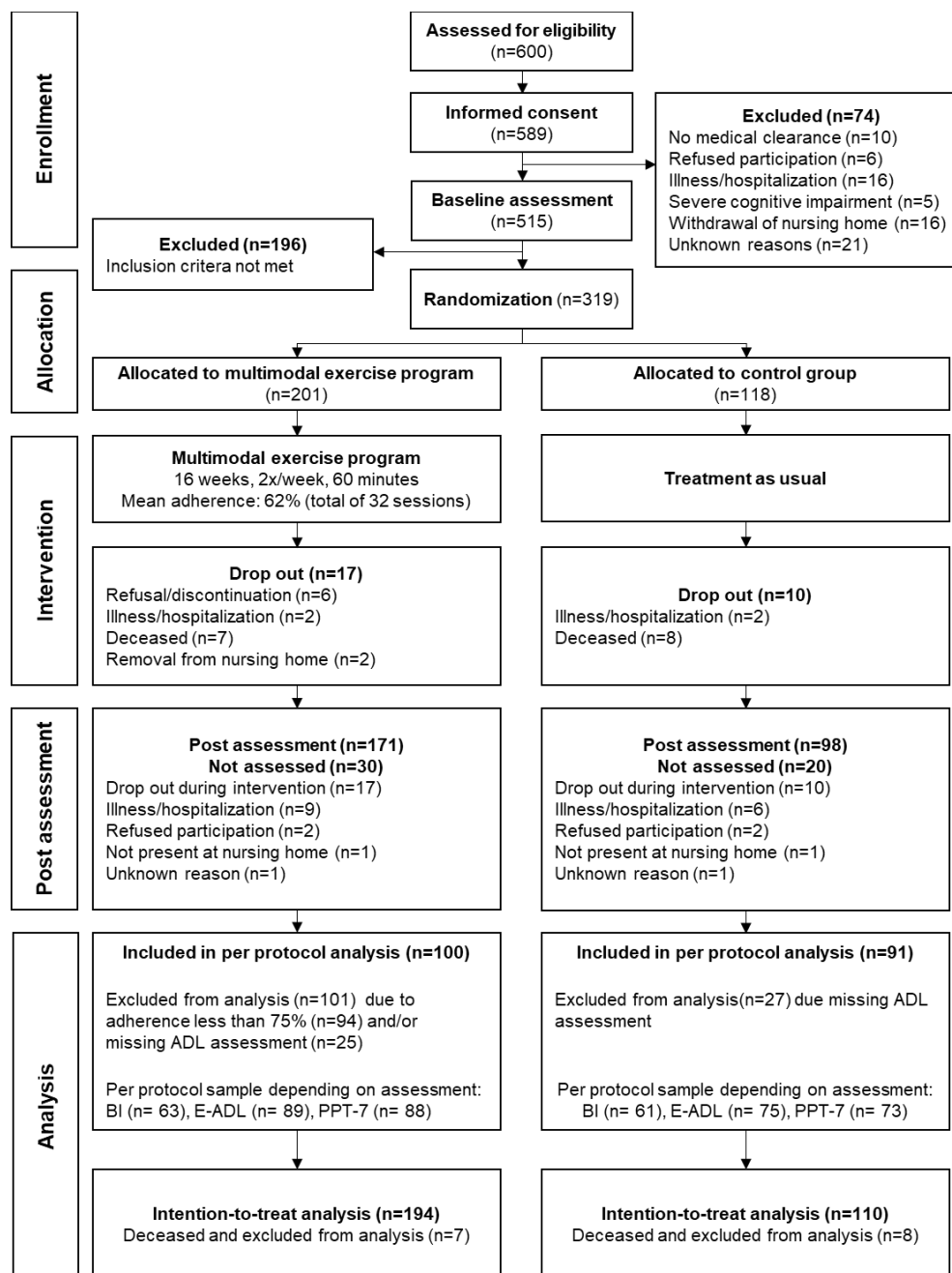


Figure 3.1: Flow of participants

BASELINE CHARACTERISTICS OF THE PER PROTOCOL SAMPLE

Table 3.1 presents the baseline characteristics of the per protocol sample (n=191). The mean age of the participants was 86 years (SD, 6 years) and 86% percent of the sample was female. A mean MMSE value of 17 (SD, 4) indicated moderate cognitive impairment at baseline. More than three quarters of the per protocol sample used walking aids (walker: 70%; walking sticks: 8%). Mean value on the CIRS morbidity index was 9 (SD, 5) and the mean number of required medications was 7 (SD, 4). In 22% of the per protocol sample, the intake of anti-dementia medication was confirmed. Statistically significant differences in baseline characteristics of the per protocol sample between IG and CG were observed for the use of walking aids ($\text{Chi}^2(2)=6.254, p=0.044$), number of medications ($t(148)=2.622, p=0.010$) and body mass index ($t(178)=2.041, p=0.043$). Baseline characteristics of the intention-to-treat sample are provided in the Appendix (Supplementary Table 3.2).

Table 3.1: Baseline characteristics of the per protocol sample

	Total sample [n=191]	IG [n=100]	CG [n=91]	Group differences [t(df)/z/Chi ² (df), p]
Age, years [M (SD), range]	86 (6) 67-98	85 (7) 67-97	87 (5) 70-98	t(189)=1.886, p=0.061
Sex, female	86%	83%	89%	Chi ² (1)=1.418, p=0.234
Diagnosis of dementia				
- yes	70%	71%	68%	Chi ² (2)=2.701, p=0.259
- no	17%	19%	14%	
- unknown	13%	10%	18%	
Type of dementia				
- Alzheimer's disease	19%	18%	19%	Chi ² (4)=7.948, p=0.094
- Vascular dementia	23%	31%	15%	
- Mixed dementia	4%	3%	..6%	
- other	2%	3%	0%	
- no/unknown diagnosis	52%	45%	60%	
MMSE [M (SD), range]	17 (4), 10-24	17 (4), 10-24	17 (4), 10-24	t(188.103)=0.619, p=0.537
Use of walking aid				
- walker	70%	63%	77%	Chi²(2)=6.254, p=0.044
- wakening stick/s	8%	8%	9%	
- no walking aid	22%	29%	14%	
CIRS [M (SD), range]				
- Morbidity Index	9 (5), 1-26	9 (4), 1-20	10 (6), 2-26	t(113)=0.798, p=0.426
- Severity Index	1.6 (0.4), 1-3	1.5 (0.4), 1-3 not available for 33%	1.6 (0.5), 1-3 not available for 47%	z=-0.202, p=0.840
Number of medications [M (SD), range]	7 (4), 0-27	8 (4), 1-27	6 (4), 0-20	t(148)=2.622, p=0.010
BMI, kg/m² [M (SD), range]	27.8 (4.6), 17.6-48.5	28.5 (4.4), 19.7-48.5	27.1 (4.8), 17.6-38.0	t(178)=2.041, p=0.043
BMI: Body Mass Index, CG: control group, CIRS: Cumulative Illness Rating Scale, df: degree of freedom, IG: intervention group, M: mean, MMSE: Mini-Mental State Examination, n: number, SD: standard deviation				
Statistically significant results appear bold				

EFFECTS OF THE MEP ON ADL PERFORMANCE

PER PROTOCOL SAMPLE

Participants of the IG in the per protocol sample had a mean adherence of 91%. Mean values and SD of primary outcomes are presented in Table 3.2. At baseline, no statistically significant differences between IG and CG in either ADL assessments (Barthel-Index, E-ADL, PPT-7) were observed ($p > 0.05$ for all). We did not observe any statistically significant time*group effects ($p > 0.05$, $\eta_p^2 = 0.004 - 0.019$; Table 3.3). Also, there were no significant

within-group time effects from baseline- (t_0) to post-measurement (t_1) in either ADL assessments for the IG.

Table 3.2: Mean values and standard deviations of primary outcomes

		Baseline		Post		Difference baseline - post		
		Mean	SD	Mean	SD	Mean	SD	CI95
BI	IG (n=63)	69.7	18.7	72.3	18.8	-2.619	14.420	-6.251-1.013
	CG (n=61)	67.2	20.2	65.6	21.5	1.639	16.475	-2.580-5.859
E-ADL	IG (n=89)	26.3	4.3	25.9	4.3	0.416	4.293	-0.489-1.320
	CG (n=75)	26.6	4.1	26.7	3.5	-0.107	4.444	-1.129-0.916
PPT-7	IG (n=88)	12.7	4.7	13.0	5.6	-0.318	3.647	-1.091-0.455
	CG (n=73)	12.4	4.4	11.8	4.7	0.548	3.606	-0.293-1.389

BI: Barthel Index, CG: control group, E-ADL: Erlangen Test of Activities of Daily Living, IG: intervention group, n: number, PPT-7: 7-item Physical Performance Test, SD: standard deviation

Table 3.3: Effects of the MEP on ADL performance (per protocol sample)

		Baseline differences		Within-group effects			Time*group effects		
		t(df)	p	t(df)	p	Effect size d	F (df _{numerator} , df _{denominator})	p	Effect size η_p^2
BI	IG n=63	t(122)=0.707	0.481	t(62)=-1.442	0.154	0.254	F(1.122)=2.350	0.128	0.019
	CG n=61			t(60)=0.777	0.440	0.015			
E-ADL	IG n=89	t(162)=0.445	0.657	t(88)=0.914	0.363	0.106	F(1.162)=0.584	0.446	0.004
	CG n=75			t(74)=-0.208	0.836	0.052			
PPT-7	IG n=88	t(159)=0.469	0.640	t(87)=-0.818	0.415	0.087	F(1.159)=2.274	0.134	0.014
	CG n=73			t(72)=1.298	0.198	0.152			

BI: Barthel Index, CG: control group, CI₉₅: 95% confidence interval, df: degrees of freedom, E-ADL: Erlangen Test of Activities of Daily Living, IG: intervention group, M: mean, n: number, PPT-7: 7-item Physical Performance Test, SD: standard deviation

INTENTION-TO-TREAT ANALYSIS

An analysis of missing data indicated missing values ranging between 3.7% (PPT-7 at baseline) and 23.6% (BI at baseline), and 226 of 319 data sets were incomplete with respect to

ADL performance. Two-way repeated measures ANOVAs showed no statistically significant time*group effects for either ADL outcome ($p > 0.05$, $\eta^2 = 0.000-0.013$). For E-ADL, the intervention group showed a statistically significant decrease from baseline to post assessment ($t(277) = 2.301$, $p = 0.022$). We observed no other statistically significant within-group time effects. Details of the statistical analysis of the intention-to-treat sample are shown in the Appendix (Supplementary Table 3.3).

EXPLORATIVE RESPONDER-ANALYSIS (PER PROTOCOL, INTERVENTION GROUP)

A responder analysis in the intervention group of the per protocol sample showed that 20.2% (E-ADL), 30.7% (PPT-7), and 31.7% (BI) of participants of the IG responded positively to the MEP (Supplementary Table 3.4). The majority of participants of the IG showed no changes in the primary outcomes (50.0%-68.3%), and between 19.3% and 27.0% had a decrease in their ADL performance that was greater than 10%. With regard to the Barthel-Index, no negative-responders were observed (Supplementary Table 3.4). The comparison of baseline values in cognitive function and motor performance between different groups of ADL responders revealed statistically significant results for BI and E-ADL performance (Table 3.4). With regard to the Barthel-Index, positive-R performance at baseline was significantly worse compared to non-R for SPPB ($p = 0.002$, $d = -0.993$), 30-STS ($p = 0.008$, $d = -0.786$) and FICSIT-4 ($p = 0.036$, $r = -0.378$). A one-way ANOVA revealed significant differences between E-ADL responder groups for FICSIT-4, and CDT. The post-hoc analysis showed statistically significantly worse performance of positive-responders in FICSIT-4 at baseline, compared to non-responders ($p = 0.012$, $MD = -1.146$, $CI_{95} [-2.084-0.208]$). For CDT, the post-hoc analysis was not significant. We found no statistically significant differences between PPT-7 responders for baseline motor and cognitive performance.

EXPLORATIVE REGRESSION ANALYSIS (PER PROTOCOL SAMPLE)

For baseline Barthel-Index, weak to moderate correlations with baseline cognitive function and motor performance were found ($|r| = 0.141-0.349$, $p < 0.05$). In a multiple regression analysis model, baseline FICSIT-4 and TUG were statistically significant regression coefficients ($p < 0.05$). This model explained 14.3% of variance in baseline BI ($F(2,152) = 13.819$, $p < 0.005$). For baseline E-ADL, weak correlations with baseline cognitive function and motor performance were found ($|r| = 0.118-0.170$, $p < 0.05$) and only baseline MMSE was a statistically significant coefficient in multiple regression analysis ($p < 0.05$). The model explained 2.4% of the variance in baseline E-ADL performance ($F(1,197) = 5.843$, $p = 0.017$). For baseline PPT-7, weak to high correlations with baseline cognitive function and motor performance were found

($|r|=0.198-0.609$, $p<0.05$). In multiple regression analysis, a model with TUG, gait speed calculated from the 6MWT, FICSIT-4, 30-STS and DS forward as coefficients explained 51.4% of the variance in PPT-7 performance ($F(5,196)=43.581$, $p<0.005$). Please refer to Table 3.5 for the results of the multiple regression analyses.

Table 3.4: Statistically significant differences between positive-responders, non-responders and negative-responders (per pro-tocol, intervention group)

	Positive-R	Non-R	Negative-R	Between group difference	Post-hoc analysis
	Mean (SD)	Mean (SD)	Mean (SD)	$F(df_{\text{numerator}}, df_{\text{denominator}})/$ $\text{Chi}^2(df)/t(df)/z, p$	
BI					
SPPB (n=48)	5.4 (3.1)	7.8 (2.3)	-	$t(46)=-3.243$, $p=0.002$, $d=-0.993$	-
30s CST (n=52)	7.1 (3.1)	9.7 (3.3)	-	$t(50)=-2.758$, $p=0.008$, $d=-0.786$	-
FICSIT (n=59)	1.7 (1.3)	2.6 (1.5)	-	$z=-2.907$, $p=0.036$, $r=-0.378$	-
E-ADL					
FICSIT (n=88)	1.5 (1.3)	2.7 (1.4)	2.1 (1.4)	$F(2,85)=4.474$, $p=0.014$, $\eta^2=0.095$	$p=0.012$, $MD=-1.146$, $CI_{95} [-2.084-0.208]^a$
CDT (n=82)	2.5 (1.0)	3.3 (1.3)	2.7 (1.4)	$\text{Chi}^2(2)=6.070$, $p=0.048$	n.s.

30s CST: modified 30 seconds chair stand test, BI: Barthel-Index, CDT: Clock Drawing Test, CI_{95} : 95% confidence interval, df: degrees of freedom, E-ADL: Erlangen Test of Activities of Daily Living, FICSIT: Frailty and injuries: cooperative studies of intervention techniques, M: mean, n: number, n.s.: not significant, SD: standard deviation, SPPB: Short Physical Performance Battery, STS: Sit-to-Stand Test.

^a post-hoc analysis: statistically significant better performance of non- compared to negative responders

Table 3.5: Impact of underlying motor and cognitive function on ADL performance (per protocol analysis)

	Coefficients					Model			
	B	SE	β	t	p	R ²	Ad-justed R ²	F(df _{numerator} , df _{denominator}), p	f ²
BI (n=155)									
Constant	70.985	4.896		14.497	<0.001				
FICSIT	3.801	1.143	0.271	3.326	0.001				
TUG	-0.348	0.145	-	-2.406	0.017				
			0.196			0.154	0.143	F(2)=13.819, p<0.001	0.182
E-ADL (n= 199)									
Constant	24.689	1.071		23.044	<0.001				
MMSE	0.145	0.060	0.170	2,417	0.017				
						0.029	0.024	F(1)=5.843, p=0.017	0.029
PPT-7 (n=202)									
Constant	5.330	1.822		2.926	0.004				
TUG	-0.095	0.029	-	-3.310	0.001				
			0.236						
Walking Speed	6.563	1.517	0.291	4.328	<0.001				
FICSIT	0.703	0.174	0.216	4.033	<0.001				
30s CST	0.204	0.070	0.170	2.894	0.004				
DS, counting forward	0.491	0.184	0.132	2.676	0.008				
						0.526	0.514	F(5)=43.581, p<0.001	1.120

30s CST: modified 30 seconds chair stand test, BI: Barthel Index, df: degrees of freedom, DS: Digit Span, E-ADL: Erlangen Test of Activities of Daily Living, FICSIT: Frailty and Injuries: Cooperative Studies of Intervention Techniques, MMSE: Mini Mental State Examination, n: number, PPT-7: 7-item Physical Performance Test, SE: standard error, TUG: Timed Up and Go Test

3.1.5 DISCUSSION

EFFECTS OF THE MEP ON ADL PERFORMANCE

The primary aim of this paper was to investigate the influence of a 16-week multimodal exercise program on ADL performance in IWD. We did not observe any significant time-group effects (η_p^2 : 0.004-0.019) of the 16-week MEP on ADL performance in IWD. Therefore, we could not confirm our hypothesis that participants of the MEP improved their ADL performance compared to the CG. Previous studies that investigated the effects of PE on ADL performance

in IWD living in nursing homes yielded heterogeneous results. While some studies did not find any significant effects (Henskens et al., 2018; Lamb et al., 2018), others found a slowed deterioration of ADL compared to a control group (Bürge et al., 2017; Littbrand et al., 2009; Rolland et al., 2007; Toots et al., 2016) or positive effects of PE on ADL performance (Bossers et al., 2016). Nevertheless, all these studies differed in terms of sample characteristics, setting, intervention period and intervention content, hampering a comparison and a critical handling with these findings is thus recommended (Forbes et al., 2015). Studies that yielded positive effects had longer intervention periods, higher training frequency, smaller groups or one-to-one sessions, and/or an adaption of intensity of exercise content during the intervention. We could not reach our aim to increase intensity throughout the intervention, which may be a main reason for our non-significant results. Moreover, even though two training sessions are recommended for nursing home residents (Souto Barreto et al., 2016), this was feasible for our sample but might not have been sufficient. Furthermore, the baseline differences in walking-aid use were not further addressed within our analysis, but may have influenced the intensity adaption throughout our intervention period. Instructing a group in which some IWD use walking aids and others do not may have complicated the implementation of intensity adaptations, especially with regard to ensuring the safety of the participants. These mentioned challenges underline the difficulty to adapt exercise intensities in a highly heterogeneous sample.

Another reason for our non-significant results may be the high variability of ADL performance that was also reported in a previous study (Bürge et al., 2017). Moreover, even though the BI, E-ADL and PPT-7 were used in other studies with IWD before, it must be noted that they may not be specific enough to detect subtle changes in ADL performance in IWD. The sensitivity of the BI and its objectivity in assessing ADL performance of IWD living in nursing homes must be seen critical (Yi, et al., 2020). Nevertheless, we decided to use the BI as a proxy-based evaluation tool, and to include an external assessment in addition to the performance-based tests as they may have been influenced by daily form or mood of the participants. However, we are aware that the BI may not have captured the effects of our MEP. Moreover, the E-ADL was rated as too easy for individuals with mild dementia (Luttenberger et al., 2012). Originally, the PPT-7 was not developed for IWD and therefore may not be feasible to detect small changes from baseline to post measurement as in our study. Nevertheless, previous longitudinal studies showed that ADL performance of IWD residing in long-term care facilities deteriorates over time (Johansen et al., 2020). Therefore, a small improvement or even maintenance of ADL performance over time could be a valuable outcome.

Indeed, our explorative responder-analysis revealed between 20.2 and 31.7% positive-responders with regard to ADL performance in the IG. Nevertheless, the majority of the participants did not respond to the MEP (i.e., non-R, between 50 and 68%). We observed worse motor performance (balance, mobility, and lower limb function) in positive-R compared to non-R. These results imply that the intensity of our MEP worked well for individuals with weak baseline performance. From a training science point of view, it is crucial to individually modify intensity of interventions in order to achieve an improvement (Bürge et al., 2017; Littbrand et al., 2009; Littbrand et al., 2011). Originally, our MEP was designed to be carried out with increases of intensity of PE to achieve adaptations in participants of the IG. Due to the high heterogeneity of our sample in terms of disease severity, age, and other personal characteristics, we had to intensify our safety efforts and the majority of exercises were carried out while participants were seated. This resulted in lower training stimuli and may be one explanation as to why less performance adaptations might have been achieved. This consideration is supported by the fact that previous research found positive effects of PE on ADL-performance when PE was provided in one-to-one guided sessions (Bossers et al., 2016). Therefore, more person-centred approaches considering individual skills and impairments may be warranted (Prizer & Zimmerman, 2018) and an individualization of instructions depending on the degree of cognitive impairment may be also useful. These factors underline the need for individualized MEPs tailored to the specific needs of an IWD in order to impact physical performance and cognitive function. Indeed, the concept of individualized medicine which has already become popular in prevention and treatment of Alzheimer's disease (Hampel et al., 2017) is also transferable to the design and conduct of individualized exercise programs for IWD (Müllers et al., 2019). Of note, the feasibility of individualized exercise programs for IWD in nursing homes has to be discussed, as time available for PE programs in geriatric care settings is often limited. Organizational and structural aspects from both nursing homes and health care systems could support and facilitate the implementation of PE interventions in nursing homes (e.g. by engaging volunteers) (Souto Barreto et al., 2016). While previous studies have shown the cost-effectiveness of PE interventions for IWD in community settings (Nickel et al., 2018), the evaluation of costs and personal resources in nursing homes is lacking to date. One may only speculate, that individualized PE interventions may require more personal resources at first, but save financial and personal resources in the long-term if they are effective. Mobile health applications may therefore be an effective and efficient possible solution in the implementation of individualized exercise programs in IWD (Barisch-Fritz et al., 2020). In detail, they may represent an easy to administer

tool, that could support nursing home staff while conducting PE interventions with information on exercises, training plans, possible risk factors or required training material. Furthermore, mobile health applications offer the opportunity to individually adapt PE programs for example by integrating data-based or artificial intelligence algorithms (Helbostad et al., 2017). Of note, the monitoring of exercise intensity may be a further advantage of mobile health applications. Previous research used and recommended a combination of heart-rate monitoring and rating of perceived exertion (Sanders et al., 2020), but this was mainly done by research assistants and may be too time-consuming for nursing home staff. For a feasible and applicable monitoring of exercise intensity in IWD, a protocol of exercise repetitions or exercise time, as well as externally rated exertion by nursing home staff could be implemented in a mobile health application. Despite all these advantages and possibilities of mobile health interventions, studies examining their usability and feasibility of in nursing homes are sparse (Barisch-Fritz et al., 2020).

