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Long-term care in community-dwelling older adults in Germany: needs and approaches

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Learn from yesterday,

Live for today,

Hope for tomorrow.

The important thing is not to stop questioning.

Albert Einstein

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List of abbreviations

ABMHS	Andersen’s Behavioral Model of Health Services Use
ADAS-Cog	Alzheimer’s Disease Assessment Scale – Cognitive Subscale
ADCS-ADL	Alzheimer’s Disease Cooperative Study – Activities of Daily Living Inventory
ADLs	Activities of daily living
BMI	Body mass index
BSFC-s	Burden Scale for Family Caregivers, short version
CE plane	Cost-effectiveness plane
CEA	Cost-effectiveness analysis
CEAC	Cost-effectiveness acceptability curve
CG	Control group
CI	95% confidence interval
DCC	Day care center
DeTaMAKS	German acronym for “Dementia in Day care (German: “Tagespflege”) with Motor stimulation, Activities of daily living stimulation, Cognitive (German: “Kognitiv”) stimulation, and Social functioning”
ETAM	Erlangen Test of Activities of Daily Living in Persons with Mild Dementia or Mild Cognitive Impairment
GEE	Generalized estimating equation
GDP	Gross domestic product
GNPAR	German National Physical Activity Recommendations for older adults
HAQ-DI	Health Assessment Questionnaire Disability Index
IADLs	Instrumental activities of daily living
IG	Intervention group
IQR	Interquartile range
ITT	Intention to treat
KORA	Cooperative Health Research in the Region of Augsburg
LTC	Long-term care
MAKS	Non-pharmacological treatment with four components – Motor stimulation, Activities of daily living stimulation, Cognitive stimulation, and Social functioning
MCI	Mild cognitive impairment
MMSE	Mini-Mental Status Examination
NOSGER	Nurses’ Observation Scale for Geriatric Patients, social behavior subscale
NPI-Q	Neuropsychiatric Inventory Questionnaire

List of abbreviations

OR	Odds ratio
PA	Physical activity
RKI	Robert Koch Institute
SA	Sensitivity analysis
SD	Standard deviation
SNCI	Statutory nursing care insurance
WHO	World Health Organization

List of publications included in this thesis

Steinbeisser, K., Schwarzkopf, L., Grill, E., Schwettmann, L., Peters, A., Seidl, H.: Gender-linked determinants for utilization of long-term care in community-dwelling adults 65+ in Germany: results from the population-based KORA-Age study. *Exp Gerontol* (2021). <https://doi.org/10.1016/j.exger.2021.111500>

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Summary

Background

Worldwide, demographic change is leading to aging populations. By 2030, one in six people will be ≥ 60 years of age. This trend is linked to expanding burdens on financial and social resources for health care systems, societies, and individuals. One cause of this trend is older adults' considerable need for long-term care (LTC) services. Hence, health professionals and policy-makers must seek effective, need-based approaches to be able to provide adequate LTC or even prevent the necessity of utilization of LTC. The main objective of this thesis is to comprehensively identify relevant needs and approaches for target-oriented LTC for the important subpopulation of community-dwelling older adults and its vulnerable subgroups in Germany. Three articles contribute to this field of interest with the following aims:

- (1) Identify determinants for utilization of informal and formal LTC in females and males in order to detect particular needs of relevant subgroups
- (2) Examine the association of various types of physical activity with LTC to identify vulnerable subgroups with respect to utilization of LTC, and to detect promising approaches with respect to utilization of LTC
- (3) Analyze the cost-effectiveness of a non-pharmacological intervention compared to care as usual, and thus identify a potentially promising approach for appropriate and cost-effective LTC for individuals with cognitive impairments in day care centers

Methods

All research questions addressed community-dwelling adults ≥ 65 years of age. Articles (1) and (2) derived data from the population-based Cooperative Health Research in the Region of Augsburg (KORA)-Age study in southern Germany at t_1 (2011/12) and t_2 (2016). Article (3) analyzed data from a randomized-controlled trial with waitlist group design in day care centers across Germany. The particularities of the underlying data were considered through adequate statistical models in each article:

- (1) Potential determinants were selected based on Andersen's Behavioral Model of Health Services Use. Generalized estimating equation (GEE) logistic models detected relevant determinants for utilization of informal and formal LTC in females and males at t_1 and t_2 . Determinants for a transition to LTC between t_1 and t_2 were analyzed by a longitudinal logistic regression model. The amount of LTC was examined descriptively.
- (2) GEE logistic models identified associations of walking, exercise, and walking+exercise with utilization of LTC at t_1 and t_2 in the entire cohort and stratified by females and males.

The proportion of individuals meeting the suggested minimum values in the German National Physical Activity Recommendations for older adults was examined descriptively.