Our MEP was originally designed to primarily improve cognitive function and motor performance (Barisch-Fritz et al., 2021; Trautwein et al., 2020), and to address ADL performance indirectly. PE interventions which include ADL specific tasks and take into account the complex requirements of ADL performance could be more effective. Therefore, we investigated the underlying mechanisms of ADL performance using multiple regression analysis. Explained variance ranged from 2.4% (E-ADL) to 51.4% (PPT-7) with statistically significant coefficients for both cognitive function and motor performance. The small explanation of variance in E-ADL was expected, as the test contains tasks for upper extremities that were not captured with our assessment battery (Graessel et al., 2009). Nevertheless, our results may contribute to a deeper understanding of different sub-dimensions of ADL performance. If relevant cognitive and motor functions are carefully selected for the conceptualization of PE interventions, potential transfer effects on ADL performance could be more beneficial (Hagovska & Nagyova, 2017). Our results showed that assessments for balance and mobility explained the variance in the BI. For the performance of the PPT-7, walking speed, lower limb strength and memory were additionally important. These results are partly in line with previous studies (Garcia-Pinillos et al., 2016; E. Portegijs et al., 2016). However, beyond cognitive function and motor performance, other factors like having a depression, or feeling pain during specific tasks of daily life (e. g. sit-to-stand transfers) may influence ADL performance in IWD (Mlinac & Feng, 2016) and should be considered in the conceptualization of PE interventions.

STRENGTHS AND LIMITATIONS

The strengths of our study are the high methodological quality and the large sample size. Furthermore, we implemented a MEP that was based on theoretical considerations and proofed to be feasible conducted in a sample of IWD living in nursing homes within a pilot study. In addition, we designed the MEP to be highly suitable in everyday life of nursing homes. Our previously assumed dropout rate was lower than expected which may be an indicator for the acceptability of the MEP in the participating nursing homes. Indeed, after the conclusion of our intervention study, many of the 36 participating nursing homes continued the MEP and we received positive feedback from nursing home staff and participants. Furthermore, nursing staff received a special training to continue the MEP following the intervention study. This training included information on how to adapt intensity level during exercise sessions when needed. Another strength of the study was the comprehensive acquisition of ADL performance using one proxy-based questionnaire, and two performance-based assessments.

Nevertheless, our study has some limitations that must be considered while interpreting the results. First, we did not reach the intended sample size of 405 IWD, because the number of participants that did not fulfil our inclusion criteria was higher than expected. However, a sensitivity analysis (G*Power 3, Version 3.1.9.2) showed that we were still able to detect small to medium effects. Second, our intervention program was initially designed with adjustments of exercise intensity during the 16-week intervention period. However, due to the high heterogeneity of individual characteristics of our study participants such as age or disease severity, we had to increase our safety efforts and could possibly not achieve an adequate training stimulus for all participants. Moreover, the theoretical recommendation of two training sessions per week (Souto Barreto et al., 2016) was only partially feasible within our study. Hence, we strongly recommend including strategies to support adherence as proposed by van der Wardt et al. (2017). Another factor that may limit our findings is that we did not control for any other interventions that might have taken place during the conduct of our study in the IG no CG. Therefore, we cannot rule out that other social or therapeutic interventions may have biased our results. Another limitation is related to the number of incomplete data sets which reduced the sample size for statistical analysis in the per protocol analysis. Especially the BI as a proxy-based measurement filled in by nursing home staff was less often completed than the other assessments carried out by our study staff. Other reasons for incomplete data sets may be daily form and mood, depressive symptoms, other severe impairments or schedule conflicts. As we did not assess depressive symptoms with an evaluated assessment tool, we were not able to

make assumptions about the possible influence of depression on ADL performance. Finally, our study did not include a follow-up assessment or a long-term monitoring of the continuation of the MEP in the participating nursing homes, so we do not have any results about the long-term effects of our intervention.

3.1.6 CONCLUSION

Our study showed that a one-size-fits-all MEP is not effective in improving ADL performance in a heterogeneous group of IWD. Nevertheless, improving or maintaining ADL performance of IWD living in nursing homes is critically important, as it is related to a better quality of life and a reduced care effort for nursing home staff. According to our responder-analysis, particularly IWD with poor baseline motor performance responded positively to our exercise program, implying an insufficient exercise intensity for participants with better baseline values. Cognitive function and motor performance explained up to 51.4% of ADL performance with more motor than cognitive assessments as significant cofounders.

Our results are relevant for further research as they underline the need for individualized MEP for IWD, and a more critical handling with theoretical recommendations transferred into practice. Given the lack of intensity-adjustments during our intervention period, future PE interventions should consider monitoring the progression of exercise intensity more precisely. In line with the concept of individualized medicine, further intervention studies should consider the individual cognitive and motor impairments of IWD at baseline or at regular times of an intervention program to customize PE intervention content. Furthermore, future studies should account for the high heterogeneity in this target group with regard to disease severity, or cognitive function and motor performance status, and identify more homogeneous subgroups, e.g., by performing a cluster analysis. Using mobile health applications may help to indicate individual deficits (e.g. in balance, gait performance) at baseline and may therefore, present an effective and efficient solution for individually tailoring exercise interventions. However, this may only be applicable in small training groups or one-on-one guided training sessions. Further studies should investigate the usability and feasibility of mobile health applications for implementing individual exercise in nursing homes. Finally, studies comparing the effects of an individualized PE intervention on ADL performance, compared to a general PE intervention and a control group, are warranted.

REFERENCES

All references of Manuscript I are included in the List of References at the end of this thesis.

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Author Contribution: All authors contributed to the study conception, design, and implementation of the study. J. Bezold, S. Trautwein, and B. Barisch-Fritz analyzed the data. J. Bezold interpreted the data. J. Bezold wrote the first draft of the manuscript and all authors provided critical feedback on previous versions of the manuscript. All authors approved the final manuscript.

DECLARATIONS

Conflict of interest: J. Bezold, S. Trautwein, B. Barisch-Fritz, A. Scharpf, J. Krell-Roesch, C. R. Nigg and A.Woll declare that they have no competing interests.

All procedures performed in studies involving human participants or on human tissue were in accordance with the ethical standards of the institutional (ethics committee of the Karlsruhe Institute of Technology, Karlsruhe, Germany) and/or national research committee and with the 1975 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

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SUPPLEMENTARY MATERIAL*Supplementary Table 3.1: Sample exercises of the multimodal exercise program*

	Basic exercise	Progression
Strength		
<i>Imagination</i>	„Aqua Fitness“	“Tight rope dance”
<i>Starting position</i>	seated, arms stretched above head, holding a pool noodle	Standing upright behind chair, arms stretched above head, holding a skipping rope
<i>Motor task</i>	Lateral flexion with pool noodle	Lateral flexion with rope
<i>Sets a. repetitions/ duration</i>	3x2 on each side	2x3
<i>Cognitive task</i>	none	Answering questions about circus (e.g. Have you ever been to a circus? Which circus act did you like most?)
Balance		
<i>Imagination</i>	„Safari – Washing an elephant”	“World Trip – Washing an elephant”
<i>Starting position</i>	Starting position: Seated, one arm horizontally stretched, flexion in hip joint to shift body weight forward	Standing upright behind chair, one arm horizontally stretched, flexion in hip joint to shift body weight forward
<i>Motor task</i>	Slow and large arm movements in horizontal plane holding a small sandbag (~1Ibs), leaning to left and right side	Slow and large arm movements in horizontal plane holding a small sandbag (~1Ibs), leaning to left and right side
<i>Sets and repetitions/ duration</i>	1 minute	1,5 minutes
<i>Cognitive task</i>	Answering questions about elephants (e.g. Do you know any different kinds of elephants)	Counting to 180 in steps of 6
Endurance		
<i>Imagination</i>	„Walking to soccer training”	“Walking through the jungle”
<i>Starting position</i>	Seated	Standing upright behind chair
<i>Motor task</i>	“Walking”, lifting legs with active arm use	“Walking” in place, lifting legs with active arm use
<i>Sets and repetitions/ duration</i>	1 minute	3 minutes
<i>Cognitive task</i>	Answering questions about soccer and its rules (e.g. How many referees are involved in a soccer game?)	Naming animals living in the jungle
Flexibility		
<i>Imagination</i>	„Safari – Wood chopping“	“Laola wave during Olympic games”
<i>Starting position</i>	Seated	Standing upright behind chair
<i>Motor task</i>	Extension and flexion of the trunk, bringing arms in extension with maximal individual range of motion	Extension and flexion of the trunk, bringing arms in extension with maximal individual range of motion (trying to increase range of motion)
<i>Sets and repetitions/ duration</i>	3x10	3 minutes
<i>Cognitive task</i>	Synchronous performance with the other participants	performing according different signals: 1=moving fast, 2=moving slow, 3=change direction of laola wave

Supplementary Table 3.2: Baseline characteristics of the intention-to-treat sample

	Total sample [n=304]	Intervention group [n=194]	Control group [n=110]	Group differences [t(df)/z/Chi ² (df), p]
Age, years [M (SD)]	86 (6)	86 (6)	87 (6)	t(302)=1.135, p=0.257
Sex, female	86%	85%	89%	Chi ² (1)=1.223, p=0.269
Diagnosis of dementia				Chi ² =3.693, p=0.158
- yes	66%	67%	65%	
- no	18%	20%	15%	
- unknown	16%	13%	21%	
Type of dementia				Chi ² =9.005, p=0.050
- Alzheimer's disease	17%	19%	14%	
- Vascular dementia	15%	18%	10%	
- Mixed dementia	3%	2%	4%	
- Other	1%	2%	0%	
- unknown	30%	26%	37%	
- no confirmed/unknown diagnosis	34%	34%	36%	
MMSE [M (SD), range]	17 (4)	17 (4)	17 (4)	t(250.853)=0.389, p=0.698
Use of walking aid				Chi ² (2)=4.104, p=0.128
- walker	72%	69%	75%	
- woking stick/s	6%	4%	8%	
- no walking aid	22%	24%	16%	
- unknown	2%	3%	1%	
CIRS [M (SD), range]				
- Morbidity Index	9 (5)	9 (4)	10 (6)	t(176)=0.469, p=0.639
- Severity Index	1.6 (0.4)	1.6 (0.4)	1.6 (0.4)	t(176)=0.024, p=0.981
Number of medications [M (SD), range]	7 (0.3)	7 (0.3)	6 (0.4)	t(232)=2.686, p=0.007
BMI, kg/m² [M (SD), range]	28.0 (0.3)	28.5 (0.4)	27.2 (0.5)	t(268)=2.307, p=0.021

BMI: Body Mass Index, CIRS: Cumulative Illness Rating Scale, df: degree of freedom, M: mean, MMSE: Mini-Mental State Examination, n: number, SD: standard deviation

Statistically significant results appear bold

Supplementary Table 3.3: Effects of the MEP on ADL performance (intention-to-treat analysis)

		Baseline [M (SE)]	Group differences at baseline [t(df), p]	Post [M (SD)]	Difference baseline - post [M (SE), [CI ₉₅]]	Within group time effects [t(df), p]	Time*group effects F(df _{numerator} , df _{denominator}), p	Effect size η^2
BI	IG=19 4	66.84(1.53)	t(186)=-0.122, p=0.093	67.52(1.55)	-0.69(1.49), [-3.65, 2.28]	t(34)=-0.461, p=0.648	F(302.000)=0.016-3.951, p=0.048-0.901*	0.000-0.07
	CG=10	67.14(2.09)		66.23(2.21)	0.91(1.87), [-2.77, 4.59]	t(84)=0.489, p=0.182		
E-ADL	IG=19 4	26.45(0.30)	t(1879)=-0.076, p=0.939	25.64(0.34)	0.81(0.35), [0.12, 1.50]	t(277)=2.301, p=0.022	F(302.000)=0.000-0.777, p=0.379-0.988	0.000-0.13
	CG=10	26.49(0.39)		25.88(0.39)	0.61(0.46), [-0.28, 1.59]	t(456)=1.338, p=0.182		
PP T-7	IG=19 4	12.22(0.35)	t(3375)=-0.052, p=0.958	11.87(0.45)	0.35(0.35), [-0.34, 1.04]	t(54)=1.006, p=0.319	f(302.000)=0.096-2.094, p=0.149-0.757	0.000-0.07
	CG=10	12.25(0.42)		11.46(0.49)	0.78(0.41), [-0.28, 1.59]	t(60)=1.908, p=0.61		

BI: Barthel Index, CG: control group, CI95: 95% confidence interval, df: degrees of freedom, E-ADL: Erlangen Test of Activities of Daily Living, IG: intervention group, M: mean, n: number, PPT-7: 7-item Physical Performance Test, SD: standard deviation

* statistically significant in single imputations

Statistically significant results appear bold for $\alpha=0.05$, considering adjusted significance levels using Bonferroni-Holm correction no statistically significant results were observed

Supplementary Table 3.4: Responder in ADL performance (per protocol)

	All		positive-R		non-R		negative-R	
	n	Mean change (SD)	[%]	Mean change (SD)	[%]	Mean change (SD)	[%]	Mean change (SD)
BI	63	5.9 (10.7)	31.7	19.3 (7.1)	68.3	-0.4 (4.1)	-	-
E-ADL	89	-0.4 (4.3)	20.2	5.6 (2.6)	52.8	0.0 (1.4)	27.0	-5.7 (2.1)
PPT-7	88	0.3 (3.6)	30.7	4.6 (1.7)	50.0	-0.4 (1.5)	19.3	-4.7 (1.6)

BI: Barthel Index, E-ADL: Erlangen Test of Activities of Daily Living, n: number, negative-R: negative-responder, non-R: non-responder, positive-R: positive-responder, PPT-7: 7-item Physical Performance Test, SD: standard deviation.

4 MANUSCRIPT 2: USING BODY-WORN SENSORS TO OBJECTIVELY ASSESS FALL RISK IN INDIVIDUALS WITH DEMENTIA

Slightly modified version of the published paper.

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Sensor-based fall risk assessment in older adults with or without cognitive impairment: a systematic review.

4.1.1 ABSTRACT

Background: Higher age and cognitive impairment are associated with a higher risk of falling. Wearable sensor technology may be useful in objectively assessing motor fall risk factors to improve physical exercise interventions for fall prevention. This systematic review aims at providing an updated overview of the current research on wearable sensors for fall risk assessment in older adults with or without cognitive impairment. Therefore, we addressed two specific research questions: 1) Can wearable sensors provide accurate data on motor performance that may be used to assess risk of falling, e.g., by distinguishing between faller and non-faller in a sample of older adults with or without cognitive impairment?; and 2) Which practical recommendations can be given for the application of sensor-based fall risk assessment in individuals with CI? A systematic literature search (July 2019, update July 2020) was conducted using PubMed, Scopus and Web of Science databases. Community-based studies or studies conducted in a geriatric setting that examine fall risk factors in older adults (aged ≥ 60 years) with or without cognitive impairment were included. Predefined inclusion criteria yielded 16 cross-sectional, 10 prospective and 2 studies with a mixed design.

Results: Overall, sensor-based data was mainly collected during walking tests in a lab setting. The main sensor location was the lower back to provide wearing comfort and avoid disturbance of participants. The most accurate fall risk classification model included data from sit-to-walk and walk-to-sit transitions collected over three days of daily life (mean accuracy = 88.0%). Nine out of 28 included studies revealed information about sensor use in older adults with possible cognitive impairment, but classification models performed slightly worse than those for older adults without cognitive impairment (mean accuracy = 79.0%).

Conclusion: Fall risk assessment using wearable sensors is feasible in older adults regardless of their cognitive status. Accuracy may vary depending on sensor location, sensor attachment and type of assessment chosen for the recording of sensor data. More research on the use of sensors for objective fall risk assessment in older adults is needed, particularly in older adults with cognitive impairment.

This systematic review is registered in PROSPERO (CRD42020171118)

Key words: risk of falling, wearable sensors, elderly, cognition, dementia

4.1.2 INTRODUCTION

With increasing age, cognitive function and motor abilities decline and risk of falling increases (Ambrose et al., 2013). One in three individuals over the age of 65 years experiences one or more falls in any given year, and this prevalence increases to 40% among individuals aged 80 years and older (Patel et al., 2020). Falling often leads to severe injuries, hospitalization, loss of autonomy in activities of daily living, reduced quality of life, and an accelerated need for help in older adults (Fernando et al., 2017; Patel et al., 2020). Furthermore, fall-related mortality increases with age (Joshi et al., 2020). Individuals with cognitive impairment (CI) fall twice as often as their unimpaired peers and have a threefold increased risk of suffering a bone fracture after a fall (Cox & Vassallo, 2015; Lamoth et al., 2011).

A number of motor disabilities are known to be related to a higher risk of falling (Damián et al., 2013; Mohler et al., 2016), for example negative changes in gait under single and dual task conditions, balance or lower extremity strength (Ambrose et al., 2013; Fernando et al., 2017; Huijben et al., 2018). In individuals with CI, accelerated decline of motor performance is associated with an increased risk of falling as compared to cognitively unimpaired older adults (Taylor et al., 2014; W. Zhang et al., 2019).

Physical exercise interventions in fall prevention are promising, as they are associated with improved gait performance, balance and mobility in older adults (Chan et al., 2015; Sherrington et al., 2019). Therefore, the identification and quantification of modifiable fall risk factors may be important for the design of effective physical rehabilitation or fall prevention programs that specifically address the needs and burdens of older individuals at high risk of falling (Thibaud et al., 2012). Since falling events in geriatric settings are usually recorded by fall diaries implying a higher risk to recall bias (Rapp et al., 2012), there is a need for the identification and investigation of fall-related factors that may serve as more reliable indicators of a person's fall risk than recorded total number of prior falls.

To date, such key factors of motor performance are commonly assessed using questionnaires, scales or objective clinician-rated functional performance tests, such as the Short Physical Performance Battery (SPPB) (Guralnik et al., 1994) or the Timed- Up and Go Test (TUG) (Podsiadlo & Richardson, 1991), usually evaluated by timekeeping or scoring. Nevertheless, not all of these assessments are feasible, particularly for older individuals with CI and the scales often show a high inter-rater variability (Rivolta et al., 2019).

Within the last ten years, wearable technology providing objective data has become more prevalent in clinical settings (Montesinos et al., 2018). Small and lightweight body-worn sensors like accelerometers or gyroscopes hold great promise in the field of fall detection, but also in fall risk assessment (Bet et al., 2019; Patel et al., 2020). Moreover, these devices are more economic than gold standard methods of motion analysis systems (Kluge et al., 2017) and more applicable in clinical and non-clinical settings as their high level of portability allows the examination of human motion in field instead of laboratory testing (Díaz et al., 2020).

Fall detection using wearable sensors can reduce fall-related injuries and healthcare costs, and is often used as an alarm system in case of an emergency, i.e. accidental fall. The recognition of fall events can be used to trigger helping systems (e.g. alarming signals to caregivers) and may help to understand the mechanism underlying the fall incident (Chaccour et al., 2017; Nooruddin et al., 2022). Thereby, fall detection systems may prevent an individual from remaining in a helpless position on the floor for an extended period of time (Nooruddin et al., 2022). A recent review on single and multiple sensor-based fall detection concluded wearable sensor-based solutions to be of accuracy to detect fall-events in older adults (Nooruddin et al., 2022). Nevertheless, fall detection systems using multiple input sources may lead to high costs and their use is often restricted to indoor locations (Nooruddin et al., 2022; Shu & Shu, 2021). Furthermore, fall detection systems may help to identify external fall risk (e.g., uneven ground) but they are limited in providing information about internal fall risk factors, e.g., dysfunctional patterns of gait or required motor tasks that are of interest to conceptualize fall prevention strategies. To this end, using wearable sensors for fall risk assessment may comprehensively capture characteristics of different motor tasks allowing an estimation of human motion (e.g. spatio-temporal characteristics of balance or gait or transfer performance from sitting to standing) (Howcroft et al., 2013; Montesinos et al., 2018).

Current reviews on body-worn sensors for the assessment of fall risk focus either on methodological aspects such as applied classification methods and model assessment outcomes, or on practical aspects such as type, number and location of sensors and are often limited to older people without CI (Gillain et al., 2018; Howcroft et al., 2013; Montesinos et al., 2018; Patel et al., 2020; R. Sun & Sosnoff, 2018). Moreover, most of published reviews are limited to either a supervised or a unsupervised setting or included studies with other quantitative measures like instrumented walkways or motion capturing systems (Dolatabadi et al., 2018).

Therefore, the overarching aim of the present systematic review was to provide an overview and update of the existing body of literature that examined the feasibility of body-worn sensors for the assessment of motor fall risk among older adults. Furthermore, we deliberately aimed at including studies that focused on older adults with CI to give practical advice on the use of wearable sensors in individuals with CI. To this end, we addressed two specific research questions: 1) Can wearable sensors provide accurate data on motor performance that may be used to assess risk of falling, e.g., by distinguishing between faller and non-faller in a sample of older adults with or without cognitive impairment?; and 2) Which practical recommendations can be given for the application of sensor-based fall risk assessment in individuals with CI?

The following paragraphs contain a detailed description of the methodological procedure of this systematic review, i.e. search strategy, study selection and data synthesis. In the results section we present study design, detection of fall status, use of sensors to assess fall risk, and classification models of the included studies. Furthermore, results of studies including individuals with CI are presented separately. Finally, we summarize our findings in accordance with the objectives with this systematic review and discuss the strengths and limitations as well as practical implications.

4.1.3 METHODS

PROTOCOL

We followed the Preferred Reporting Item for Systematic review and Meta-Analysis (PRISMA) guidelines in preparing this systematic review (Moher et al., 2009). Furthermore, we registered this review in PROSPERO (CRD42020171118).

SEARCH STRATEGY AND ELIGIBILITY CRITERIA

We performed a literature search using PubMed, Web of Science and Scopus databases with no time filter set. Articles were searched using the following combination of key words: (fall risk OR fall risk factor*) AND (sensor* OR objectively measured OR objective measurement OR acceleromet*). Population or cognitive status were not included in the search term because we did not want to restrict our results, for example by potentially excluding articles that had mixed study populations. Rather, we deliberately kept our literature search as inclusive as possible. No filter was applied at this stage. The complete literature search can be found in supplementary material (Additional file 1). We screened the reference lists of included articles for relevant secondary literature. The initial database search was conducted in July 2019 with an updated search in August 2020. The following inclusion criteria for the studies were defined:

- a) Original research articles in peer reviewed journals in English language;
- b) Studies including individuals with a mean age of 60 years or older, with or without presence of CI;
- c) Studies assessing fall-related motor performance using body-worn, sensor-based tools in a clinical or community-based setting or in nursing homes, and;
- d) Studies sub-dividing their sample into fallers and non-fallers, or into individuals at high and low fall risk based on prospective or retrospective falls, clinical assessments or the combination of these methods.

Studies were excluded if a) the mean age of the reported sample was younger than 60 years, b) the individuals showed concomitant severe chronic conditions (e. g., stroke, Parkinson's Disease), and c) only environmental sensor-based systems (e.g. 2D video analysis) were applied. As the focus on fall risk assessment may provide more pertinent information that enables the design of new preventive approaches, i.e., physical exercise interventions, we also excluded studies with the purpose of fall detection.

STUDY SELECTION

After detection and removal of duplicates, two authors (JB and JKR) independently screened all titles and abstracts of the literature search. Both authors repeated this process by screening the abstracts (or full texts if more information was needed) of the remaining articles based on the above defined inclusion criteria. In case of any discrepancy, a third author (TE) was consulted. If there was disagreement about the final inclusion of an article, the third author read the full text and made a final decision. Literature management was performed using Citavi Software (Version 6.3.0.0, Swiss Academic Software GmbH).

DATA EXTRACTION AND DATA SYNTHESIS

First, relevant data of the included studies were independently extracted and systematically recorded by two authors (JB and JKR) using a standardized data extraction form. Second, the collected data was cross-checked to ensure complete and correct data extraction. We extracted first author's name, publication date, study design, sample size and population characteristics (i.e., sex, age, cognitive status). We also collected information on fall classification methods that was used to differentiate between fallers and non-fallers or individuals at high and low fall risk. Additionally, the following specific characteristics about the use of body-worn

sensors were collected: type of sensor(s), location of sensor(s), activities while sensor data were collected (e.g., during clinical assessment of the TUG) and the parameters of sensor data collected. Furthermore, results of prediction models were extracted and accuracy, sensitivity and specificity were extracted. Accuracy is defined as the ability to discriminate between fallers and non-fallers or between people at high and people at low fall risk. Sensitivity describes the true-positive proportion and specificity describes the true-negative proportion. An accuracy of 50% means that no discrimination exists and that this performance can be achieved by chance (Swets, 1988). After data extraction, one author (JB) synthesized the data.

ASSESSMENT OF METHODOLOGICAL QUALITY

Two authors (JB and JKR) independently assessed the methodological quality of each study included in this systematic review using the Newcastle-Ottawa Scale (NOS) for cross-sectional and for prospective or cohort studies (Modesti et al., 2016; Wells et al., 2020). The scale uses an evaluation system with stars across three categories, i.e. selection (cross-sectional: 0-5 stars; prospective: 0-4 stars), comparability (cross-sectional: 0-2 stars; prospective: 0-2 stars) and outcome (cross-sectional: 0-3 stars; prospective: 0-3 stars). A higher number of total stars (cross-sectional: range 0-10; prospective: 0-9) reflects a higher study quality with regard to the respective categories.

4.1.4 RESULTS

After the identification of 527 studies and the screening of 307 abstracts, 82 full-text articles were checked for the inclusion criteria. Finally, a total of 27 studies were included in this systematic review (Figure 1). An updated search in July 2020 resulted in one additional article. Screening the reference lists resulted in no additional articles.

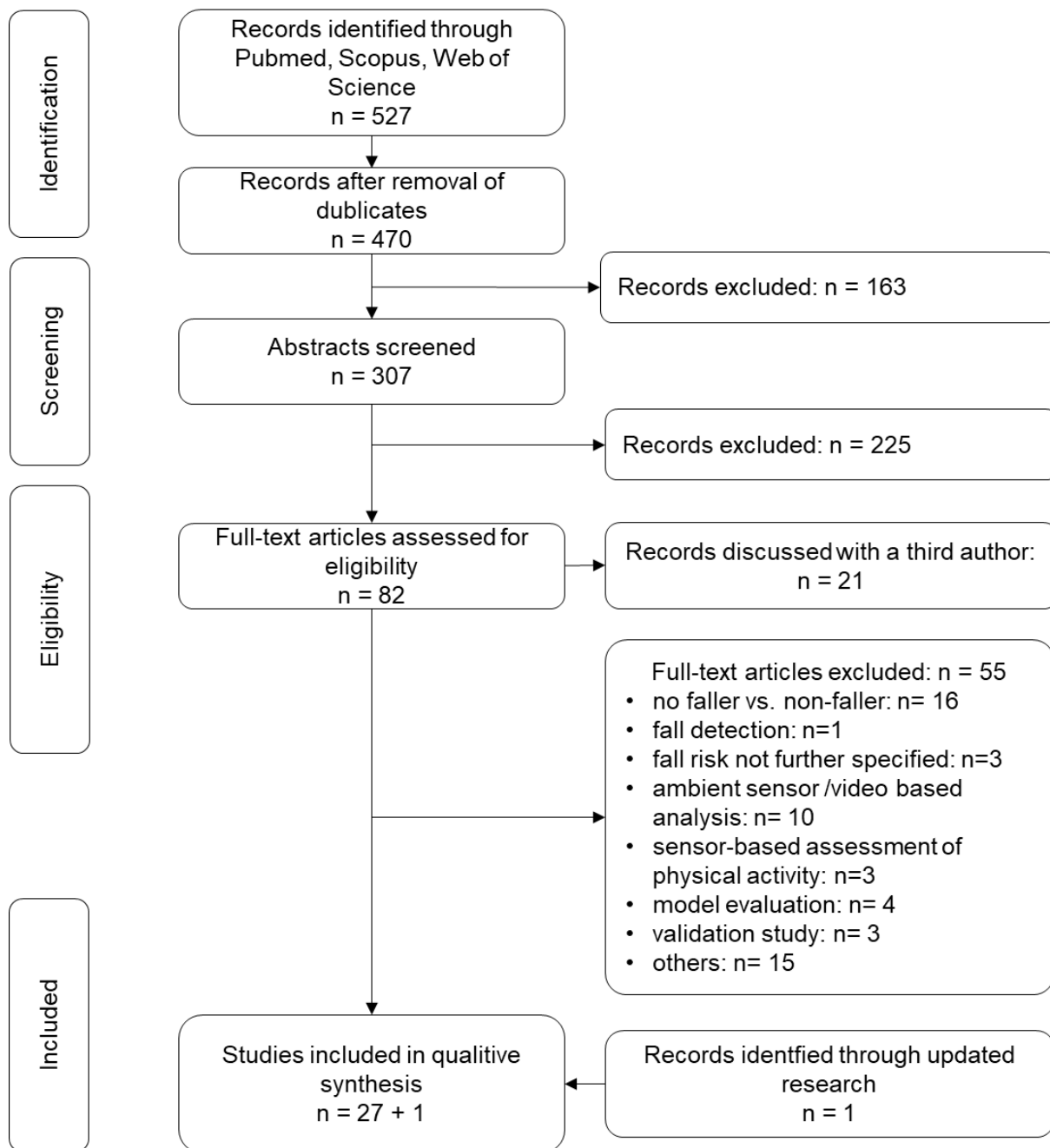


Figure 4.1: Flow chart of the literature search

STUDY DESIGN AND SAMPLE CHARACTERISTICS

The included studies were published between 2009 and 2020. Sixteen of the included studies had a cross-sectional design, ten studies had a prospective / longitudinal design and two studies combined cross-sectional with prospective design. The follow-up period of included prospective studies differed between 2 and 24 months. Seventeen studies were conducted in a supervised setting (e. g., clinical setting), whereas six studies collected unsupervised sensor data during daily life. Five studies combined the two settings.

A total of 2,896 participants (range = 35-303; 65% females) were included in the studies. Twenty studies included community-dwelling participants, eight studies were conducted in patients who were hospitalized or residing in a geriatric care facility. The mean age of the older participant groups ranged between 68 and 86 years. Two studies (Iluz et al., 2016; Rivolta et al., 2019) included younger control groups with a mean age between 21 and 35 years, however, we did not consider these groups for the purpose of this review. CI was an exclusion criterion in most of the studies (n = 14) and only one study deliberately focused on older people with dementia (Gietzelt et al., 2014). To determine cognitive status, the Mini-Mental-State Examination (score 0-30) (Folstein et al., 1975), the MiniCog (score 0-5) (Borson et al., 2003) or the Short Orientation-Memory-Concentration Test (score 0-26) (Wade & Vergis, 1999) were used. The remaining studies did not explicitly state CI as an exclusion criterion but required to be able to understand the test instructions. Further information about study characteristics and the main findings of the studies is presented in Table 1.

Table 4.1: Study design, sample characteristics and main results

Author, year	Study design, sample including number of participants, mean age (SD) and sex	Cognitive Status	Record of falls/ fall history	Main findings
Bautmans et al. (2011)	Cross-sectional Community-based Total n=121, 80 (5), 50% female; Younger adults n=40, 22(1), 50% female	Cognitively intact according to MMSE (MMSE \geq 24)	Retrospective 6 months, Tinetti Assessment Tool, Timed-Up and Go HFR n=40, LFR n=41	- Participants with HFR showed slower gait speed (p<0.05) - With cut-off value 1.58 m/s gait speed discriminates between HFR and LFR with 78% sensitivity and 76% specificity
Bizovska et al. (2018)	Prospective study Community-based Total n=131, 71 (6), 82% female	CI as exclusion criterion	Prospective 1 year SF=35, MF=15, NF=81	- Trunk medial-lateral acceleration in short-term Lyapunov exponent differed between MF and NF (p<0.05) but not after Bonferroni correction; - Poor MF predictive ability of trunk medio-lateral short-term Lyapunov exponent but results improved when combining with clinical examination
M. A. Brodie et al. (2017)	Cross-sectional Community-based Total n=96, 75 (8), 59% female	CI as exclusion criterion according to Mini-Cog	Retrospective 12months F=33, NF=63	- Fallers showed significantly reduced gait endurance and increased within-walk variability (p<0.05)
M. A. D. Brodie et al. (2015)	Cross-sectional Community-based Total n=96, 80 (4), 67% female	No information about CI	Retrospective 1 year, Physiological Profile Assessment Tool F=35, NF=61	- 8-step mediolateral harmonic ratio identified significant differences in between F and NF based on age, walking speed and physiology (p<0.05)
Buckinx et al. (2015)	Prospective study Nursing homes Total n=100, 86 (6), 80% female	No information about CI	Prospective 2 years F=75, NF=25	- Gait characteristics were not predictive of long-term falls
Buisseret et al. (2020)	Prospective study Nursing homes	CI included, 16% with dementia	Prospective 6 months F= 23, NF=50	- When the Timed-Up and Go test results are coupled with indicators of gait variability measured during a six-minute walk test,

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Author, year	Study design, sample including number of participants, mean age (SD) and sex	Cognitive Status	Record of falls/ fall history	Main findings
	Total n= 73, 83 (8) 62% female			accuracy of fall prediction improved from 68% to 76%
Ejupi et al. (2017)	Cross-sectional Community-based Total n=94, 80 (7), 68% female	CI as exclusion criterion according to Mini-Cog and MMSE	Retrospective 12months F=34, NF=64	- F showed significantly lower maximum acceleration, velocity and power during sit-to-stand movements compared to NF (p<0.05)
Gietzelt et al. (2014)	Cohort-study Nursing homes Total n=40, 76 (8), 50% female	CI included (MMSE 9.3±8.0)	Prospective for 2, 4 and 8 months F=13, NF=27	- It is possible to classify gait episodes of F and NF for mid-term monitoring (4 months) during daily life using body-worn sensors (75.0% accuracy)
Greene et al. (2012)	Prospective study Community-based Total n=226, 72 (7), 73% female	CI as exclusion criterion	Prospective 2 years F=83, NF=143	- Sensor-derived features yielded a mean classification accuracy of 79.69% for 2-year prospective falls
Howcroft et al. (2016)	Cross-sectional Community-based Total n=100, 76 (7), 56% female	CI as exclusion criterion according to self-reports	Retrospective 6 months F=24, NF=76	- Best fall classification model using pressure-sensing insoles and head, pelvis and shank accelerometers (84.0% accuracy) - Best single-sensor model with parameters derived from a head sensor during single task (84.0% accuracy)
Howcroft et al. (2018)	Prospective study Community-based Total n=75, 75 (7), 59% female	CI as exclusion criterion according to self-reports	Prospective 6months F=28, NF=47	- F had significantly lower dual-task head anterior-posterior Fast Fourier Transform first quartile, single-task left shank medial-lateral Fast Fourier Transform first quartile, and single-task right shank superior maximum acceleration (p<0.05)
Hua et al. (2018)	Cross-sectional Community-based Total n=67, 76 (6), 100% female	No information about CI	Retrospective 1 year, Short Physical Performance Battery HFR n=19, LFR n=48	- Coefficient of variance, cross-correlation with anteroposterior accelerations, and mean acceleration were the top features for classification in HFR and LFR group

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Author, year	Study design, sample including number of participants, mean age (SD) and sex	Cognitive Status	Record of falls/fall history	Main findings
Ihlen et al. (2018)	Prospective study Community-based Total n=303, 76 (7), 50%	Including CI (MMSE \geq 19)	Prospective 6months SF=58, MF=46, NF=199	<ul style="list-style-type: none"> - Higher phase-dependent multiscale entropy of trunk acceleration at 60% of step cycle in F compared to NF (p<0.05) - PGME has predictive ability of falls among SF
Ihlen et al. (2016)	Cross-sectional Community-based Total n=71, 78 (5), 65% female	Cognitively intact according to MMSE score (\geq 24)	Retrospective 12months F= 32, NF=39	<ul style="list-style-type: none"> - Refined composite multiscale entropy and refined multiscale permutation entropy of trunk velocity and trunk acceleration can distinguish between daily-life walking of F and NF (75.0-88.0% sensitivity, 85.0-90.0% specificity)
Iluz et al. (2016)	Cross-sectional Community-based Older adults total n=71, 78 (5), 65% females; Younger adults Total n=30, 28 (4), 57% female	Cognitively intact according to MMSE score (\geq 24)	Retrospective 1 year F=33, NF=38	<ul style="list-style-type: none"> - Temporal and distribution-related features from sit-to-walk and sit-to-stand transitions during daily-life differed significantly between F and NF - Mean classification accuracy was at 88.0% and better than traditional laboratory assessment
Mancini et al. (2016)	Cross-sectional, prospective Community-based Total n= 35. 85 (5), 66% female	Dementia as exclusion criterion according to Clinical Dementia Rating Scale and/or MMSE	Retrospective 12 months, prospective 6 months Retrospective analysis: SF n=12, RF n=7, NF n=16 Prospective analysis: F n=7, NF n=28	<ul style="list-style-type: none"> - Quality of turning (mean turn duration, mean peak speed of turning, mean number of steps to complete a turn) were significantly compromised in RF compared to NF (p<0.05)
Marschollek et al. (2009)	Cross-sectional Geriatric setting Total n=110, 80 (-), 74% female	no information about CI	Retrospective n/a F= 26, NF=84	<ul style="list-style-type: none"> - Pelvic sway while walking, step length and number of steps in TUG differed significantly between F and NF (p<0.05) - Adding sensor-based gait parameters to geriatric assessment improves specificity in fall prediction from 97.6% to 100.0%
Marschollek et al. (2011)	Prospective	No information about CI	Prospective 1 year n/a	<ul style="list-style-type: none"> - Sensor-derived parameters can be used to assess individual fall-risk (58 % sensitivity, 78%

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Author, year	Study design, sample including number of participants, mean age (SD) and sex	Cognitive Status	Record of falls/ fall history	Main findings
	Geriatric setting Total n=46, 81 (-), -			specificity) and identified more persons at fall risk than a conventional clinical assessment tool
Pozaic et al. (2016)	Cross-sectional Community-based Total n=136, 73 (6), 69% female	CI as exclusion criterion according to Screening of Somatoform Disorders (>10)	Prospective 1 month F n=13, NF n=123	- Time and frequency domain-based features derived from a wrist-worn accelerometer on the dominant and non-dominant hand can significantly distinguish between F and NF (p<0.05)
Qiu et al. (2018)	Cross-sectional Community-based Total n=196, 72 (4), 100% female	No information about CI	Retrospective 5 years F n=82, NF n=114	- Sensor-based data distinguished accurately between F and NF (89.4% accuracy)
Rivolta et al. (2019)	Cross-sectional Hospital setting Older adults total n=79, 69 (17), - Younger adults total n=11, 35 (-), -	No information about CI	Tinetti Assessment Tool HFR n= 33, LFR n=46	- Sensor-based balance and gait features assessed during Tinetti Test differed significantly between individuals with HFR and LFR (p<0.05) - Linear model and artificial neural network had a misclassification error of 0.21 and 0.11, respectively, in predicting Tinetti outcome
Sample et al. (2017)	Cross-sectional Community-based Total n=150, 76 (9), 59% female	No information about CI	Retrospective 12 months F=59, NF=91	- Sensor-based data collected during Timed-Up and Go resulted in a more sensitive model (48.1% sensitivity, 82.1% specificity) than including Timed-Up and Go time duration only (18.2% sensitivity, 93.1% specificity)
Senden et al. (2012)	Cross-sectional Community-based Total n=100, 77 (6), 56% female	CI as exclusion criterion	Tinetti Assessment Tool HFR n=19, LFR n=31, NFR n=50	- Walking speed, step length and root mean square had high discriminative power to classify the sample according to the Tinetti scale (76.0% sensitivity, 70.0% specificity).
van Schooten et al. (2015)	Cross-sectional, prospective	CI included (MMSE≥18)	Retrospective 6 months; prospective 6 months	- Sensor-derived parameters of the amount of gait (number of strides), gait quality (complexity, intensity, smoothness) and their

Author, year	Study design, sample including number of participants, mean age (SD) and sex	Cognitive Status	Record of falls/ fall history	Main findings
K. Wang et al. (2017)	Community and residential care home Total n=169, 75 (7), 54% female	No information about CI	Retrospective analysis: F n=60, NF n=109	interactions can predict prospective falls (67.9% sensitivity, 66.3% specificity).
	Prospective Total n=81, 84 (4), 44% female		Prospective analysis: F n=59, NF n=110 Prospective 12 months MF n=11, NF n=70	
A. Weiss et al. (2011)	Cross-sectional Community-based Total n=41, 72 (7), 66% female	Cognitively intact according to MMSE score (≥ 24)	Retrospective 1 year F n=23, NF n=18	<ul style="list-style-type: none"> - Sensor-derived Timed-Up and Go duration was significantly higher in F compared to NF ($p < 0.05$) - Jerk Sit-to-Stand, SD and average step duration correctly classify 87.8% of F and NF (91.3% sensitivity, 83.3% specificity)
Aner Weiss et al. (2013)	Prospective Community-based Total n=71, 78 (5), 65% female	Cognitively intact according to MMSE score (≥ 24)	Prospective 6 months F n=39, NF n=32	<ul style="list-style-type: none"> - Gait variability differed significantly between F and NF ($p < 0.05$);
Zakaria et al. (2015)	Cross-sectional Hospital setting Total n=38, 67 (7), 47% female	No information about CI	Timed-Up and Go HFR n= 21, LFR n=17	<ul style="list-style-type: none"> - Sensor-derived parameters of Timed-Up and Go phases can classify into people at HFR and people at LFR.

SD: standard deviation, n: number, MMSE: Mini-Mental State Examination, HFR: high fall risk, LFR: low fall risk, CI: cognitive impairment, SF: single faller, MF: multiple faller, NF: non-faller, F: faller, NFR: no fall risk

DETECTION OF FALL STATUS

Classification into fallers and non-fallers or in older adults at high risk or low risk of falling was conducted using three different methods: retrospective assessment (e.g., fall history questionnaire), prospective assessment (e.g., fall diaries) or clinical assessment of fall risk (e.g., Tinetti Score, TUG, SPPB). Moreover, five of the studies combined two of these methods (Table 4.1). The majority of studies compared fallers and non-fallers. A faller was defined as a person having at least one fall over a certain period of time, usually the past or prospective 12 months. Eight studies compared older adults at high and low risk of falling (Bautmans et al., 2011; Hua et al., 2018; Rivolta et al., 2019; Zakaria et al., 2015) or non-fallers and multiple fallers (Bizovska et al., 2018; Ihlen et al., 2018; Mancini et al., 2016; Wang et al., 2017). Multiple fallers were defined as participants that had fallen at minimum twice during the investigation period.