- (3) A cost-effectiveness analysis from a societal perspective regarding the effects of cognitive abilities and capabilities to perform activities of daily living, as well as costs, was conducted. To obtain cost-effectiveness acceptability curves and cost-effectiveness planes, incremental differences in both effects and costs were simultaneously bootstrapped. Incremental differences were calculated via generalized linear models.

Results

- (1) The determinants higher age, multimorbidity, and disability had statistically significant associations with utilization of and transition to LTC. In both females and males, living alone showed a statistically significant association with utilization of LTC. Regarding living alone, the strength of association was twice as strong in males compared to females. Males used a higher amount of informal LTC than females, whereas females used a higher amount of formal LTC than males.
- (2) Walking, exercise, and walking+exercise all had a statistically significant association with non-utilization of LTC. In the entire cohort and in males, walking+exercise showed the strongest associations; in females, exercise showed the strongest associations.
- (3) The non-pharmacological intervention was determined to be a cost-effective approach for individuals with cognitive impairments. Six months post baseline, the results showed better effects in the intervention group in comparison to the control group, as well as lower costs.

Conclusion

This thesis gives detailed insight into the connections of needs and approaches with utilization of LTC in the highly relevant subpopulation of community-dwelling older adults. To successfully reach vulnerable subgroups, the particular needs detected in females and males, as well as in older adults with specific characteristics, must be considered in the planning of approaches. Such approaches should integrate physical activity and non-pharmacological interventions similar to the one analyzed in this thesis as promising strategies. Further advantages of those are their cost-effectiveness and relatively low costs. Altogether, these detailed analyses of the large cohorts pertaining to research on LTC trends help health professionals and policy-makers in Germany and countries with comparable LTC systems to precisely plan for future needs in LTC and develop sustainable, demand-oriented approaches. In the long-term, this will allow provision of accessible, economical, and valuable LTC with a focus on aging with dignity.

Zusammenfassung

Hintergrund

Weltweit führt der demographische Wandel zu einer alternden Bevölkerung. Bis 2030 wird jeder sechste Mensch 60 Jahre oder älter sein. Diese Entwicklung ist mit einer zunehmenden Belastung der finanziellen und sozialen Ressourcen für Gesundheitssysteme, für die Gesellschaft und für den Einzelnen verbunden. Eine Ursache für diese Entwicklung ist der erhebliche Bedarf älterer Menschen an Pflegeleistungen. Gesundheitsfachkräfte und politische Entscheidungsträger*innen müssen folglich nach effektiven, bedarfsgerechten Ansätzen suchen, um eine adäquate Pflege zu gewährleisten oder sogar der Notwendigkeit einer Inanspruchnahme von Pflege vorzubeugen. Das Hauptziel dieser Arbeit besteht darin, relevante Bedarfe und Ansätze für zielgruppenorientierte Pflege für die wichtige Subpopulation der im häuslichen Setting lebenden („community-dwelling“) älteren Personen und ihrer besonders hilfebedürftigen Subgruppen in Deutschland umfassend zu identifizieren. Drei Artikel tragen mit folgenden Zielen zu diesem Interessensfeld bei:

- (1) Identifikation von Determinanten für die Inanspruchnahme von informeller und formeller Pflege bei Frauen und Männern, um die besonderen Bedarfe relevanter Subgruppen zu ermitteln
- (2) Untersuchung der Assoziation verschiedener Bewegungsarten mit Pflege, um besonders hilfebedürftige Subgruppen im Hinblick auf die Inanspruchnahme von Pflege zu identifizieren und zukunftsweisende Ansätze hinsichtlich einer Inanspruchnahme von Pflege zu ermitteln
- (3) Analyse der Kosteneffektivität einer nicht-pharmakologischen Intervention im Vergleich zur Standardversorgung und somit die Identifikation eines potenziell zukunftsweisenden Ansatzes für angemessene und kosteneffektive Pflege für Personen mit kognitiven Einschränkungen in Tagespflegeeinrichtungen

Methodik

Alle Forschungsfragen adressierten Personen im Alter von mindestens 65 Jahren, die im häuslichen Setting leben. Artikel (1) und (2) basierten auf Daten der populationsbasierten Kooperativen Gesundheitsforschung in der Region Augsburg (KORA)-Altersstudie in Süddeutschland zu t_1 (2011/12) und t_2 (2016). Artikel (3) analysierte Daten einer randomisiert-kontrollierten Studie mit Wartegruppen-Design von Tagespflegeeinrichtungen in ganz Deutschland. Die Besonderheiten der zugrunde liegenden Daten wurden in jedem Artikel durch adäquate statistische Modelle berücksichtigt:

- (1) Potenzielle Determinanten wurden mit Hilfe des Andersen's Behavioral Model of Health Services Use ausgewählt. Logistische GEE-Modelle („generalized estimating equations models“) identifizierten Determinanten für die Inanspruchnahme informeller und formeller Pflege bei Frauen und Männern zu t_1 und t_2 . Die Determinanten für einen Übergang zu Pflege zwischen t_1 und t_2 wurden anhand eines longitudinalen, logistischen Regressionsmodells analysiert. Der in Anspruch genommene Pflegeumfang wurde deskriptiv erfasst.
- (2) Logistische GEE-Modelle identifizierten die Assoziation von Spazierengehen, Sport und Spazierengehen+Sport mit einer Inanspruchnahme von Pflege zu t_1 und t_2 in der Gesamtkohorte und stratifiziert nach Frauen und Männern. Der Anteil an Personen, der die empfohlenen Mindestwerte der Nationalen Empfehlungen für Bewegung für Ältere erfüllt, wurde deskriptiv untersucht.
- (3) Eine Kosteneffektivitäts-Analyse aus gesamtgesellschaftlicher Perspektive untersuchte die Effekte kognitive Fähigkeiten, die Fähigkeit, die Aktivitäten des täglichen Lebens selbstständig durchzuführen sowie die Kosten. Die Kosteneffektivitäts-Akzeptanz-Kurven und Kosteneffektivitäts-Ebenen wurden durch gleichzeitiges Bootstrapping der inkrementellen Differenzen der Effekt-Parameter und der Kosten ermittelt. Die inkrementellen Differenzen wurden durch Generalisierte Lineare Modelle berechnet.

Ergebnisse

- (1) Die Determinanten höheres Alter, Multimorbidität und Behinderung zeigten statistisch signifikante Assoziationen mit einer Inanspruchnahme von Pflege und einem Übergang zu Pflege. Sowohl bei Frauen als auch bei Männern bestand eine statistisch signifikante Assoziation zwischen alleinlebend und der Inanspruchnahme von Pflege. Bei Männern war die Assoziation der Determinante alleinlebend doppelt so hoch wie bei Frauen. Männer nahmen mehr informelle Pflege in Anspruch als Frauen, während Frauen mehr formelle Pflege in Anspruch nahmen als Männer.
- (2) Spazierengehen, Sport und Spazierengehen+Sport wiesen alle eine statistisch signifikante Assoziation mit der Nicht-Inanspruchnahme von Pflege auf. In der Gesamtkohorte sowie bei den Männern zeigte Spazierengehen+Sport die stärkste Assoziation; bei Frauen zeigte Sport die stärkste Assoziation.
- (3) Die nicht-pharmakologische Intervention wurde als kosteneffektiver Ansatz für Menschen mit kognitiven Einschränkungen ermittelt. Sechs Monate nach Studienbeginn zeigten sich für die Interventionsgruppe bessere Effekt-Parameter und geringere Kosten im Vergleich zur Kontrollgruppe.

Schlussfolgerung

Diese Arbeit gibt einen detaillierten Einblick in die Bedarfe und Ansätze hinsichtlich der Inanspruchnahme von Pflege in der hochrelevanten Subpopulation der im häuslichen Setting lebenden älteren Personen. Um besonders hilfebedürftige Subgruppen erfolgreich zu erreichen, müssen bei der Planung von Ansätzen die ermittelten speziellen Bedarfe von Frauen und Männern, ebenso wie von älteren Menschen mit besonderen Charakteristika, beachtet werden. Solche Ansätze sollten Bewegung und nicht-pharmakologische Interventionen, welche ähnlich zu der in dieser Arbeit analysierten sind, integrieren. Weitere Vorteile dieser Ansätze sind deren Kosten-Effektivität und relativ niedrigen Kosten. Insgesamt unterstützen diese detaillierten Analysen der großen Kohorten, die Pfl egetrends erforschen, Gesundheitsfachkräfte und politische Entscheidungsträger*innen dabei, in Deutschland und in Ländern mit vergleichbaren Pflegesystemen den zukünftigen Pflegebedarf präzise zu planen und nachhaltige, bedarfsorientierte Ansätze zu entwickeln. Langfristig wird dies die Bereitstellung einer leicht zugänglichen, wirtschaftlichen und wertvollen Pflege ermöglichen, bei der Altern in Würde im Mittelpunkt steht.

1 General introduction

1.1 Aging populations as a public health concern

Within the last decades, life expectancy at birth across countries in the Organization for Economic Cooperation and Development (OECD) rose to a mean of 81.0 years in 2019 [1]. In Germany, it increased to a mean of 81.4 years [1, 2]. This development in combination with declining fertility rates induced a demographic change, with older adults making up a large share of today's populations. While in 1960 the share of adults ≥ 65 years was less than 9.0%, in 2019 it increased to more than 17.3% and it is projected to rise further in upcoming decades. In Germany, the share was even higher with 21.5% in 2019 and is projected to rise to approximately 28.0% by 2050 [1].