USE OF SENSORS TO ASSESS FALL RISK

To obtain the data, the included studies used between one and five inertial sensors. that were mainly located close to the centre of the body at the lower back (Bautmans et al., 2011; Bizovska et al., 2018; M. A. D. Brodie et al., 2015; Buckinx et al., 2015; Ihlen et al., 2018; Ihlen et al., 2016; Mancini et al., 2016; Qiu et al., 2018; Senden et al., 2012; van Schooten et al., 2015; Wang et al., 2017; A. Weiss et al., 2011; Aner Weiss et al., 2013; Zakaria et al., 2015) or legs (Bizovska et al., 2018; Greene et al., 2012; Howcroft et al., 2016; Howcroft et al., 2018; Qiu et al., 2018; Sample et al., 2017) of the participants. Less frequently used sensor locations were chest (M. A. Brodie et al., 2017; Ejupi et al., 2017; Rivolta et al., 2019; Sample et al., 2017), pelvis (Howcroft et al., 2016; Howcroft et al., 2018; Hua et al., 2018), waist (Marschollek et al., 2009; Marschollek et al., 2011), foot (Mancini et al., 2016; Rivolta et al., 2019; Wang et al., 2017), head (Howcroft et al., 2016; Howcroft et al., 2018) and wrist (Pozaic et al., 2016). The majority of the studies used sensor-derived data to distinguish between the different fall status groups or for fall classification during clinical testing (e. g. gait analysis under single or dual task conditions. Nine studies assessed walking and other related tasks during daily life, i.e. in homes of participants with a duration of three to eight days (Table 4.2).

Table 4.2: Use of body-worn sensors to assess fall risk

assessment while sensor was used	applied sensors (range of sampling rates in Hertz)	body location	assessed variables
gait analysis (between 7.62 and 400m) (Bautmans et al., 2011; Bizovska et al., 2018; M. A. D. Brodie et al., 2015; Buckinx et al., 2015; Howcroft et al., 2016; Howcroft et al., 2018; Hua et al., 2018; Iluz et al., 2016; Marschollek et al., 2011; Senden et al., 2012)	DynaPort, Trigno wireless systems, Locometrix, X16-1C, ActiGraph, GT3X+, Freescale, DAAF, ETB-Pegasus (30Hz-296.3Hz)	head, waist, lower back, pelvis	temporal and spatial gait variables, local dynamic stability variables, variables of gait symmetry, acceleration variables, angle variables
daily-life walking between three to eight days (M. A. Brodie et al., 2017; Gietzelt et al., 2014; Ihlen et al., 2018; Ihlen et al., 2016; Iluz et al., 2016; van Schooten et al., 2015; Aner Weiss et al., 2013)	Senior Mobility Monitor, SHIMMER platform, Dynaport, Opal, BMA280 (50Hz-128Hz)	chest, lower back, wrist, upper legs, lower legs	temporal and spatial gait variables, variables of gait symmetry and gait variability, variables of gait complexity and gait smoothness, angle variables, acceleration variables
Timed-Up and Go Test (Greene et al., 2012; Marschollek et al., 2009; Marschollek et al., 2011; Sample et al., 2017; A. Weiss et al., 2011; Zakaria et al., 2015)	SHIMMER platform, Freescale, Opal, Mobi8 System, combined sensor (100Hz-256Hz)	chest, waist, lower back, upper legs, foot	temporal and spatial gait variables, angular velocity variables, energy variables, angle variables
Tinetti Test (Rivolta et al., 2019)	GENEActiv (50Hz)	chest	temporal and spatial gait variables, balance variables
six-minutes walking test (Buisseret et al., 2020)	DYSKIMOT (100Hz)	lower back	acceleration variables, variables of gait variability
others			
standardized protocol with walking and sit to stand transitions (Ejupi et al., 2017)	not specified (50Hz)	around the neck	temporal gait variables, acceleration variables

assessment while sensor was used	applied sensors (range of sampling rates in Hertz)	body location	assessed variables
pecially developed test battery (Qiu et al., 2018)	Xsens (100Hz)	lower back, upper legs, lower legs	temporal and spatial gait variables, angle variables, angular velocity variables,
semi-supervised walking and stair ascent and descent (Wang et al., 2017)	Opal (128Hz)	lower back, ankle	temporal gait variables, variables of gait variability, variables of movement vigour

All applied sensors contained an accelerometer, a gyroscope or a combination of both.

CLASSIFICATION MODELS

Nineteen studies applied different types of machine learning models (e.g. receiver operating curves, Naïve Bayes, decision tree) and logistic regression analysis in order to correctly assign the study participants to the right category (e.g. faller and non-faller) using the sensor data. Besides sensor-derived variables, four studies also included height, body mass index, age (Rivolta et al., 2019; Sample et al., 2017; Aner Weiss et al., 2013), fall efficacy and information processing speed (Qiu et al., 2018). Prediction models achieved sensitivities between 48.1% and 91.3%, specificities between 66.3% and 100.0% and accuracies between 68.0% and 90.0% (Table 4.3). When comparing the analysed classification models of the different assessment conditions, the best model was found for daily-life data of three consecutive days with accuracy of 90.6%, sensitivity of 91.7% and specificity of 89.2% (Iluz et al., 2016). The models with sensor-derived data of laboratory assessment were on average not as precise, but accuracies, sensitivities and specificities were still acceptable (best in-lab data model (Qiu et al., 2018): accuracy = 89.4%, sensitivity = 92.7%, specificity = 84.9%).

Table 4.3: Fall risk classification models

Author	model	Acc (%)	Sen (%)	Spe (%)
Bautmans et al.(2011)	logistic regression analysis, ROC	77.0	78.0	78.0
Bizovska et al.(Bizovska et al., 2018)	logistic regression analysis, ROC	-	53.0	85.0
Buisseret et al.(Buisseret et al., 2020) ^a	binary classification, ROC	85.7	50.0	73.9
Greene et al.(Greene et al., 2012)	ROC	79.7	73.1	82.6
Gietzelt et al.(Gietzelt et al., 2014)	decision tree	75.0	78.2	71.2
Howcroft et al.(Howcroft et al., 2016)	support vector machine and neural networks	80.0-84.0	50.0-66.7	89.5
Hua et al.(Hua et al., 2018)	random forests	73.7	81.1	-
Ihlen et al.(Ihlen et al., 2018)	Partial Least Square Regression Analysis	76.0 (SF) 68.0 (MF)	71.0 (SF) 67.0 (MF)	80.0 (SF) 69.0 (MF)
Ihlen et al.(Ihlen et al., 2016)	Partial Least Square Discriminatory Analysis	-	59.0-88.0	77.0-92.0
Iluz et al.(Iluz et al., 2016)	Ada Boost, Support Vector Machine, Bag, Naïve Bayes	87.1-90.6	83.8-89.2	87.2-94.4
Marschollek et al.(Marschollek et al., 2011)	logistic regression, classification model	70.0	58.0	78.0
Marschollek et al.(Marschollek et al., 2009) ^a	classification trees	90.0	57.7	100.0
Qui et al.(Qiu et al., 2018) ^a	logistic regression, Naïve Bayes, decision tree, boosted tree, random forest, support vector machine	79.7-89.4	87.2-92.7	69.2-84.9
Rivolta et al.(Rivolta et al., 2019) ^a	linear model, artificial neural network	-	71.0-86.0	81.0-90.0
Sample et al.(Sample et al., 2017) ^a	stepwise logistic regression, max-rescaled R ² value	-	48.1	82.1
Senden et al.(Senden et al., 2012)	linear regression analysis, ROC	-	76.0	70.0
van Schooten et al.(van Schooten et al., 2015)	logistic regression analysis, ROC	-	67.9	66.3
Weiss et al.(Aner Weiss et al., 2013) ^a	binary logistic regression analysis	71.6	62.1	78.9

Author	model	Acc (%)	Sen (%)	Spe (%)
Weiss et al.(A. Weiss et al., 2011)	binary logistic regression analysis	87.8	91.3	83.3

^a These models also include data of clinical assessment (e. g. body mass index). Acc: accuracy, Sen: sensitivity, Spe: specificity, ROC: receiver operating curve, SF: single faller, MF: multiple faller.

RESULTS FOR INDIVIDUALS WITH CI

Since most of the included studies were conducted in a community setting, participants with severe CI are less likely to have participated. In addition to the only study that included individuals with severe dementia (Gietzelt et al., 2014), five studies were conducted in a geriatric or hospital setting but provided no information concerning the cognitive status of their participants (Buckinx et al., 2015; Marschollek et al., 2009; Marschollek et al., 2011; Rivolta et al., 2019; Zakaria et al., 2015) and three more studies did not explicitly exclude participants with CI (Buisseret et al., 2020; Ihlen et al., 2018; van Schooten et al., 2015). Overall, these nine studies may reveal information about the use and ability of sensors and sensor-derived data to distinguish between groups of fall status or to predict fall risk in a sample of older individuals with CI.

Six of the nine studies (Buckinx et al., 2015; Buisseret et al., 2020; Gietzelt et al., 2014; Ihlen et al., 2018; Marschollek et al., 2011; van Schooten et al., 2015) had a prospective design with between six- and 24-months follow-up. Three studies had a cross-sectional design (Marschollek et al., 2009; Rivolta et al., 2019; Zakaria et al., 2015) and collected sensor-derived data during clinical assessments. Sensors were placed at the lower back (Buckinx et al., 2015; Buisseret et al., 2020; Ihlen et al., 2018; van Schooten et al., 2015), the shank (Gietzelt et al., 2014), the waist (Marschollek et al., 2009) and the chest (Rivolta et al., 2019; Zakaria et al., 2015) and sensor data were collected within seven (Gietzelt et al., 2014; Ihlen et al., 2018) or eight (van Schooten et al., 2015) days of daily-life, a 20-metre gait analysis (Buckinx et al., 2015; Marschollek et al., 2009), the TUG (Marschollek et al., 2011; Zakaria et al., 2015), the Tinetti Test (Rivolta et al., 2019) or a walking test (Buisseret et al., 2020). Only two studies gave information on how the sensor was applied to the participant's body. In the study of Gietzelt et al. (Gietzelt et al., 2014), sensors were applied by instructed nursing staff while in the study of van Schooten et al. (van Schooten et al., 2015) study participants had to attach the sensor by themselves.

For daily-life data of gait quality (e.g. gait velocity, step frequency) classification models of those studies including older adults with CI revealed accuracies between 68.0-76.0%, sensitivities of 67.0-78.2% and specificities of 66.3-80.0% (Gietzelt et al., 2014; Ihlen et al., 2018; van Schooten et al., 2015) and therefore performed worse than the best model found for individuals without CI (Iluz et al., 2016). For sensor data collected during clinical assessments accuracies of 70.0-90.0%, sensitivities of 50.0-86.0% and specificities of 73.9-100.0% were achieved (Buisseret et al., 2020; Marschollek et al., 2009; Marschollek et al., 2011; Rivolta et al., 2019).

QUALITY ASSESSMENT

All studies included in this systematic review used reasonable methodology (Table 4.4) measured with NOS. Most studies did not apply randomized stratified sampling. Furthermore, not all included studies controlled for age and sex differences or other important factors resulting in a lower evaluation of the category “comparability”. Overall, cross-sectional and prospective studies achieved a mean score of six stars out of ten and nine total stars.

Table 4.4: Evaluation of study quality according to Newcastle-Ottawa Scale

Cross-sectional studies	Selection (5 stars)	Comparability (2 stars)	Outcome (3 stars)	Total Score (10 stars)
Bautmans et al., 2011	★★★	★	★★★	7
Brodie et al., 2015	★★	★	★★★	6
Brodie et al., 2017	★★★	★	★★★	7
Ejupi et al., 2017	★★	★	★★	5
Howcroft et al., 2016	★★★	★	★★★	7
Hua et al., 2018	★★★★★	★	★★★	8
Ihlen et al., 2016	★★	-	★★★	5
Iluz et al., 2016	★	★	★★★	5
Mancini et al., 2016*	★★★	★	★★★	7
Marschollek et al., 2009	★★★	★	★★★	7
Pozaic et al., 2016	★★★	★	★★★	7
Qui et al., 2018	★★★	★	★★★	7
Rivolta et al., 2019	★★★	★	★★★	7
Sample et al., 2017	★★★	★	★★★	7
Senden et al., 2012	★★★	★	★★★	7

van Schooten et al., 2015*	★★★	-	★★★	6
Weiss et al., 2011	★★	-	★★★	5
Zakaria et al., 2015	★★	-	★★★	5
Prospective studies	Selection (4 stars)	Comparability (2 stars)	Outcome (3 stars)	Total score (9 stars)
Bizovska et al., 2018	★★★	★	★★	6
Buckinx et al., 2015	★★	★	★★★	6
Buisseret et al., 2020	★★★	★	★★★	7
Gietzelt et al., 2014	★★	★	★★★	6
Greene et al., 2012	★★★	★	★★★	7
Howcroft et al., 2018	★★★	-	★★★	6
Ihlen et al., 2018	★★	★	★★	5
Marschollek et al., 2011	★★	★	★★★	6
Mancini et al., 2016 ^a	★★	★	★★	5
van Schooten et al., 2015 ^a	★★★	★	★★	6
Wang et al., 2017	★★	-	★★	4
Weiss et al., 2013	★★★	★	★★	6

^a Mancini et al. (Mancini et al., 2016) and van Schooten et al. (van Schooten et al., 2015) had a mixed study design and were therefore considered for both types of study design.

4.1.5 DISCUSSION

As a consequence of the aging process, falls are a major issue in geriatric populations and require special consideration in the design and conduct of effective physical exercise interventions. Therefore, a comprehensive understanding of motor performance is required to detect underlying fall risk factors more precisely. Assessment of motor performance in geriatric settings is usually based on scales, questionnaires and time-keeping, and wearable sensors may present a more objective and reliable approach. This systematic review provides an update of the existing body of literature concerning the assessment of fall risk factors in motor performance using wearable sensors with a special consideration of older adults with CI.

All studies included in this systematic review, except for one prospective study (Buckinx et al., 2015), found that sensor-derived data are successful in distinguishing between groups of faller status, or are useful in fall classification models. When classification ability of sensor data was compared to conventional clinical assessment, sensor-derived variables

outperformed data of clinical assessment (Howcroft et al., 2016). Wearable sensors may thus be considered a good alternative to conventional clinical assessment methods for fall risk assessment.

With regard to the setting of data collection, our review shows that data derived from both daily-life and clinical assessments was used to predict, classify or distinguish between groups of fall status. For in-lab sensor-based gait analysis, using the mean of at least two walks for more reliable data was recommended (Bautmans et al., 2011). Furthermore, gait features may differ depending on walking distance (Bautmans et al., 2011) and longer walking distance in clinical assessment may better reflect everyday walking (Howcroft et al., 2018). Nevertheless, sensor data of in-lab assessments might be biased because participants might be affected by the awareness of direct observation or cameras and therefore might not behave naturally (e. g. adjustment of gait) (Hua et al., 2018; Iluz et al., 2016; Mancini et al., 2016; Wang et al., 2017). Hence, daily-life data might better represent everyday functioning and fall-risk than data collected in an in-lab setting (Iluz et al., 2016; Mancini et al., 2016; Rispens et al., 2015).

With regard to sensor wearing time, some studies comprised data collection from three up to eight consecutive days. A full week of recording sensor data may cover the range of motor performance of older adults better than a time span of only three days (Aner Weiss et al., 2013), however, drop-out rate may be higher and feasibility may worsen with increasing wearing time. In addition, it may be important to not only take into account sensor data from gait but also from different activities, like sit-to-stand transitions (van Schooten et al., 2015).

When assessing sensor data during daily-life, various environmental conditions cannot be controlled. Moreover, movement behaviour in daily-life does not follow a protocol, so the amount of sensor data might differ significantly between study participants (Iluz et al., 2016). In contrast, in a supervised setting (e. g. nursing homes or hospitals), all participants are assessed in the same facility and environmental conditions are standardized and comparable (Buckinx et al., 2015).

The placement of the sensors differed within the included studies. The most-often used sensor location was the lower back for which a high user acceptance was reported in previous studies (Giansanti et al., 2009). However, Howcroft et al. (Howcroft et al., 2016) examined different sensor positions and concluded that sensors placed at the head or pelvis provided the best classification capability among single-sensor models. Only one study group used wrist-worn sensors for detection of sit-to-stand transitions, but the performance was comparable to

studies using waist-worn devices (Pozaic et al., 2016). An advantage of wrist-worn sensors might be the non-intrusiveness and the similarity to a wristwatch (Hassan et al., 2017).

Several parameters of motor performance identified through sensor data may provide valuable information about motor deficits that are associated with fall risk, as well as indications for further fall prevention programs. Interestingly, sensor-derived parameters that were associated with fall risk were not associated with clinical fall risk assessments (e.g. TUG). This may indicate that not all fall-related movements can be detected by conventional clinical assessments (Greene et al., 2012), thereby highlighting the importance of body-worn sensors. To overcome the potential limitations of clinical assessments, a combination of daily-life sensor data and outcomes of clinical assessments to improve fall prediction was recommended (Bizovska et al., 2018; Ihlen et al., 2018).

Although individuals with CI represent the group with the highest risk of falling in older adults, they are often excluded from studies examining sensor-based methods to assess fall risk. Therefore, the secondary aim of this systematic review was to provide practical recommendations for using sensors in fall risk assessment in individuals with CI. Since recording of data during daily-life provides slightly better results, this may be one approach to consider for individuals with CI. The daily-life recording in the included studies ranged from three to eight days and was considered feasible regardless of the cognitive status of included participants. Previous studies with individuals with CI and dementia also reported good feasibility of sensor-based data collection of up to three days (Abel et al., 2019; Fleiner et al., 2016; Schwenk et al., 2014). Recording of daily-life data should thus be preferred to in-lab data collection as individuals with CI are more likely to be affected from test instructions or external distraction (Fernandez-Duque & Black, 2008). However, individuals with CI may be less active during the day which may hamper collection of high-quality data (Hartman et al., 2018).

Furthermore, it must be noted that both the location and the method of attachment of sensors appear to be of high importance when collecting sensor-based data on individuals with CI. The application of more than one sensor may provide more detailed information but is less practicable in this target group (Rivolta et al., 2019). In addition, particularly in individuals with CI, researchers or instructed nursing staff need to be present to assume or supervise the placement and correct wearing position of the sensor (Gietzelt et al., 2014; Marschollek et al., 2009). From a practical point of view, the location of the sensor should be carefully chosen, and clinicians and researchers may want to ensure that participants are not disturbed by the device

(Hassan et al., 2017; Shany et al., 2012). Moreover, researchers and/ or clinicians may need to consider technical aspects such as battery life span, data transmission or storage capacity when selecting an appropriate sensor for research or clinical practice (Rivolta et al., 2019).

Furthermore, some studies concluded, that additional information concerning other fall-risk related factors (e. g. age) might improve fall prognosis (Gietzelt et al., 2014), and more studies are needed to examine the interplay between cognitive functioning and motor performance for fall risk assessment (Mancini et al., 2016).

STRENGTH AND LIMITATIONS

To the best of our knowledge, this review was the first to particularly focus on, and to also provide practical implications for using body-worn sensors in fall risk assessment in individuals with CI. However, several limitations must be noted. For example, we included studies with different study designs, which may limit the comparability of findings between studies. Furthermore, regarding our secondary aim, we only identified one study particularly focusing on individuals with CI. Therefore, we also considered studies not explicitly excluding individuals with CI for our practical recommendations. Nevertheless, this limits our ability to make assumptions about the use and practicability of wearable sensors in persons with CI. More research is needed to address this important topic, particularly as individuals with CI exhibit more gait abnormalities such as asymmetry as compared to persons without CI. In addition, besides motor performance, cognitive abilities as well as other factors such as medication intake, mental health, or support from caregivers also play a significant role when assessing risk of falling (W. Zhang et al., 2019). However, this review solely focused on sensor-based characteristics of motor performance. Of note, wearable sensors are also widely used in fall detection which we did not address with our systematic review. Combining wearable sensors for both fall risk assessment as well as fall detection may thus be an effective prevention strategy in clinical settings.

4.1.6 CONCLUSION

In conclusion, wearable sensors appear to be feasible tools to assess fall risk in older adults regardless of CI, in both an in-lab setting and during daily-life when measured for a period of up to eight days. Overall, sensor-derived data of daily-life were more useful in distinguishing between or predicting groups of faller status, indicating that the wide range of variables from daily-life data provides more valuable information about fall risk as compared to data collected in an in-lab setting. Similar results were observed when focusing on older adults with

CI. Nonetheless, there exists a considerable lack of studies particularly examining sensor-based fall risk assessment in individuals with CI. Future research is needed to further specify which sensor-derived parameters of motor performance measured in daily life are most accurate and reliable predictors of fall risk. Furthermore, more research should focus on use of wearable sensors for fall risk assessment in older adults with CI to improve exercise programs for fall prevention.

REFERENCES

All references of Manuscript II are included in the List of References at the end of this thesis.

List of abbreviations: CI: Cognitive impairment; NOS: Newcastle-Ottawa Scale; PRISMA: Preferred Reporting Item for Systematic review and Meta-Analysis; SPPB: Short Physical Performance Battery; TUG: Timed-Up and Go Test

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DECLARATIONS

Ethics approval and consent to participate: Not applicable.

Consent for publication: Not applicable.

Competing interests: The authors declare that they have no competing interests.

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SUPPLEMENTARY MATERIAL

Additional File 1

Search strategy

Details of the search strategy used are provided below.

PubMed

((fall risk[Title/Abstract] OR fall risk factor*[Title/Abstract])) AND (sensor*[Title/Abstract] OR objectively measured[Title/Abstract] OR objective measurement[Title/Abstract] OR acceleromet*[Title/Abstract])

Scopus

(TITLE-ABS-KEY (fall AND risk OR fall AND risk AND factor*) AND TITLE-ABS-KEY (sensor* OR objectively AND measured OR objective AND measurement OR acceleromet*))

Web of Science

(fall risk OR fall risk factor*) AND TITLE: (sensor* OR objectively measured OR objective measurement OR acceleromet*)

5 MANUSCRIPT 3: USABILITY OF THE INCOPE-APP AIMING AT INDIVIDUAL PHYSICAL ACTIVITY FOR PERSONS WITH DEMENTIA IN NURSING HOMES

Slightly modified version of the published paper.

Published in: JMIR Aging

Published on: August 22th, 2023

Reference:

Krafft, J., Barisch-Fritz, B., Krell-Roesch, J, Trautwein, S., Scharpf, A., & Woll, A. (2023). A Tablet-based App to Support Nursing Home Staff in Delivering an Individualized Cognitive and Physical Exercise Program for Individuals with Dementia (InCoPE-App): A Mixed-methods Usability Study. *JMIR Aging*, 6, e46480.
<https://doi.org/10.2196/46480>.

A Tablet-based App to Support Nursing Home Staff in Delivering an Individualized Cognitive and Physical Exercise Program for Individuals with Dementia (InCoPE-App): A Mixed-methods Usability Study.

5.1.1 ABSTRACT

Background: The promotion of physical activity in individuals with dementia living in nursing homes is crucial for preserving physical and cognitive functions and the associated quality of life. Nevertheless, the implementation of physical activity programs in this setting is challenging, as the time and expertise of nursing home staff are limited. This situation was further exacerbated by the COVID-19 pandemic. Mobile health apps may be a sustainable approach to overcome these challenges in the long term. Therefore, the Individualized Cognitive and Physical Exercise-App (the InCoPE-App) was developed to support nursing home staff in delivering and implementing tailored cognitive and physical exercise training for individuals with dementia.

Objective: This study aims to assess the usability of the InCoPE-App in terms of user performance and user perception in a laboratory setting using a mixed methods approach.

Methods: Nursing home staff were encouraged to perform 5 basic tasks within the InCoPE-App. Their thoughts while using the app were captured by implementing a think aloud protocol. Then, participants completed the System Usability Scale questionnaire. The think aloud transcripts were qualitatively evaluated to unveil usability issues. All identified issues were rated in terms of their necessity to be fixed. Task completion (ie, success rate and time) and perceived usability were evaluated descriptively.

Results: A total of 14 nursing home employees (mean age 53.7, SD 10.6 years; n=13, 93% women) participated in the study. The perceived usability of the InCoPE-App, as assessed by the System Usability Scale questionnaire, can be rated as “good.” The main usability issues concerned navigation logic and comprehensibility of app content.

Conclusions: The InCoPE-App is a user-friendly app that enables nursing home staff to deliver and implement cognitive and physical exercise training for individuals with dementia in nursing homes. The InCoPE-App can be used with little training, even by people aged ≥ 50 years, who may have low digital literacy. To achieve sustainable use and high user satisfaction of the InCoPE-App in the long term, it should be implemented and evaluated in a field study.

Keywords: dementia; individualized physical exercise; mobile health; usability

5.1.2 BACKGROUND

More than 55 million people worldwide have dementia, with approximately 10 million new cases every year (World Health Organization, 2023). By 2050, the number of individuals with dementia is expected to increase to up to 150 million individuals worldwide (Patterson, 2018; Pickett et al., 2018). As dementia is a noncurable disease, treatment possibilities to stop or slow the progression of disease-specific symptoms (eg, declining cognitive function and physical performance) are critical. In addition to pharmacological therapies, nonpharmacological approaches such as physical activity (PA) have gained increasing attention. A growing body of research has shown that PA may have a beneficial impact on cognitive and physical performance in individuals with dementia (Forbes et al., 2015). However, only small and mainly nonsignificant effects of PA on quality of life (QoL) among individuals with dementia have been reported (Lam et al., 2018; Ojagbemi & Akin-Ojagbemi, 2019). Overall, results from studies are conflicting, mainly owing to heterogeneous sample sizes and characteristics and differing intervention contents, periods, frequency, and duration of PA training (Forbes et al., 2015). Some studies also pointed out the heterogeneous prerequisites of individuals with dementia such as varying interindividual degrees of cognitive and motor impairments. Thus, a one-size-fits-all PA approach may fall short (Müllers et al., 2019). In addition, individual vulnerabilities and needs of individuals with dementia may need to be considered when designing, planning, and conducting PA interventions (Barisch-Fritz et al., 2021; Bezold, Trautwein, et al., 2021; Trautwein et al., 2020).

According to several studies (Auer et al., 2018; Hoffmann et al., 2014; Kowalska et al., 2013; Schäufele et al., 2013) and a systematic review (Seitz et al., 2010), up to 80% of individuals living in nursing homes in European countries experience dementia. Individuals with dementia residing in nursing homes often have decreased life expectancy (Brent, 2022), more advanced dementia stages, and more impaired physical performance compared with community-dwelling individuals with dementia (Król-Zielińska et al., 2011). Moreover, living in a nursing home is associated with negative changes in QoL (Olsen et al., 2016). Overall, promoting PA in nursing home settings is therefore crucial. In many nursing homes, PA promotion is not regarded as a task or responsibility of nursing home staff and is usually delegated to external providers (eg, physiotherapists) (Frahsa et al., 2020). During the COVID-19 pandemic, this practice was no longer feasible, as many nursing homes in Germany and other European

countries were closed to visitors or external service providers, and PA programs had been discontinued in many nursing homes owing to increased safety measures (Frahsa et al., 2020). The resulting social isolation and restricted movement possibilities led to worsening of cognitive function and physical performance among individuals with dementia, as perceived by nursing home staff (Geissler et al., 2021). Moreover, some studies reported significant impact on the mental well-being of nursing home residents (eg, QoL) (Kaelen et al., 2021). A conclusion that can be drawn from the COVID-19 pandemic with its far-reaching health consequences is that PA promotion in nursing homes should be designed and implemented in a way that allows continuation even as new challenges arise (eg, changing circumstances owing to the pandemic or similar events) and without access to external PA instructors. Therefore, mobile health (mHealth) apps may be a viable solution in this context. Various definitions of the term mHealth exist and most include key aspects such as mobile computing, medical sensor, and communications technologies (Istepanian et al., 2004), health information and services (Nacinovich, 2011), patient monitoring devices, and personal digital assistants (World Health Organization, 2011) to improve health outcomes. mHealth can be considered as a subsection of eHealth (Nacinovich, 2011). mHealth solutions are considered to be feasible, can be implemented at little or no cost (Bhattacharya et al., 2018), and have wide reach among various patient groups or populations.

So far, a large number of mHealth apps for use in care settings are available, with most of them providing support for medication management or health information, and they can be accessed free of charge from app stores (Barisch-Fritz et al., 2020). However, to the best of our knowledge, no mHealth app for individualized PA promotion in nursing homes is available so far (Diener et al., 2022). mHealth apps are promising tools in this setting and may help alleviate nursing home staff shortages; for example, a standardized, mHealth-based training manual may facilitate the instructions of PA sessions. Moreover, such an app may contain pictures and detailed exercise descriptions and information about the possible risk factors of certain exercises. These advantages may reduce the potential barriers for nursing home employees to deliver PA programs to individuals with dementia and enable the implementation of PA even in times of a pandemic. Nevertheless, a recent Cochrane review showed that health care workers with limited experience in using mobile apps and low digital literacy had concerns about making mistakes when using a mobile device (Odendaal et al., 2020), which might, in turn, affect the usability and acceptability of such apps.

However, to guarantee the long-term use and acceptability of mHealth apps in nursing homes, the feasibility and usability of an app must be considered, ideally in the design and development phase of the app (Shackel, 2009). Usability indicates how a product is perceived by an intended user to achieve a specific goal in a specific context of use (Thirumalai et al., 2018). Nevertheless, most of the currently existing mHealth apps have not been scientifically designed and empirically evaluated (Maramba et al., 2019; Nouri et al., 2018), and publications addressing their feasibility and usability are lacking (Guo et al., 2020). This is a main research gap, particularly because theory-based design and development of apps with subsequent scientific evaluation of usability and acceptability may be among the most important criteria to ensure the long-term implementation of mHealth apps, particularly in special settings such as nursing homes (Zapata et al., 2015). Moreover, studies have shown that involving nursing home staff in the development process of a mobile app makes them feel valuable and appreciated, which, in turn, could have a positive impact on acceptance (Tsertsidis, 2021). Therefore, an iterative development process of an app including qualitative and quantitative methods to integrate possible end users in the development process is recommended (Cho et al., 2018), where designing, testing, and redesigning of a mobile app are embedded in a regular circle (Shackel, 2009). Examples for qualitatively collected data could be the identification of specific problems. In contrast, quantitative data may provide insight into use times or success rates (Guo et al., 2020). A multistep development approach is intended to increase end users' acceptability of an mHealth app and to ensure long-term use.

OBJECTIVE

To address the current need for a scientifically derived mHealth-based PA promotion for individuals with dementia in nursing homes, we developed the Individualized Cognitive and Physical Exercise-App (the InCoPE-App). The InCoPE-App is a tablet-based app aimed at assisting nursing home staff in delivering tailored cognitive and physical exercise training for individuals with dementia in a nursing home setting. The content of the InCoPE-App is based on previous studies of our research group on PA for individuals with dementia (Barisch-Fritz et al., 2021; Bezold, Trautwein, et al., 2021; Trautwein et al., 2020). The goal of this study was to evaluate the usability of the InCoPE-App with possible end users, that is, nursing home staff, using a mixed methods approach in a laboratory setting. Specifically, we examined user performance and perception, existing problems, and possible solutions regarding the InCoPE-App by integrating qualitative and quantitative methods. The results of this study will be used for further improvement and adaption of the InCoPE-App with the ultimate goal of implementation

and long-term use of the app in nursing homes. Furthermore, this procedure can be used as an example for future studies of app development in nursing home settings.

If and when the InCoPE-App has high usability, we anticipate that its use by nursing home staff will likely increase PA among individuals with dementia residing in nursing homes, as the app is designed such that it empowers nursing home staff to administer tailored physical exercise training to individuals with dementia in an easy and low-threshold way. Importantly, the InCoPE-App can be used by staff without previous PA-specific training or expertise.

5.1.3 METHODS

STUDY DESIGN AND PARTICIPANTS

To evaluate the usability of the InCoPE-App, we used a mixed methods approach. We used a combination of qualitative and quantitative methods and considered a sample of 14 individuals, as previous studies have shown that 8 participants are sufficient to identify the main usability problems of a system (Jaspers, 2009). Participants were recruited in April 2021 from 5 nursing homes in South-Western Germany. To be included in the study, participants (ie, nursing home staff) were required to have had previous experience with PA programs for individuals with dementia in the nursing home setting. Before the study, eligible participants received a project description regarding the objectives, participation, and benefits of the study and provided written consent for participation. The study was registered in the German National Register of Clinical Trials (DRKS00024069).

ETHICS APPROVAL

The study was approved by the Ethics Committee of the Karlsruhe Institute of Technology (Karlsruhe, Germany).

THE INCOPE-APP – CONTENT AND DEVELOPMENT

The InCoPE-App was designed to be used by nursing home staff and not by individuals with dementia themselves, as individuals with dementia in nursing homes would not be able to perform structured physical exercise alone, and they need supervision for safety reasons. Specifically, the InCoPE-App supports nursing home staff in assessing current levels of cognitive and physical performance of individuals with dementia and, based on this assessment, guiding and delivering physical exercise sessions to individuals with dementia, without the need of having completed specific training or certification in sports or exercise science or kinesiology. A unique feature of the InCoPE-App is its integrated algorithm that uses data from 1 cognitive (ie, Mini Mental Status Examination (Folstein et al., 1975)) and 3 physical performance tests

(ie, Frailty and Injuries: Cooperative Studies of Intervention Techniques (Rossiter-Fornoff et al., 1995), 6-meter walk test (Graham et al., 2008), and modified 30-second chair stand test (Blankevoort et al., 2013; Jones et al., 1999)) to tailor the recommended exercise program to the participant's individual needs (Figure 5.1). The cognitive and physical tests integrated into the InCoPE-App are oriented to recommendations for individuals with dementia (Bossers et al., 2012; Trautwein, Barisch-Fritz, et al., 2019). On the basis of the individual performance results, each individual with dementia is assigned to one of four exercise clusters, which are integrated in the app (Barisch-Fritz, Bezold, Scharpf, et al., 2022b): (1) individuals with below-average cognitive and physical performance, (2) individuals with average cognitive performance and above average physical performance, (3) individuals with above average cognitive performance and below average physical performance, and (4) individuals with above average cognitive and physical performance. The clustering into these 4 groups is based on previous studies by our group that have demonstrated the need for individualization of PA programs for individuals with dementia (Barisch-Fritz et al., 2019; Barisch-Fritz et al., 2021; Bezold, Trautwein, et al., 2021; Trautwein et al., 2020). Depending on the cluster assignment, the InCoPE-App generates an exercise plan that fits the current performance level and needs of the individual with dementia. To adjust the exercise plan to individual changes in cognitive and physical performance, the InCoPE-App reminds the nursing home staff to repeat and record cognitive and physical performance tests every 3 weeks. In general, the exercise plan integrated into the InCoPE-App consists of ritualized warm-up and cooldown and 2 individualized workout phases that integrate exercises for balance, mobility, and upper and lower body strength (Barisch-Fritz et al., 2019).

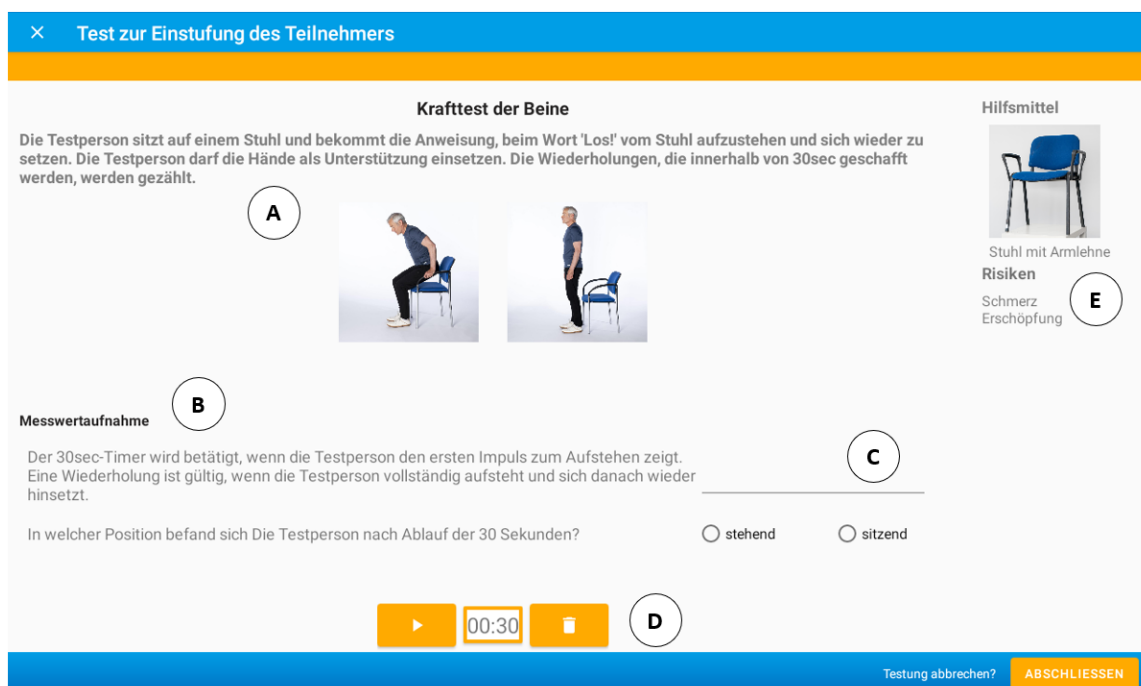


Figure 5.1: Chair-stand Test. ^A Written and illustrated description of the test procedure. ^B Description of measurement recording. ^C Input field for measured value. ^D Integrated stop watch. ^E Required tools/equipment and possible risks.

The generated exercise plan is presented in the app through brief descriptions along with pictures of the exercises to provide guidance about how to perform the exercises correctly and avoid common mistakes (Figure 5.2). Each training session lasts 60 minutes and is intended to be performed in one-on-one sessions or small groups of up to 2 individuals with dementia. For more information about the main functions of the InCoPE-App, refer to Multimedia Appendix 1.

The iterative development process of the InCoPE-App included several steps (Figure 5.3), of which 3 are already completed. First, we defined a general product vision of the InCoPE-App. We then conducted a web-based survey to collect information about sex, age, profession, and daily tasks from nursing home staff. Furthermore, we gathered information about potential previous implementations of PA programs or interventions in participants' nursing homes. On the basis of the results of this study, we were able to sketch personas as possible end users of the InCoPE-App (Barisch-Fritz et al., 2020). In the second step, based on our product vision and the design of personas, we developed the first prototype of the InCoPE-App 1.0 in collaboration with a software expert team. The InCoPE-App was developed on Android 9.0. For study purposes, an offline-capable version of the InCoPE-App was locally installed on

Manuscript 3: Usability of the InCoPE-App aiming at individual physical activity for persons with dementia in nursing homes

tablets (Lenovo Tab M10; 10 inch). Currently, the app is available only in German. The usability of the InCoPE-App 1.0 was tested by 7 experts in the areas of psychology, IT, sports science, and software development using a think aloud protocol and the System Usability Scale (SUS) (Barisch-Fritz, Bezold, Barisch, et al., 2022). The expert review unveiled relevant information about the usability of the InCoPE-App. The experts rated the InCoPE-App as acceptable but also noted some usability problems.

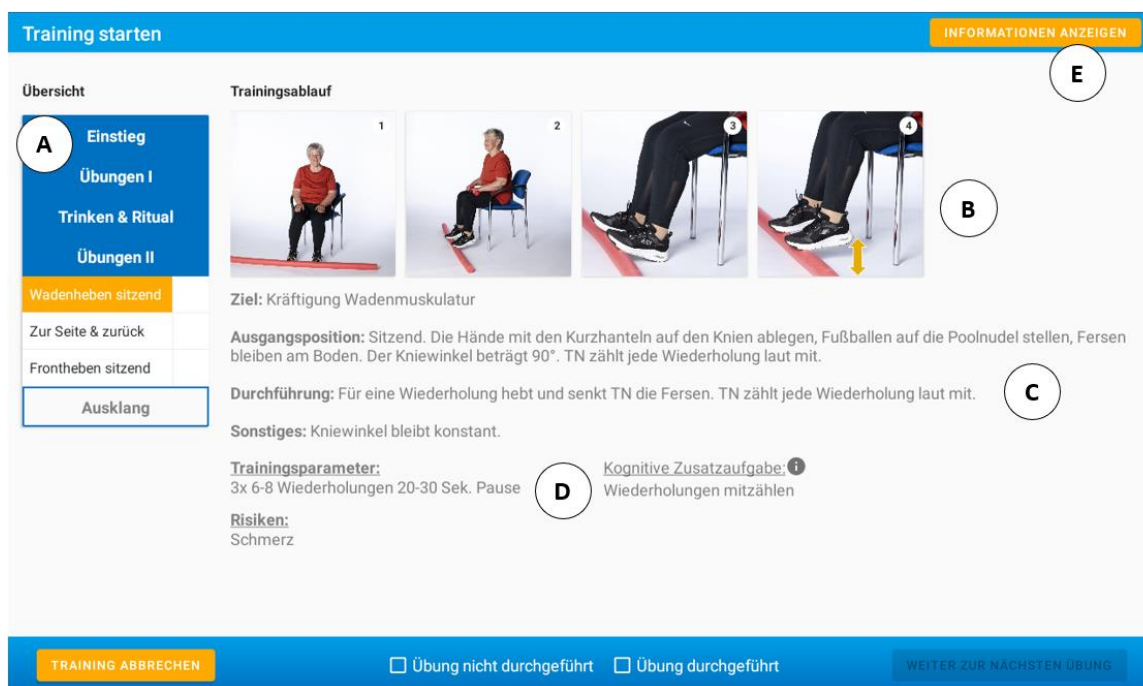


Figure 5.2: Exercise for lower limb strength. ^A Overview of training schedule. ^B Exercise sequence in pictures. ^C Description of aims and correct conduct of the exercise. ^D Training parameters (e.g., repetitions), possible risks (e.g., pain), and cognitive input (e.g., counting the repetitions). ^E Further information (e.g., required equipment).

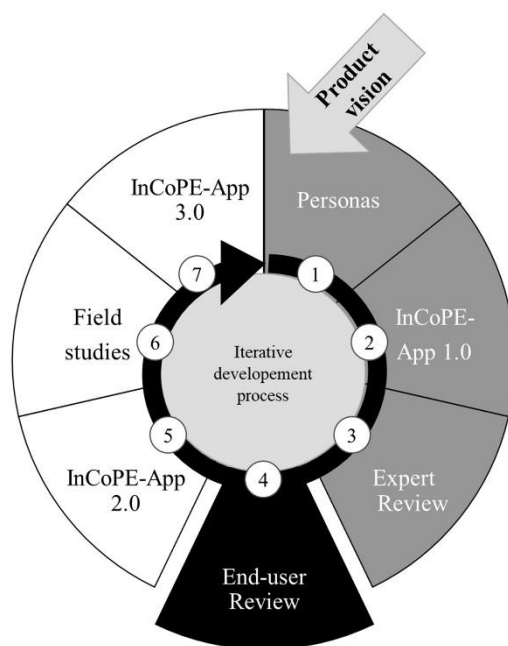


Figure 5.3: Iterative development process of the InCoPE-App (Step 1: Results are published in (Barisch-Fritz et al., 2020); Step 3: Results are published in (Barisch-Fritz, Bezold, Barisch, et al., 2022)).

OUTCOMES AND PROCEDURES

After the participants signed the consent form, demographic information and data about general smartphone, tablet, and app use were collected from each participant using a short survey. Usability was assessed qualitatively and quantitatively in individual sessions during the first use of the InCoPE-App. To collect qualitative usability data, the think aloud technique was applied as it was found to be the most frequently used qualitative approach in usability testing of eHealth applications (Maramba et al., 2019). At the beginning, we explained to the participants that they would be required to speak their running thoughts aloud while interacting with the InCoPE-App. To become familiarized with this method, participants received a sample task within the InCoPE-App (ie, “Go to ‘exercise pool,’ choose exercise ‘Rope Pulling’ and tell me possible risks of this exercise”). Then, they were asked to perform 5 tasks (Table 5.1) with the InCoPE-App along a standardized protocol. These tasks were representative of a real-world situation when using the InCoPE-App in the nursing home setting (Jaspers, 2009). During the think aloud session, a researcher was present and only interrupted participants if they stopped talking for >10 seconds while performing the tasks. Running thoughts of the participants were recorded via a voice recorder. Following the think aloud session, participants were asked three final questions: (1) “Which parts of the InCoPE-App are well designed?” (2) “Which parts of

the InCoPE-App need to be revised?” and (3) “Do you have any other further comments on the InCoPE-App?”

Table 5.1: Standardized “Think Aloud” protocol

Task	Description of the task
1	“Create a new test person.”
2	“Start and complete cognitive and physical testing with the test person”.
3	“Create an exercise plan and replace two exercises.”
4	“Start and finish a training session with the test person”.
5	“Start and finish a training session with two participants simultaneously.”

For quantitative usability assessment, the time spent on each individual task and all tasks overall was assessed by using the screen recorder function of the tablet. Furthermore, the success rate of each task was coded as “success,” “problem,” or “failure,” as described by Ehrler et al., 2018. After the think aloud protocol, participants completed the German version of SUS (Brooke, 1996; Gao et al., 2020), which is one of the most frequently used questionnaires in usability research (Maramba et al., 2019). The German version of SUS has reasonable reliability (0.84), concurrent validity (0.74), and sensitivity (0.83) (Gao et al., 2020). SUS comprises 10 statements about the usability of a system (eg, “I think that I would like to use this system frequently”), each rated on a scale ranging from “I don’t agree” to “I totally agree.” Negatively worded statements (even numbers) are coded from 4 to 0, whereas positively worded (odd numbers) statements are coded from 0 to 4 (Lewis, 2018). The items are added to a sum score (minimum 0; maximum 40 points), which is multiplied by 2.5 (sum score—minimum 0; maximum 100 points). Published literature suggests a mean SUS score of 68 as a useful “benchmark” (Sauro & Lewis, 2016). Furthermore, the total SUS score can be interpreted as follows: scores <60 indicate substantial usability problems, scores between 60 and 80 indicate marginal to good usability, and scores >80 indicate good to excellent usability of a system (Brooke, 1996). According to the Subjective Rating Scale of Bangor et al., 2009, a mean SUS score of 71.4 indicates good usability.

DATA COLLECTION AND ANALYSIS

Each think aloud session and the 3 interview questions were recorded with a voice recorder (Philips DVT2050) and transcribed verbatim using a transcription software (software F4transkript, from audiotranskription, dr.dresing&pehl GmbH). The transcribed protocols contained time stamps to estimate the time for task completion. To identify usability problems,

bottom-down developed categories (ie, navigation, screen layout, graphics, comprehensibility, and overall usability) were used to analyze the protocols divided according to the think aloud tasks. This categorization was adjusted and based on a proposal by Kushniruk & Patel, 2004. Two researchers (JK and ST) coded the transcripts independently. In case of ambiguities and discrepancies, a third researcher (BBF) was consulted. The identified usability problems were further rated by 1 researcher (JK) using the Nielsen severity scale (0=I do not agree that this is a usability problem at all, 1=cosmetic problem only, 2=minor usability problem, 3=major usability problem, and 4=usability catastrophe) (Nielsen, 2010). This allows ranking of the usability problems and helps to prioritize them for a further revision cycle of the InCoPE-App. For presentation in this paper, the quotations from the final interviews were translated from German to English.

The total SUS score, time spent on each task and in total (derived from the screen records), and frequencies of identified usability problems were evaluated descriptively (mean, SD, and range) using SPSS (version 27.0; IBM Statistics). The success rate for each task was evaluated in percentages.

5.1.4 RESULTS

PARTICIPANTS

We included 14 employees (n=13, 93% women and n=1, 7% men) from 5 nursing homes. The mean age was 53.7 (SD 10.6) years. Data about general smartphone and tablet use showed that all participants (14/14, 100%) owned a smartphone, with 93% (13/14) of the participants reporting daily use. Only 21% (3/14) of the participants reported using a tablet. Of the 14 participants, 12 (86%) had several apps installed on their personal smartphones or tablets and 7 (50%) reported daily app use. For study purposes, all participants (14/14, 100%) used the InCoPE-App installed on a tablet. Participants' demographics and information about technical experience are presented in Table 5.2.

Table 5.2: Sample characteristics (n= 14)

Characteristics	Values
Age (years), mean (SD)	53.7 (10.6)
Sex, n (%)	
Female	13 (93)
Male	1 (7)
Age group (years), n (%)	
20-29	1 (7)
30-39	1 (7)
40-49	1 (7)
50-59	6 (43)
>60	5 (36)
Certificate of secondary education, n (%)	
Hauptschule (diploma after 5 y)	5 (36)
Realschule (diploma after 6 y)	2 (14)
High school diploma (diploma after 8-9 y; university entrance qualification)	5 (36)
University degree	2 (14)
Use of mobile devices, n (%)	
Smartphone	14 (100)
Tablet	3 (21)
Frequency of smartphone use, n (%)	
Daily	13 (93)
Several times/wk	1 (7)
Several times/mo	— ^a
Rarely	—
Never	—
Frequency of tablet use, n (%)	
Daily	1 (7)
Several times/wk	2 (14)
Several times/mo	1 (7)
Rarely	—
Never	10 (71)
Use of apps, n (%)	12 (86)
Frequency of mobile app use, n (%)	
Daily	7 (50)
Several times/wk	3 (21)
Several times/mo	—
Rarely	2 (14)
Never	—

^aNot applicable.

SUS SCORES

The mean SUS score was 72.3 (SD 18.9; range 45-95), indicating good to marginal usability. According to the Adjective Rating Scale by Bangor et al., 2009, usability can be rated as *good*. When dividing the sample into 3 age groups (ie, nursing home staff aged <50 years: 4/14, 29%; aged between 50 and 60 years: 5/14, 36%; and aged >60 years: 5/14, 36%), the mean SUS scores were 77.5 (SD 16.2), 78 (SD 17.1), and 60 (SD 22.1), respectively, indicating better usability in participants aged <60 years. The results for single items of the SUS are presented in Table 5.3.

Table 5.3: Single items of the System Usability Scale

Item	Statement	Score of the total group (N=14), mean (SD) ^a	Score of participants aged ≤50 years (n=4), mean (SD) ^b	Score of participants aged 51-59 years (n=5), mean (SD) ^c	Score of participants aged ≥60 years (n=5), mean (SD) ^d
1	“I think that I would like to use this system frequently.”	3.2 (1)	3.5 (0.6)	3.6 (0.9)	2.6 (1.1)
2	“I found the system unnecessarily complex.”	2.9 (1.2)	3.3 (1)	2.6 (1.7)	2.8 (1.1)
3	“I thought the system was easy to use.”	2.8 (0.7)	3 (0.8)	3 (0.7)	2.4 (0.5)
4	“I think that I would need the support of a technical person to be able to use this system.”	2.7 (1.4)	3.8 (0.5)	2.6 (1.3)	2 (1.6)
5	“I found the various functions in this system were well integrated.”	3.1 (0.8)	3 (0.8)	3.4 (0.5)	2.8 (1.1)
6	“I thought there was too much inconsistency in this system.”	3.2 (0.7)	3.3 (0.5)	3.4 (0.9)	3 (0.8)
7	“I would imagine that most people would learn to use this system very quickly.”	3.2 (0.8)	3.3 (1)	3.6 (0.5)	2.8 (0.8)
8	“I found the system very cumbersome to use.”	2.9 (1.1)	2.5 (1.3)	3.0 (1.2)	3.0 (1)
9	“I felt very confident using the system.”	2.4 (1)	2.8 (0.5)	2.8 (0.8)	1.6 (1.1)
10	“I needed to learn a lot of things before I could get going with this system.”	2.9 (1)	2.8 (1.3)	3.2 (0.8)	2.6 (1.1)

^aTotal mean 72.3 (SD 18.9).

^bTotal mean 77.5 (SD 16.2).

^cTotal mean 78 (SD 17.1).

^dTotal mean 60 (SD 22.1).

THINK ALOUD SESSION AND FINAL INTERVIEWS

The mean duration of the think aloud sessions in total was 45 minutes and 56 seconds (SD 5 min and 42 s; range 33 min and 34 s to 53 min and 7 s), including the instructions and the familiarization task at the beginning. The most time-consuming part was cognitive and physical testing (mean 16 min and 26 s, SD 3 min and 44 s; Table 4). Creating a test person profile was completed by all participants without any problems. Most usability problems (n=71) arose with cognitive and physical testing. The last task (“Start and finish a training with two participants simultaneously”) could not be performed by any participant (Table 5.4).

Table 5.4: Task duration and task completion

Task	Duration, mean (SD)	Completion (N=14), n (%)		
		Success	Problem	Failure
“Create a new test person.”	3 min, 53 s (2 min, 4 s)	14 (100)	0 (0)	0 (0)
“Start and complete cognitive and physical testing with the test person.”	16 min, 26 s (3 min, 44 s)	3 (21)	10 (71)	1 (7)
“Create an exercise plan and replace two exercises.”	3 min, 54 s (1 min, 36 s)	3 (21)	4 (29)	7 (50)
“Start and finish a training session with the test person.”	5 min, 14 s (2 min, 19 s)	2 (14)	8 (57)	4 (29)
“Start and finish a training session with two participants simultaneously.”	— ^a	0 (0)	0 (0)	14 (100)

^aNot applicable.

On the basis of the think aloud protocols, 71 different usability problems could be identified that were mentioned 134 times in total. The categorization of the usability problems according to Kushniruk and Patel (2004) revealed most problems in the category, “navigation” (64/134, 47.8%), within the InCoPE-App. In particular, problems with finding the button to start a training for 2 participants simultaneously were mentioned by 79% (11/14) of the participants. The frequency of the mentioned problems and the most common examples are displayed in Table 5.5.

Table 5.5: Frequency (n= 134) and rating of mentioned usability problems identified via Think Aloud Protocol

Category	Mentioned frequency (N=134), n (%)	Most common problems and rating
Navigation	64 (47.8)	<ul style="list-style-type: none"> Finding the start button to initiate a training for 2 people—“Usability catastrophe” Changing or replacing exercises in an exercise plan—“Major usability problem” Noticing the stopwatch during assessment—“Usability catastrophe”
Screen layout	20 (14.9)	<ul style="list-style-type: none"> Small font type—“Major Usability Problem” Overloaded screens during exercising—“Major Usability Problem”
Graphics	6 (4.5)	<ul style="list-style-type: none"> No “zoom in” function—“Cosmetic problem only”
Comprehensibility	28 (20.9)	<ul style="list-style-type: none"> Uncertainty in cognitive test procedures—“Usability catastrophe” Unclear scientific terminology—“Major Usability Problem”
Overall usability	16 (11.9)	<ul style="list-style-type: none"> Drag-and-drop function is not intuitive—“Minor usability problem” Lot of information on most of the screens, owing to which app use was perceived as time consuming—“Minor usability problem”

Of the 71 identified usability concerns, 4 (6%) were rated as *usability catastrophe* according to Nielsen 48 and must be corrected before the InCoPE-App can be used in the field. Of the 71 problems, 29 (41%) were rated as a *major usability problem* with high priority to fix; 23 (32%) as *minor usability* with low priority to fix; and 8 (11%) as *cosmetic problems only*, which should only be fixed if there will be extra time for app development. Of the 71 problems, 7 (10%) mentioned usability concerns were rated as *not a usability problem at all*. Examples are displayed in Table 5.5.

During the final interviews, participants were able to explain which parts of the InCoPE-App were well designed. They explicitly mentioned that creating a test person within the InCoPE-App was very simple and easy to conduct:

I think, the beginning, when creating a participant profile – this was very good and clear.

Moreover, the participants highlighted the good interface and the clear user paths within the InCoPE-App:

I liked that it [the app] is well pictured.

What I totally like is that something is highlighted in orange, when I have to do [enter] something...and it is suggested to me.

The participants also liked the instructions on the training screens within the InCoPE-App:

So you're just being carried through the exercise plan, exercise by exercise. That is well designed.

[The exercise plan] is already divided into what counts as warm-up, the workout part itself, and the cool-down. I found that to be very clear.

Overall, the participants appreciated that using the app only needs little practice and is beginner-friendly:

I generally have very little idea about a tablet or a smartphone... For me it was plausible. It [the app] has also actually indicated to me what I have to do next.

You also tried to keep it as simple as possible.

In addition to the question about the parts of the InCoPE-App they liked the most, the participants were asked to name the parts that need to be revised in their opinion. Regarding this aspect, it was mentioned that exercise videos instead of pictures would be more user-friendly:

It [the training] would take too long with the participant. I would be lost in details. Videos and especially a voice explaining it [the exercises] to me briefly, that would be very helpful for me.

This statement was accompanied by comments about information overload on the screens within the InCoPE-App:

That is a lot of text. You lose a lot of time. By the time I read this, the participants no longer have any desire [to exercise].

I would have liked it better if the text had been shortened and presented in sections.

In contrast to the comments about the beginner-friendliness of the InCoPE-App, a person also mentioned barriers to the first use:

Well, if you don't use a tablet every day, you don't know where to push [a button]. For me as a person with limited media experience, it was hard.

Finally, when participants were asked for further comments about the InCoPE-App, they underlined that even though they had some problems with the app at first or with technologies in general, they liked the app:

At the beginning, I was really concerned. I thought that I have no idea about computer and tablets and so on. ...And I think, this is a great application, even I can handle that.

5.1.5 DISCUSSION

PRINCIPLE FINDINGS

Promoting physical and cognitive exercise for individuals with dementia in nursing homes is critically important, particularly in terms of the reduction of PA in this setting during the COVID-19 pandemic. Nevertheless, most interventions available today have limitations regarding long-term use and implementation. With the InCoPE-App, we aimed to develop an effective and easy-to-use app that requires a multistage development process considering feedback from future end users. In this study, we analyzed the usability of the InCoPE-App, which assists nursing home staff in delivering a tailored cognitive and physical exercise program for individuals with dementia in nursing homes.

Here, we applied a mixed methods approach to get an in-depth impression of how the InCoPE-App is perceived by potential end users. Our results show that the usability of the InCoPE-App can be rated as “good” (Bangor et al., 2009). Considering the results of the single items of SUS, the least agreement was given to the statement, “I felt very confident using the system.” In contrast, the highest agreement was given to the statements, “I would imagine that most people would learn to use this system very quickly” and “I think I would like to use this system frequently.” These results indicate that on the one hand, participants felt that they needed additional information or training with the InCoPE-App. However, in contrast, they assumed

that app use can be learned quickly. Overall, participants would like to use the InCoPE-App frequently and did not find the app to be unnecessarily complex.

On the basis of think aloud task completion, cognitive and physical testing required the most time. It can be assumed that this corresponds well with real-life situations, as conducting tests among individuals with dementia requires a rather large amount of time and personnel resources. We observed that, particularly, reading test instructions was time consuming. However, it is likely that time to read instructions within the InCoPE-App may decrease with more regular app use. The most difficult task (100% failure) was to start a simultaneous training of 2 individuals. This app feature needs to be revised with high priority and has to be placed more prominently within the app menu. Overall, we can assume that the InCoPE-App is a user-friendly tool and that most of the problems mentioned by participants could be solved by frequent app use.

COMPARISON WITH PREVIOUS STUDIES

Although mobile devices have become increasingly popular over the past decade (Odenaal et al., 2020), so far, there is no scientifically evaluated mHealth app available in the context of PA promotion in nursing homes (Diener et al., 2022). To the best of our knowledge, our study is the first to evaluate the usability of an mHealth-based app, developed to assist nursing home staff in implementing tailored cognitive and physical exercise for individuals with dementia in nursing homes. A unique feature of the InCoPE-App is that it is not used by the group considered vulnerable (ie, individuals with dementia) directly but by nursing home staff who serve as a mediator. To the best of our knowledge, there are no studies that have used this approach.

The methods used in our study are consistent with the current literature and recommendations for usability testing (Jaspers, 2009). Both applied methods exhibit important advantages in gathering a comprehensive impression of the usability of the InCoPE-App. So far, SUS is the most frequently applied questionnaire in the usability testing of digital health solutions (Maramba et al., 2019). Although there are usability scales specially tailored for mHealth solutions (eg, mHealth Usability Questionnaire (L. Zhou et al., 2019)), these newly developed scales have not been widely used, and only a few comparative studies exist (Hajesmaeel-Gohari et al., 2022). As the sole administration of SUS as a stand-alone usability method is not recommended (Broekhuis et al., 2019), using a think aloud protocol is a complementary approach that provides direct insight into a person's cognitive and problem-solving processes while using an app and

is therefore essential and effective for uncovering usability issues in addition to a quantitative questionnaire (Broekhuis et al., 2019; Jaspers, 2009). A recent systematic review showed that, even for the evaluation of usability among older participants, questionnaires and qualitative assessments such as think aloud protocols are commonly used and feasible methods (Q. Wang et al., 2022). Furthermore, other studies in the context of health care rehabilitation also used a mixed methods approach to assess usability (Ehrler et al., 2018; Rai et al., 2020; Reeder et al., 2019).

In our study, we obtained a mean SUS score that is slightly above the benchmark of 68 points according to Sauro and Lewis (Sauro & Lewis, 2016) and the mean SUS for “good” usability according to Bangor et al. (2009). A recent meta-analysis by Hyzy et al. (2022) explicitly focused on the SUS sum scores of 114 digital health apps and reported a mean score of 76.16 (SD 15.12) for all the included apps. By further categorizing the included apps, they observed a mean SUS score of 83.28 (SD 12.39) for “physical activity” apps (n=66) and a mean SUS score of 71.3 (SD 12.72) for “health care” apps (Hyzy et al., 2022). Owing to the unique content of the InCoPE-App, the content-related results of the think aloud protocols and task completion are not comparable with other studies. Nevertheless, a study by Ehrler et al. (2018), which examined a mobile app for nurses in a hospital setting, identified “navigation within an app” to be one of the major problems. This is consistent with our results, as 47.8% (64/134) of the problems mentioned by study participants were related to the navigation structure within the InCoPE-App. These results imply that mobile apps to be used by staff in health care settings should be intuitive to navigate because complex navigation is perceived as time consuming and may thus be a barrier for long-term use by the end users (Ahmad et al., 2022). Nevertheless, as the usability results of our study can be interpreted as “good,” we assume that the InCoPE-App is well designed and suitable for its primary target group, that is, nursing home staff.

The perceived usability of the InCoPE-App could also be related to the mean age and the experience with mobile apps in our sample, that is, participants aged <60 years had fewer problems with using the InCoPE-App when compared with those aged >60 years. This was also observed in another study, where older participants reported more usability problems than younger ones, who were also more likely to have used apps before study participation (Ehrler et al., 2018). Furthermore, existing literature has already demonstrated generational differences and a high likelihood of problems when implementing digital (health) solutions among older adults (Calvo-Porrall & Pesqueira-Sanchez, 2020; Guo et al., 2020). Thus, an age-based digital divide in mHealth adoption has been proposed in the literature (Fox & Connolly, 2018).

Moreover, individuals often experience a loss in digital literacy if and when they do not use digital devices on a regular basis (Odendaal et al., 2020). To overcome possible age-related and experience-related barriers to app use, current literature recommends education and familiarization training (Ehrler et al., 2018; Mayer et al., 2019). Moreover, as the fear of making mistakes could also be perceived as a barrier (Odendaal et al., 2020), “undo” functions should be included in an app (Ehrler et al., 2018).

STRENGTHS AND LIMITATIONS

The main strength of our study is the novelty of the presented the InCoPE-App and its user-centered development and testing process. This helps to gain new insights into a, thus far, little-explored research field. Although our participants were predominantly women and aged >50 years, they can be considered to be representative of the population of end users (ie, nursing home staff) who will use the system in the future. It is very crucial to include a representative target group to generate valid usability data and to avoid biases (Jaspers, 2009). In addition, our sample was heterogeneous in terms of age, education, and technical experience. This allowed us to detect usability problems from different perspectives and gave us a nuanced impression of the potential end users. Moreover, engaging individuals with less access to or knowledge about technology is very important to ensure high usability of a system for individuals with low digital literacy (Richardson et al., 2021). Another strength of the study is the mixed methods approach. Particularly in usability research, 1 method alone is not suitable to cover all the important aspects of a system’s usability. Combining SUS with the think aloud task and the interview questions therefore allowed us to gain deep insight into the usability problems, as opposed to only evaluating usability on the basis of a sum score.

A limitation of our study is the relatively late inclusion of the end users in the direct development process of the InCoPE-App. Although we created fictitious end users on the basis of a questionnaire in early development stages (Barisch-Fritz et al., 2020), the main content and the basic structure of the data model has been developed and finalized without the input of nursing home staff. In other studies, end users were included from the very beginning of the app development process (Rai et al., 2020). It is likely that some of the frequently mentioned usability problems (eg, navigation within the app) could have been avoided by the early inclusion of end users in the development process. Another limitation is that members of our research team ranked the usability problems according to the method of Nielsen (2010), and it is possible that the end users would have rated the severity of the problems differently. Thus, the revision of the app based on the prioritization done by the researchers may not fully correspond to the

expectations and wishes of the end users as they may have chosen another prioritization. Therefore, in future studies, end users should also be included in this step. Furthermore, it should be differentiated which usability problems should be further addressed from different perspectives (eg, experts, developers, researchers, and end users).

5.1.6 CONCLUSION

The InCoPE-App is a novel and innovative app that assists nursing home staff in delivering tailored cognitive and physical exercise to individuals with dementia residing in nursing homes. We showed that the usability of the current version of the InCoPE-App can be rated as good according to 14 potential end users. Furthermore, even older participants found the InCoPE-App as easy to use after some familiarization. Nevertheless, certain aspects such as navigation features within the app must be further improved to increase the usability of the app in the future. To overcome potential barriers to using the app, further development should follow a “less is more” approach, for example, by minimizing navigation screens or reducing the complexity and length of text on the screens. Overall, the inclusion of end users in the app’s development process continues to be critically relevant and highly important. Therefore, the InCoPE-App was further tested in an 18-week intervention study (Barisch-Fritz, Bezold, Scharpf, et al., 2022a).

REFERENCES

All references of Manuscript III are included in the List of References at the end of this thesis.

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Authors’ contribution: All authors (JK, BB-F, JK-R, AS, ST and AW) contributed to the study conception, design and implementation of the study. JK, BB-F, and AS collected the data. JK, ST, and BB-F analysed and interpreted the data. JK wrote the manuscript and all authors provided critical feedback. All authors approved the final version of the manuscript.

Conflicts of interest: None declared.

Abbreviations: InCoPE: Individualized Cognitive and Physical Exercise; IWD: Individuals with dementia; M: Mean; N: Number; PA: Physical activity; SD: Standard deviation; SUS: System Usability Scale

Multimedia Appendix: Main functions of the InCoPE-App.

SUPPLEMENTARY MATERIAL

Supplementary Table 5.1: Main functions of the InCoPE-App

Function	Description
(1) Main menu	The main menu allows the user to navigate between all app functions.
(2) Exercise pool	The exercise pool shows and describes each exercise integrated in the app and with various degrees of difficulty. This function also allows access to single exercises without starting an entire training program with an individual participant.
(3) Test pool	The test pool presents each cognitive or physical performance assessment integrated in the app. This function also allows access to single tests without starting the entire test battery.
(4) Participant overview	The required action/ next steps (i.e., test, training) is displayed for each participant.
(5) Participant's details	The personal information of a chosen participant is shown (e.g., age, height, type of dementia). Furthermore, serious events (e.g., illness) can be tracked.
(6) Performing test battery	This function allows to assess and record the current cognitive and physical performance of a participant. A test battery of cognitive and physical performance tests is integrated. Each test and its recorded measurements/data (e.g., required time, repetitions) are described. Furthermore, results can be entered directly. The results are used to automatically create an individualized exercise training plan for each participant.
(7) Training schedule preview	The training schedule preview allows the user to take a look at the exercise training plan before starting the training. Furthermore, the equipment needed for the exercises is listed.
(8) Training	This function leads a user through an entire training session with a participant. Each exercise is described in detail, including written descriptions, pictures, and common mistakes or possible risks. At the end of each training session, the training can be rated from 0 to five stars.

6 GENERAL DISCUSSION

This thesis expands on the existing body of literature regarding the effectiveness of PA interventions for IWD in nursing homes. Furthermore, it discussed the advantages and limitations of individualization and digitalization in this context. Within three manuscripts (I-III), six research questions (Q1-Q6) were answered, leading to the following main findings of this thesis (Text box 4, Text box 5, Text box 6).

Text box 4: Findings from Manuscript I

Finding 1: A multimodal, dementia-specific exercise program for individuals with dementia had no significant overall effects on activities of daily living. This may be due to the lack of an increase of exercise intensity during the intervention. (Bezold, Trautwein et al., 2021)

Finding 2: Responses to the multimodal, dementia-specific exercise program were dependent upon individual motor and cognitive performance at baseline. Positive-responders had worse baseline motor performance compared to non-responders. Up to 51.4% of the variance in activities of daily living could be explained by baseline cognitive and motor performance. (Bezold, Trautwein et al, 2021)

Text box 5: Findings from Manuscript II

Finding 3: Body-worn sensors can provide accurate fall risk classification based on motor performance data in older adults and regardless of their cognitive status, and outperformed data of clinical assessment. The accuracy varies depending on the type and attachment location of the sensor. Daily-life data collected over three to eight days may be a better indicator of fall risk than data collected in a lab setting. (Bezold, Krell-Roesch et al, 2021a)

Finding 4: There is a considerable lack of studies including individuals with cognitive impairment. Collecting data through daily life-recording may provide better results in this target group compared to in-lab data. Moreover, the location of the sensor(s) should be carefully chosen to ensure that participants are not disturbed by it. (Bezold, Krell-Roesch et al., 2021a)

Text box 6: Findings from Manuscript III

Finding 5: The usability of the InCoPE-App is rated as “good” by nursing home staff after first use. Nevertheless, they expressed the need for familiarization to be able to work properly with the InCoPE-App. Older participants had more problems using the InCoPE-App than younger ones. (Krafft et al., 2023)

Finding 6: Nearly half of the mentioned usability problems were related to the navigation structure of the InCoPE-App. The results show that there is a need for a “less is more” approach, i.e. including intuitive navigation by minimizing navigation screens and reducing the complexity and amount of information provided on screens. (Krafft et al., 2023)

In the following sections, the results generated as part of this thesis will be discussed in a larger context. First, the need for individualization of PA interventions for IWD will be described using the findings from *Manuscript I* and compared to previous and current literature on that topic (Chapter 5.1). Furthermore, the advantages and limitations of digital health solutions in dementia care with a focus on PA promotion will be summarized based on *Manuscript II* and *Manuscript III* (Chapter 5.2). This chapter will close with a summary of the overall strengths and limitations of this thesis (Chapter 5.3).

6.1 INDIVIDUALIZATION OF PHYSICAL ACTIVITY PROGRAMS FOR INDIVIDUALS WITH DEMENTIA

As *Manuscript I* demonstrated, an overall PA program for IWD was not effective for all participants in improving ADL performance. Time*group analyses showed no effects in favor of the intervention group (Bezold, Trautwein, et al., 2021). This was also found for physical performance outcomes (i.e., gait parameters, strength, balance, mobility) within the “Physical activity against dementia” trial (Barisch-Fritz et al., 2021; Trautwein et al., 2020), and in several studies that implemented physical activity in a group setting of IWD (L. Liu et al., 2022). Nevertheless, up to 32% of the participants were positive-responders and improved their ADL performance (Bezold, Trautwein, et al., 2021). Thus, reasons for (not) responding to the intervention need to be discussed and summarized, in order to provide directions for future studies on the design and conduct of effective physical activity interventions IWD.

The results of *Manuscript I* are not surprising in light of the fact, that causes, as well as symptoms of dementia are diverse, leading to a high heterogeneity in cognitive and physical functioning in IWD (Duara & Barker, 2022; S. Lee et al., 2021). Therefore, past studies aimed at identifying subgroups of IWD according to their cognitive function using factor or cluster analyses (Duara & Barker, 2022; Peter et al., 2014; Phillips et al., 2019). In comparison, heterogeneity of IWD in terms of physical function has not been studied in detail (Duara & Barker, 2022), but recent research indicates that subgroups of IWD can be also identified based on physical performance (Barisch-Fritz et al., 2020). These findings are crucial, as they allow to apply the approach of individualized medicine on non-pharmacological treatments, like PA. Nevertheless, these approaches, as well as their implication for the design of future PA interventions must be further elaborated and examined. One example is provided by a study of our research team (Barisch-Fritz et al., in press), where we described four different subgroups of IWD, based on a cluster-analysis in over 200 IWD. The subgroups are characterized by their physical and cognitive performance, and therefore, we provided a starting point for individualizing PA interventions for IWD. This is important, as usually, intensity of PA training in nursing homes is often determined based on the participant with the lowest physical performance in order to ensure safety of the residents (S. Portegijs et al., 2022). But for participants with higher physical performance level, in turn, no effective training stimulus may be provided when following this strategy. This was also shown within the results of *Manuscript I*, where mainly IWD with lower physical performance at baseline benefitted from the PA intervention, whereas IWD with higher performance level did not improve their ADL performance over the course of the intervention (Bezold, Trautwein, et al., 2021). Therefore, this thesis underlines the importance of individualized exercise programs for individuals with dementia (Barisch-Fritz et al., 2021; Cordes et al., 2021; Trautwein et al., 2020). This is also supported by other recent literature that suggests individualized dementia care in general (S. Lee et al., 2021), and particularly regarding PA promotion for IWD (Müllers et al., 2019). In cognitive therapy, the effectiveness of individualization has been already studied. For example, positive effects on global cognition in persons with cognitive impairment were found after a one-year, individualized cognitive stimulation therapy (Justo-Henriques et al., 2022). For IWD in a home care setting, Gebhard and Mess (2022) conducted a feasibility study with a PA program targeted to the individual's needs (i.e., physical capacity, biography). To this end, physical capacity was collected at baseline, but no strategy on how to further increase exercise intensity during the intervention was described. The authors reported that the intervention program is feasible to implement, and indicate preliminary effectiveness of the individualized PA program (Gebhard & Mess, 2022). Another

study also found that individually tailored adoptions of exercises for IWD seem to be an implementation facilitator in nursing homes (Hirt et al., 2021). Nevertheless, to date, individualization of care for IWD is not sufficiently included in daily routines in nursing homes (Barisch-Fritz, Bezold, Scharpf, et al., 2022b), which may result in not all IWD benefitting from the effects of PA. Moreover, to the best of this thesis author's knowledge, there are no further studies examining the effects of individualized PA interventions in IWD in nursing homes, except for the study of Gebhard and Mess (2022) in a home care setting.

If and when individualized PA interventions for IWD will be studied and implemented more frequently, some research gaps must be resolved. For example, there still seems to be an unresolved problem regarding a dose-response relationship of PA in IWD (Blankevoort et al., 2010; Borges-Machado et al., 2021; Cordes et al., 2021; Gebhard & Mess, 2022), and within studies that found effects of PA, it has not been clarified whether the improvement was due to type, amount, or intensity of exercise (W. Liu et al., 2022). This is mainly due to a low quality and high heterogeneity of studies, which limits comparability and definite conclusions (Begde et al., 2022). To further clarify dose-response relationships and to identify the critical aspects of designing effective physical activity interventions (Figure 6.1), recommendations are needed as to how exercise protocols should be documented in future studies (Andrade et al., 2022). Moreover, to date, there are only few studies reporting on the intensity of PA intervention (e.g., using the Borg Scale), or documenting the development of exercise intensity during the intervention properly (Cordes et al., 2021). In another study, pre-frail participants without dementia were able to gradually increase exercise intensity through 18 different levels according to their own estimation (Geraedts et al., 2021). The results of this study showed an improvement of physical performance and daily PA (Geraedts et al., 2021), which demonstrates that an increase of exercise intensity during a PA intervention can be useful. Furthermore, more research studies should report on adherence to exercise protocols in order to show, which IWD respond to which type of exercises. Addressing these aforementioned research gaps would significantly facilitate the design process of individualized PA interventions for IWD.

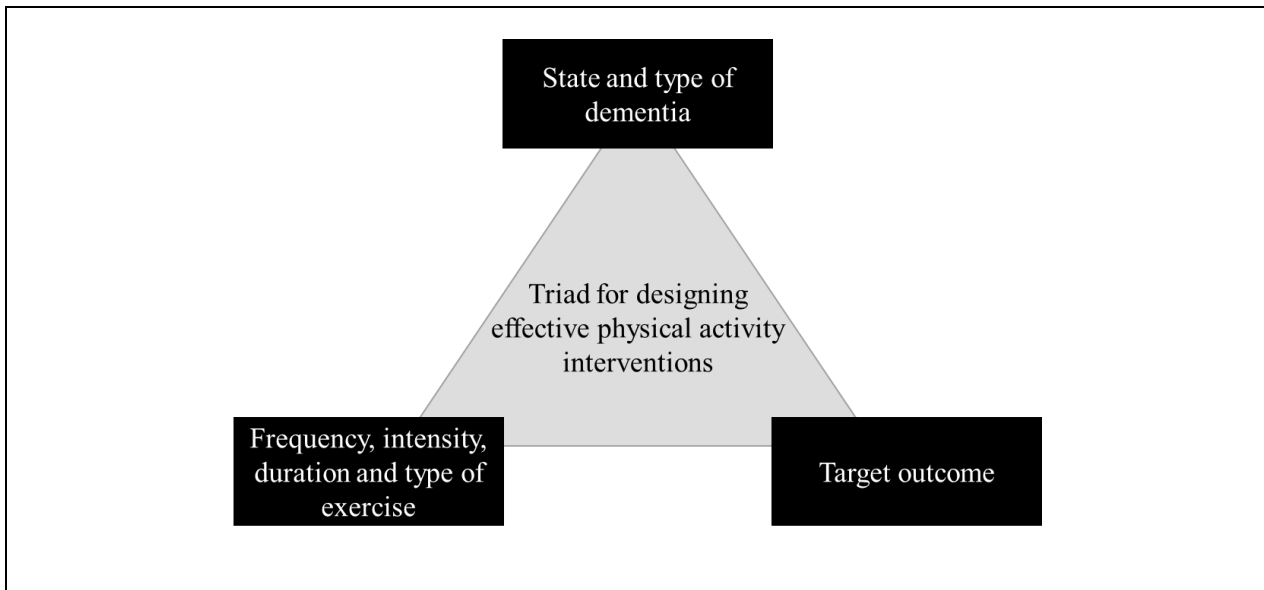


Figure 6.1: Aspects to consider when designing effective physical activity interventions for individuals with dementia (according to Borges-Machado et al., 2021)

Besides the obvious need for individualized PA interventions for IWD, one must also consider the accompanying challenges on a nursing home staff level. First, as described in the background (Chapter 1.2.3), time spent on each resident in nursing homes is limited. Therefore, group-based exercises may be more feasible and time-effective. The preparation and conduct of PA sessions for individuals or small groups may be more time-consuming, compared to planning and delivering a PA session for a larger group of IWD. Nursing home staff, who often have little expertise in sports science, could be overwhelmed with planning and implementing individualized PA sessions (Baert et al., 2015; Benjamin et al., 2011). Moreover, research has shown that a crucial factor for successful implementation of PA in nursing homes is staff motivation, which is likely to be higher when nursing home staff is convinced of the benefits of interventions for residents (Vikström et al., 2021). Therefore, there is a need for easy to implement, meaningful and low-threshold tools that support the planning and implementation of individualized PA for IWD in nursing home settings.

Also, the organization and design of PA interventions must be considered in terms of individual PA preferences of nursing home residents. For example, it is known that social factors and aspects play an important role in terms of the motivation and well-being of IWD (Ladkjær Larsen et al., 2022; Spildooren et al., 2019). As a result, studies found that motivation to exercise is higher when training takes place in a group rather than individual training setting (Spildooren et al., 2019). However, it should be also noted, that IWD may have attentional problems in a group setting and therefore may have difficulties to stay focused for more than

30min (Spildooren et al., 2019), and some individuals also refuse group exercises due to personal preferences (Gebhard & Mess, 2022). It could be one solution to offer both individual and group-based training, while aiming at forming only homogeneous training groups, so that individualized training can be also realized in group interventions (Barisch-Fritz, Bezold, Scharpf, et al., 2022a). To this end, there is a strong need for tools, that support nursing home staff in planning and transposing this approach into nursing home practice.

Furthermore, a major unsolved problem that is also related to methodological limitations of previous studies, is the way of evaluating the effectiveness of PA interventions in clinical trials or intervention studies, particularly regarding physical performance outcomes in IWD. Many physical performance tests are used frequently in studies with IWD, but their sensitivity with regard to this specific target group is rarely questioned and discussed. Consequently, in the setting of nursing homes and studies with IWD, inappropriate or proxy-related measurements are often used (Bezold, Krell-Roesch, et al., 2021; Trautwein, Maurus, et al., 2019). In most cases, these applied assessments have various limitations, show ceiling effects, have variations in test administration depending on the tester, and always require supervision of an expert (Leirós-Rodríguez et al., 2019). Therefore, there is a critical need for more objective assessment strategies that overcome these limitations, particularly regarding the assessment of physical performance, in order to better assess and potentially prove the effectiveness of PA interventions in IWD.

6.2 DIGITAL HEALTH SOLUTIONS FOR PHYSICAL ACTIVITY PROMOTION IN DEMENTIA CARE

As *Manuscript II* and *Manuscript III* have shown, DHS may be used to overcome some of the limitations of traditional physical performance assessments (i.e., sensor-based assessment) and may also present a possible solution for planning and implementing individualized PA interventions for IWD in nursing homes. In addition, the COVID-19 pandemic has changed dementia care (Giebel, 2023) and emphasized the importance of DHS, e.g. in order to reduce personal physical contact (Sohn et al., 2023). Despite the various pandemic-induced challenges for care settings, this led to many innovations in digital health services (Giebel, 2023). The recent developments are associated with opportunities but also with some challenges, which will be discussed in the following section.

6.2.1 USING DIGITAL HEALTH SOLUTIONS FOR OBJECTIVE ASSESSMENT

In light of the limitations of conventional clinical assessments, the use of DHS for objectively collecting data is discussed. For example, the application of sensor-based assessment methods in older adults has been studied within a wide context, clearly underlining the advantages of recent developments. *Manuscript II* (Bezold, Krell-Roesch, et al., 2021) underlined many of the advantages, also reported in previous publications. First, using body-worn sensors in IWD for daily-life or in-lab data collection is feasible and was accepted by participants of previous studies, with wearing times ranging from three to eight days. Second, it is possible to collect physical performance data with body-worn sensors to provide information on fall risk, or to divide between different groups of fall risk status. With sensor-based assessment methods, it is also possible to collect real-life data, instead of solely assessing physical performance while conducting clinical assessment under controlled conditions. Third, sensor-derived data often outperformed conventional clinical assessments, particularly when it comes to classification ability on fall classification models (Bezold, Krell-Roesch, et al., 2021). This was also found by another study, which showed that body-worn sensors are superior to various clinical measures (i.e., social, psychological, functional, and demographic variables), which cannot significantly discriminate between fallers and non-fallers, and are thus no predictor variables of falls (Hauer et al., 2020).

Beyond those findings, recent literature points out additional advantages of DHS for objective assessment of physical performance. Overall, body-worn sensors are a low-cost alternative to laboratory-bound equipment (e.g. optical motion capture systems, force plates, instrumented walkways) (Werner et al., 2020). Moreover, they allow for a quick and safe administration of assessments during care routines (Hauer et al., 2020), but are also suitable for long-term monitoring without the need of constant checks by a health care professional (Leirós-Rodríguez et al., 2019). Another benefit of body-worn sensors is the variety of parameters that can be obtained. For example, sensors may capture a wide range of spatio-temporal parameters during walking (e.g., gait speed, step time, cadence) (Leirós-Rodríguez et al., 2019). This was also found to be possible and reliable in older adults using a rollator for walking, where traditional instrumented gait assessment (e.g. using an instrumented walkway) is less possible (Schwenk et al., 2011), or leading to invalid or missing data (Werner et al., 2020). Sensor-derived data from gait could also contribute to the early detection of neurodegenerative or cognitive disorders such as dementia in older persons (J. Park et al., 2023). Besides the collection of gait parameters, balance assessment with body-worn sensors is also promising. For example,

sensitivity of static balance data derived from a body-worn sensor was higher than data from a force plate (Leirós-Rodríguez et al., 2019). Moreover, the sensor-derived data showed good to excellent reliability (Leirós-Rodríguez et al., 2019).

Besides the advantages of using DHS, particularly body-worn sensors, for physical performance assessment, some accompanying challenges were also described in *Manuscript II* (Bezold, Krell-Roesch, et al., 2021). For example, sensor-derived data collection in IWD is not common to date, because IWD are mostly excluded from studies. Therefore, findings regarding feasibility of sensor-based assessment in IWD could be only derived from studies including mixed samples. One main limitation that was drawn from these studies was that IWD may need more support while wearing a sensor (e.g. attachment, detachment during showering), resulting in an increased time effort for nursing home staff who need to do more regular check-ups on the sensor (Bezold, Krell-Roesch, et al., 2021).

Additionally, recent literature points out some challenges and limitations of body-worn sensors in assessing physical performance parameters. One of the biggest current challenges is that body-worn sensors and their integrated algorithms are often specifically developed for a certain research question or study purpose (Leirós-Rodríguez et al., 2019; Stavropoulos et al., 2020), and are used in controlled environments (Mc Ardle, Del Din, et al., 2021). The latter may be a problem, as some physical performance parameters, especially gait, should rather be assessed under real-life conditions to examine and understand a potential environmental impact (Mc Ardle, Del Din, et al., 2021). Moreover, the advantage of being able to obtain various parameter data with body-worn sensors can become a problem, since there is still no consensus which parameters are most relevant in IWD, e.g. when assessing gait (Mc Ardle, Del Din, et al., 2021). Therefore, instead of various isolated pilot projects, more collaborative approaches should be realized and, based thereon, “best practice” standards are needed (Mc Ardle, Del Din, et al., 2021) in order to transfer the use of body-worn sensors more into practice. But, to date, most of the studied sensors are restricted to research settings, and are largely unknown to possible end-users or distributors of such devices (Leirós-Rodríguez et al., 2019). To bring body-worn sensors into the field, the acceptance regarding ease of use, comfortability, size, weight, and battery life, are still challenging factors that need to be addressed by researchers (Stavropoulos et al., 2020). Moreover, data security and privacy are reasons of concern (Anikwe et al., 2022; Stavropoulos et al., 2020) which should be considered. In conclusion, the biggest current challenge in research regarding body-worn sensors in dementia care seems to be the clinical relevance, the ease of use, and the contribution to clinical decisions that goes above and

beyond information provided based on common clinical assessment (Mc Ardle, Del Din, et al., 2021).

6.2.2 USING DIGITAL HEALTH SOLUTIONS FOR INTERVENTION IMPLEMENTATION

As conventional PA interventions for IWD have several limitations, particularly regarding the possibility to individualize PA content, the use of DHS to implement PA interventions has been an important component of ageing research in the past years, and the possibilities are manifold. Recent literature provides examples of easy to implement PA interventions by using DHS. A feasible way is to replace exercise instructions of a physical therapist or nursing home staff by videos of an older person demonstrating the exercises on a TV screen. A feasibility study showed that such video-based exercise instruction achieved nearly 90% adherence, and participants enjoyed the exercise sessions (Spildooren et al., 2019). Nevertheless, using video-based instructions and thereby replacing a specialist who delivers an exercise program may require additional supervision during the training. On the other hand, the therapist has more time to correct the performance of participants instead of solely demonstrating them. This adds another perspective of individualization during exercise, as the instructor may individually correct each participant (Spildooren et al., 2019). Moreover, there are good overviews of very recent developments of DHS for IWD (Sohn et al., 2023), but mainly focusing on technology that requires a direct interaction of IWD with the system. It remains questionable if this is safe and target-oriented for the target group of IWD in nursing homes.

To date, there exists no mobile health app for promoting PA for IWD in nursing homes that is implemented by nursing home staff (Diener et al., 2022). The main challenge seems to be the development and implementation of low-threshold applications which are easy to use and have information and content reduced to a necessary minimum level. Such apps should simplify the work of nursing home staff and not add additional burden. Therefore, *Manuscript III* documented the first stages of an implementation process of the InCoPE-App that enables nursing home staff to deliver individualized PA interventions for IWD into nursing homes. Although the implemented InCoPE-App was a prototype, a number of learnings regarding the use of DHS for PA intervention implementation could be derived.

First, there was a general acceptance of the InCoPE-App by nursing home staff as shown by positive usability results and feedback derived from the final interviews. Moreover, task completion showed that there was a general technical affinity, but rather for younger as compared to older participants (i.e., nursing home staff). In conclusion, the first prototype of the

InCoPE-App was accepted and perceived as usable as rated by the end-users (Bezold et al, 2023). Therefore, *Manuscript III* is in line with recent literature showing that innovative DHS can support and complement care services of nursing home staff in a meaningful way (Hammarlund et al., 2021; Lariviere et al., 2021). Nevertheless, it is very important to consider technical affinity of nursing home staff. Studies have shown that this target group is very curious about new technologies in general, but also have limited technical affinity which may depend on different factors (e.g. age, sex, work position/ job title) (Rayling et al, 2023, Barisch-Fritz et al., in press). Therefore, technical solutions that are easy to implement are needed. Indeed, the InCoPE-App, as presented in *Manuscript III*, requires a minimum of technical experience and expertise, and only brief training on appropriate use for a few hours (Barisch-Fritz, Bezold, Scharpf, et al., 2022b). Therefore, the InCoPE-App can be used by nursing home staff who is generally not familiar with guiding PA interventions, particularly using technological and/or digital tools.

6.3 STRENGTHS AND LIMITATIONS

This thesis has a number of strengths and limitations that need to be mentioned beyond the explicit strengths and limitations of the particular manuscripts (the reader is referred to Chapter 3 for Manuscript I, Chapter 4 for Manuscript II, and Chapter 5 for Manuscript III).

One major strength of this thesis is its relevance for and contribution to a critically important research field, as it addresses potential solutions for an ageing society which affects many countries across the world (World Health Organization, 2017). As the prevalence of age-related diseases is high, research efforts regarding prevention, or treatment of these diseases, e.g. dementia are critical (World Health Organization, 2019; World Health Organization & Alzheimer's Disease International, 2012). This thesis has addressed reasons as to why previous studies reported conflicting results regarding the effectiveness of PA interventions in IWD (Bezold, Trautwein, et al., 2021), and presents approaches towards possible solutions (Bezold, Krell-Roesch, et al., 2021; Krafft et al., 2023). Particularly, the approach of implementing individualized PA interventions for IWD in nursing homes using a tablet-based application that supports nursing home staff, is novel and innovative, and has not been proposed in the literature yet. In addition, with its distinctive feature of not requiring an external expert, the InCoPE-App can contribute to PA promotion even in challenging times such as during the COVID-19 pandemic, when nursing homes were rather isolated from the outside world.

Another main strength of this thesis is that it was embedded in two consecutive research projects. This allows to show how PA interventions can benefit from former generated results,

and how adoptions according to these results can be transposed. This procedure goes beyond most of the previous studies in this context, which often end after evaluating one intervention concept. This thesis shows, among other things, that improving effectiveness of PA interventions for IWD should not be limited to discussing limitations of PA interventions, but should be used to further inform the development of more effective approaches based on previously generated results. Moreover, parts of the relevant data for this thesis (*Manuscript III*) was gathered during the COVID-19 pandemic, showing that even in these times, further development is possible and also needed.

In addition, the thesis includes a range of different research methods and therefore, follows a “mixed-methods” approach, which can be also regarded as a strength. In *Manuscript I*, data from a large randomized controlled trial was evaluated using inferential statistics (i.e., two-way ANOVAS with repeated measurements, multimodal regression analysis, *Manuscript I*). *Manuscript II* summarized results of existing literature by applying a systematic literature review approach. Finally, *Manuscript III* combined quantitative and qualitative methods by gathering and evaluating data from both questionnaire and interview surveys.

Another main strength of this thesis is its contribution to the sustainable implementation of PA interventions for IWD in nursing homes. For both presented interventions, developed within the “Physical activity against dementia” and InCoPE projects, the long-term implementation was one of the main objectives that was already considered during the studies’ development process. In light of the fact that nursing home staff is seen as a key stake holder for PA implementation in nursing homes (Hirt et al., 2021), but often lack knowledge and expertise on how to organize PA for IWD (Baert et al., 2015), both projects contributed to sustainable PA promotion by offering education training for nursing home staff including information on exercise training and sports science (Barisch-Fritz, Bezold, Scharpf, et al., 2022b; Trautwein et al., 2017). Moreover, within the InCoPE study, end-users of the InCoPE-App were included in the development process in order to improve acceptability and feasibility for a long-term use. As a result, many of the former participating nursing homes report that they continue to carry out the PA interventions, indicating the success of the implementation processes.

In addition to the strengths of this thesis, a number of limitations must be noted which may provide important indications for further research needs. First, this thesis focused on different outcomes within the three presented manuscripts. Within *Manuscript I*, effectiveness of PA on ADL performance in IWD was evaluated; nevertheless, ADL performance is not considered as a primary outcome in the further course of this thesis. In *Manuscript II*, fall risk was

the main outcome, characterized by physical performance parameters (e.g., gait, balance). Also, the algorithm within the InCoPE-App, as well as the target outcomes of the individualized intervention, focused on parameters of physical performance in *Manuscript III*. Nevertheless, the results of *Manuscript I* showed that ADL performance is depending on physical functioning (i.e., mobility, walking speed, lower limb strength, balance). Thus, the results are still relevant for the course of this thesis.

Moreover, some limitations regarding the design of the presented intervention contents should be mentioned. Recent literature recommends integrating organizational structures of participating nursing homes when designing PA interventions (Gebhard & Mess, 2022), e.g. by setting institution specific goals and dimensions of activities, and by developing concrete PA interventions based thereon (Thiel et al., 2021). The multimodal exercise program as part of the “Physical activity against dementia” trial, as described in *Manuscript I*, was developed based on a literature review and a pilot-study, but did not consider institutional structures. The main further development from “Physical activity against dementia” to InCoPE was the individualization of the intervention content, but PA was mainly personalized on basis of physical and cognitive performance. Individual preferences of IWD regarding PA (e.g. kind of exercises, intervention mode) were not considered. This seems to be one of the most common problems of existing PA interventions using the label “individualized”, i.e. interventions often lack emotionally tailored exercise programs, which may help IWD to enjoy and maintain engagement in PA (Gebhard & Mess, 2022). Furthermore, having two target groups, i.e. nursing home staff as app end-users and IWD as receivers of the PA intervention, was main challenge throughout the development process of the InCoPE-App. This resulted in the fact, that even though we included the end-users at different stages, we did not consider other groups of persons. For example, literature suggests, also including residents of nursing homes together with their relatives in the development process of DHS, in order to determine their special needs and possible concerns regarding a DHS to promote PA (Tsersidis, 2021).

Besides a user-centred development process, the successful implementation of DHS also requires a conscientious evaluation in the field. This also contributes to the effectiveness of such a solution. This thesis only covers a part of the development process of the InCoPE-App, and it is necessary to mention that the App was further evaluated within an 18-week cluster randomized controlled trial, aiming at evaluating the long-term usability and acceptance, as well as the effectiveness of the individualized exercise programs implemented with the help of the app (Barisch-Fritz, Bezold, Scharpf, et al., 2022a). Nevertheless, some parts of the InCoPE-App are still to be revised.

Furthermore, this thesis shed a light on two possible ways of using DHS in nursing homes in a meaningful way. It was shown that application of body-worn sensors in IWD is feasible, but understudied. Also, mHealth apps for PA interventions in nursing homes are scarce. Both technologies, i.e., body-worn sensors as well as the app-derived individualized PA intervention, are viewed and discussed separately within this thesis. Combining these two approaches may have a lot of potential for further research.

6.4 RESEARCH PERSPECTIVES

The perspectives for further research regarding PA interventions for IWD and opportunities for DHS to this end, are manifold and the possibilities have by far not been exploited yet. There are many approaches available, but often, the clinical relevance seems to be still missing and the translation into practice, especially in challenging settings like nursing homes, has not been investigated properly so far. Research in the past years regarding PA interventions for IWD has shown, that the evidence for the effectiveness is still heterogeneous regarding several outcome parameters (e.g., cognition, physical performance). Even though it is a worthwhile goal to aim at an improvement or maintenance of cognitive and physical performance, there are still many underlying and less explored processes in dementia diseases that make it difficult to achieve that goal (Gebhard & Mess, 2022; McEwen et al., 2021). Every effort of contributing to this research field should be used in order to generate new insights. Therefore, a couple of interrelated aspects will be proposed in the following section, that should be addressed, among others, by further research.

1) Determining the heterogeneity of IWD

Research had stated, that IWD are a heterogeneous target group for PA interventions in terms of cognitive function, ADL performance, or physical performance (Barisch-Fritz et al., 2021; Bezold, Trautwein, et al., 2021; Forbes et al., 2015; Trautwein et al., 2020). Nevertheless, heterogeneity should be considered beyond these parameters. For example, biography-based approaches have great potential in PA promotion for IWD (Malt-house & Fox, 2014; van Alphen, Hortobágyi, & van Heuvelen, 2016; van der Wardt et al., 2017), and may therefore be another aspect to consider for individualized PA interventions among IWD. Also, other intrapersonal factors like severity of the disease, other co-existing diseases, and preferences for or barriers to PA may impact the effectiveness of interventions, and should thus be carefully considered. Therefore, further research should apply a broader understanding of individualization. Moreover, further research should not stop at highlighting the heterogeneity of IWD, but should also examine and

clarify the underlying mechanism, for example, by conducting responder-analyses like in *Manuscript I*. Further research should focus less about general effects of PA interventions but rather address the important question, which kind of PA may be effective for each IWD.

2) *Evaluating individualized PA interventions for IWD*

To date, there are few studies investigating the effectiveness of individualized PA interventions for IWD (e.g. Barisch-Fritz et al, 2022a). Indeed, evaluating individualized interventions where intervention content differs, may be much more methodically challenging compared to standardized interventions. Therefore, more feasibility studies in this context are needed that show possible ways on how to evaluate this approach, and that probably define best-practice standards for the methodological possibilities of evaluation. Moreover, in the future, there will be a need for the comparison of individualized PA interventions with “general” interventions that do not consider individual’s preconditions, in order to show if individualized approaches are superior in terms of effectiveness (Bezold, Trautwein, et al., 2021). As previous research has shown, the detection of intervention effects regarding traditional outcomes (e.g. cognition, gait performance, balance, strength) in IWD is difficult; therefore, further studies should also collect more “soft parameters”. For example, a study by Gonçalves et al. (2020) proposed a set of core outcomes to evaluate the effectiveness of PA interventions for IWD, which includes, “preventing falls; doing what you can do; staying healthy and fit; walking better; being able to stand up and climb stairs; feeling brighter; enjoying the moment; and; feeling useful and having a purpose” (Gonçalves et al., 2020, p. 682). With regard to health services research, also factors like care effort or burden on nursing home staff and care-takers could be used as parameters of effectiveness of exercise programs.

3) *Requirements for feasibility of DHS for IWD in nursing homes*

One of the most important factors for successful implementation of DHS, be it body-worn sensors or apps, in nursing homes is the acceptance of such solutions by both, residents and nursing home staff. More research should delve into the application of DHS in those more “challenging” target groups, who are likely less familiar with such devices (Odendaal et al., 2020). Nursing home staff were identified as important stakeholders regarding DHS (Gebhard & Mess, 2022), and therefore, solutions should be designed in an easily-applicable, and less-time-consuming way. Moreover, the

usefulness of DHS should be clearly evident to nursing home staff, as the willingness to implement DHS may increase if persons see the advantages and meaningfulness of a new solution. In addition, barriers and facilitators for the use and implementation of DHS in nursing homes must be further investigated (Rayling et al., 2023). Besides that, the organizational structure of nursing homes should be carefully considered when designing and implementing DHS, in order to facilitate a long-term implementation (Thiel et al., 2021). Therefore, best-practice examples and potentially checklists, should be developed in future research.

4) *Further refinement of DHS for implementation of PA interventions*

The InCoPE-App that was presented within this thesis is one of the first DHS for implementing PA interventions for IWD in nursing homes (Diener et al., 2022). Therefore, a comparison with existing other, similar DHS is not possible. Nevertheless, the InCoPE-App may be a good example for further development in this field. Although research has shown the feasibility of , for example, exergaming in IWD (Diener et al., 2022), the digital literacy of IWD is less documented, particularly regarding safety reasons. Therefore, the approach of designing an app to support nursing home staff seems safe and worth building upon. As the COVID-19 pandemic had shown, future dementia care needs solutions that are easy to implement without the need for external experts (Cuffaro et al., 2020). DHS supporting nursing home staff in implementing PA interventions can be considered safe, even in times of a pandemic, and may guarantee a goal-oriented use. Furthermore, DHS for PA promotion offer a bouquet of other functions that could be integrated within such a solution, thereby leaving room for further development. For example, research has shown that combining music with PA interventions is effective in IWD (Prinz et al., 2021). Moreover, interfaces between different solutions could be made possible, e.g. the integration of patient information from electronic patient records. Nevertheless, further research must carefully consider data privacy and security regulations (Schinle et al., 2022).

5) *Combining approaches*

One important, and very promising perspective is the combination of both presented approaches for the use of DHS, i.e. integrating sensor-derived data in mHealth applications to reach a higher level of personalized PA interventions. Such approach would meet both the demand for more objective assessment methods and also offer the

6 General discussion

possibility of integrating intelligent algorithms into mHealth apps that could continually adapt based on the sensor-derived data. This would allow regular adjustments to training, based on regular assessment of an individual's performance. The two most obvious advantages of this approach are the superiority of sensor-based data over clinical assessments for certain outcome parameters, and the economy of time for researchers and / or nursing home staff. Such combinations are well known from wearable devices like Fitbit which can be paired with smartphone apps for training control, and may have the potential to positively influence PA, even in older adults (Yerrakalva et al., 2019). Moreover, the use of a Fitbit device without an mHealth app was also tested within a feasibility study in IWD, but the authors stated a number of challenges (e.g. familiarity with the device; additional caregiver's burden) (O'Sullivan et al., 2023). Therefore, it appears that the combination of sensor-based assessment and an mHealth app for IWD has not been investigated yet, likely due to a high number of challenges. However, research should continue to pursue this approach. A possible example, which results from the present thesis is shown in Figure 6.2.

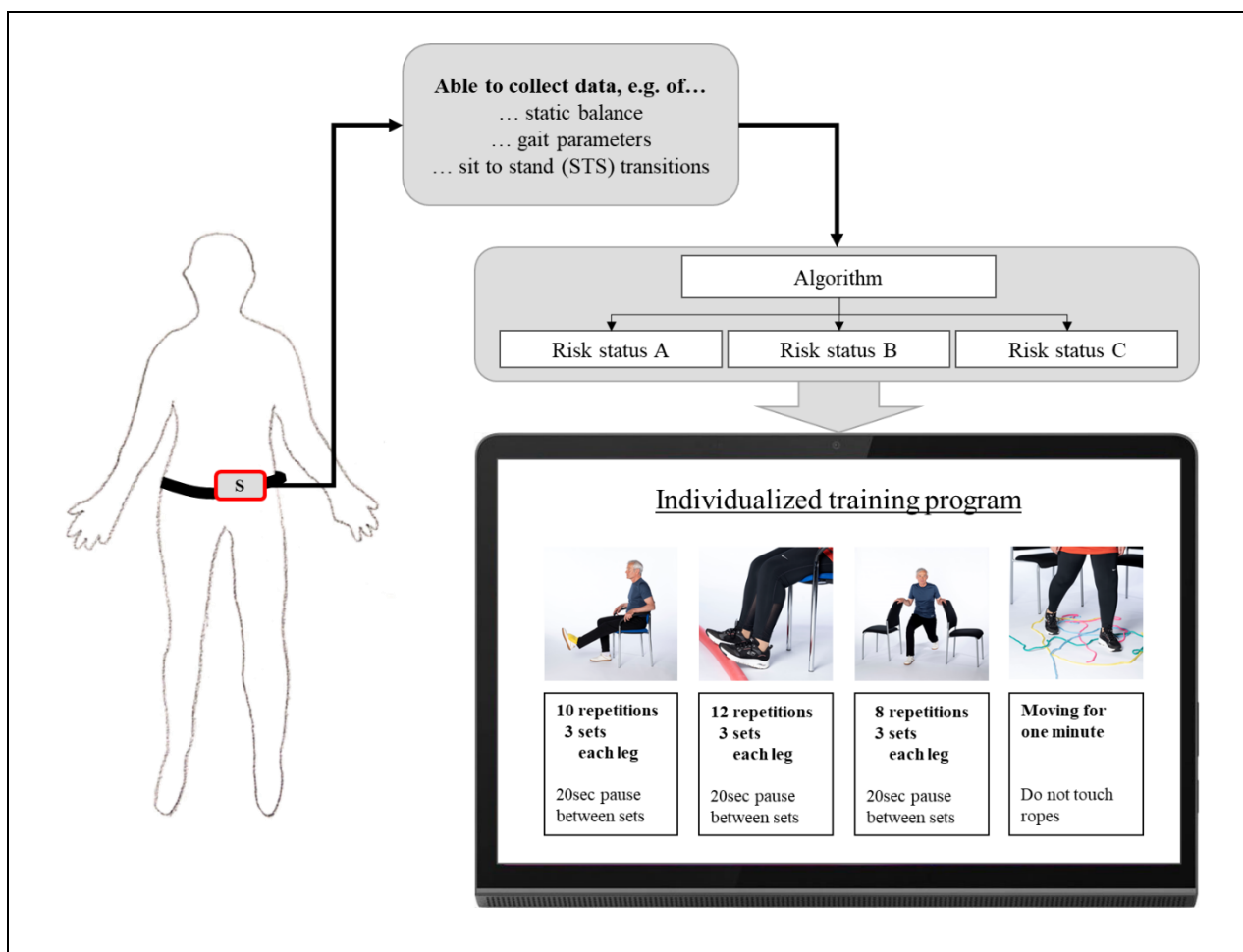


Figure 6.2: Combining the approaches of sensor-supported assessment and individualized PA interventions using mHealth apps

6) *Broaden target group*

It is important to note, that dementia is often diagnosed at an advanced stage and when symptoms become more severe, and in general there is no cure for the disease. Therefore, it is critical for future research to also evaluate the possibilities of individualized PA interventions and DHS in older persons who are (still) free of, or at risk of developing dementia. Various studies have shown effects of PA in MCI, so further individualized PA interventions should also focus increasingly on persons who are in the early or incipient stages of dementia disease.

7 CONCLUSION

The social responsibility for older persons in need of care is constantly emphasized. A contribution to the fulfilment of this responsibility has to be carried out by science in general. Here, sports science also plays an essential role. Particularly during the COVID-19 pandemic, the consequences for vulnerable target groups, like IWD in nursing homes, became more clearer as they were isolated from social contacts and experienced a lack of PA which was already present before the pandemic. Therefore, effective, sustainable, but also crisis-proofed solutions are needed. The aim of this thesis was to present and discuss possibilities, of how to implement PA interventions in IWD to prevent disease-related decline in several areas. To this end, this thesis aimed at breaking new grounds regarding the need for and implementation of individualized PA interventions by also elaborating possibilities and limitations of DHS. Therefore, it adds important knowledge to the field of designing and conducting feasible, and low-threshold PA interventions for IWD in nursing homes.

This thesis shows, that a “one-fits-all” PA intervention for IWD in nursing homes has no overall effects with regard to ADL, or only has an effect on a small part of the intended target group. These results were in line with other studies; however, using responder analyses, it became evident that a certain subgroup of participants benefited from the intervention (i.e., persons with lower physical performance at the beginning). This underlines the high heterogeneity of IWD, and supported the need for individualized PA interventions. With the example of the performance of ADL, this thesis showed, which factors were important for the improvement. Future research should further investigate, how homogeneous subgroups of IWD can be identified, in order to advance the approach of individualized PA interventions.

Regarding the effective realization of individualization, there is a need for the comprehensive and objective assessment of relevant parameters (e.g. gait performance in IWD). There are many clinical assessments that are also applied in IWD, but often do not serve their purpose and produce inaccurate results. However, in light of the progress of digitalization in the past decades, body-worn sensors have been developed that enable an objective, reliable and valid recording of physical performance, among other variables. In this thesis, this was investigated primarily with regard to fall risk factors. It became clear that the use of body-worn sensors in IWD has not yet been implemented widely, and that a dementia diagnosis was an exclusion criterion in many studies. Nevertheless, it could be shown that an application in IWD is generally feasible. This is relevant as body-worn sensors can also record physical performance in everyday life and not only under laboratory conditions. Especially for IWD, who are often

overwhelmed by or distracted under controlled conditions such as lab settings, this could lead to significantly more objective and valid data.

A possibility for the actual implementation of an individualized PA intervention using DHS was also presented and discussed in this thesis. With the InCoPE-App, a new, innovative and novel app was developed, which allows nursing home staff to record the current cognitive and motor status of persons with dementia and, based thereon, to instruct an individualized PA intervention. Contrary to previous developments, the InCoPE-App does not target IWD as end users, but nursing home staff as mediators of the PA intervention. Thus, the work and tasks of nursing home staff in the area of PA promotion is supported efficiently. Moreover, this thesis shows that the InCoPE-App is accepted by the potential end-users and has a good user-friendliness. Nevertheless, further potential for development became clear and underlines the challenges of the design and conduct of technology-based interventions in specific settings such as nursing homes. Further studies should include the conditions and individual circumstances of nursing homes in the development of DHS in order to avoid complications in the implementation process as early as possible.

Overall, in conclusion, this dissertation demonstrates the need for, the effectiveness of but also the limits of individualization of PA for individuals with dementia. It also presents solutions and challenges to using digitalization in order to implement PA interventions in nursing homes in the long-term. There is a critical need for further development and scientific research in this field.

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