Despite longer life expectancy, not all gained years are spent in good health. Across OECD countries in 2019, the average number of healthy-life years at age 65 was 9.8 for females, and 9.7 for males [1]. In Germany, the average was 12.8 healthy-life years for females, and 11.5 for males [1]. This means that older adults spend a high share of their remaining years of life coping with disability and chronic conditions (e. g., cognitive impairments) [1].

Consequently, there is a high demand for resource-intensive health and long-term care (LTC) services in old age, with the latter being one of the leading public health concerns of today's societies [1, 3]. Across OECD countries in 2019, a mean of 10.7% of adults ≥ 65 years received LTC [1]. In Germany, it was even higher with 18.4% of adults ≥ 65 years receiving LTC [1]. Furthermore, the number of individuals using LTC in the future is expected to rise [1, 4].

1.2 Individual and societal impact of long-term care

Becoming a person with increasing loss of independence means one experiences a challenging shift in life. It is associated with, e. g., large declines in mental health and health-related quality of life for the individual [5–7]. Furthermore, being in need of LTC is often associated with a high risk of experiencing poverty [8, 9]. Although many OECD countries provide public financial support for LTC recipients, out-of-pocket costs (i. e., remaining costs for LTC services after taking into account public support) are high in comparison to disposable incomes [9].

Next to the above-mentioned negative impacts on individuals in need of LTC, adequate LTC provision can also have positive impacts on the individual. Forder et al. [8] found that adequate

LTC provision for community-dwelling older adults based on the individuals' needs sustainably improves their care-related quality of life.

LTC further impacts LTC recipients' surroundings, and thus society. Among their family and friends providing informal LTC, there is usually a high prevalence of physical and psychological health problems that are associated with high needs for health care [10, 11]. If the informal caregivers are of working age, they have to decrease work hours to have time for caregiving. This is often linked with high poverty rates in this group [1, 11–13].

As the demographic change is progressing, younger populations that are decreasing in size have to find sustainable approaches to providing support to an increasing share of old populations with disability and chronic conditions [1, 4]. This trend in combination with declining availability of informal LTC services due to, e. g., greater participation of females in the labor market, lead to an increasing need of formal LTC [1]. As societies face a shortage of nursing staff currently and also in the future, sustainable and cost-effective LTC approaches are in great demand [1].

1.3 Economic impact of long-term care

LTC not only has an individual and societal impact, but also an economic impact. Barriers to participation in and contributing to social life (e. g., volunteer work) and to business in both LTC recipients and their informal caregivers lead to loss of productivity, and thus indirect costs for societies [12–15]. Aside from these indirect costs, the direct costs of LTC are also a substantial economic burden for current health care systems. In comparison to other types of services in health care, LTC expenditures have increased the most within the last years [1]. Reasons for this trend are the growth of aging populations with higher needs for LTC and declining availability of informal LTC services [1]. Thus, the demand for cost intensive formal LTC services is increasing steadily.

Total LTC expenditures made up an average of 1.5% of the gross domestic product (GDP) across 32 OECD countries in 2019. In Germany, it was around 2.2% of the GDP (i. e., €76.4 billion) in 2019 [1, 2, 16]. The majority of LTC expenditures is allocated to institution-based LTC in nursing homes [1]. Across OECD countries in 2019, around 52.1% of total expenditures for LTC were for LTC in nursing homes [1]. In contrast, 18.4% were spent on formal LTC at

home, 8.9% on informal LTC in countries remunerating informal LTC, and 20.5% on social and other services (e. g., hospitals, social providers) [1].

In Germany in 2019, total LTC expenditures of the statutory-based social LTC insurance amounted to €40.7 billion [17]. Although institution-based LTC comprised only a fifth of the total LTC provision in Germany, approximately €13.0 billion (32.0%) of the €40.7 billion were spent exclusively on this category. Formal community-based LTC funded through in-kind benefits comprised around €5.0 billion (12.2%). Informal community-based LTC paid for by cash benefits totaled approximately €11.7 billion (28.8%). Further LTC expenditures, e. g., consultations or technical care aids, comprised approximately €11.0 billion (27.0%) [17, 18]. Expenditures in all categories have steadily risen within the last decades [17]. Between 2009 and 2019, total LTC expenditures in Germany increased from €19.3 billion to €40.7 billion and are expected to further increase within the next years [17, 18].

1.4 Conceptual approach of Germany's long-term care system

LTC is described as support with daily activities for individuals who have cognitive or physical limitations and show restricted capabilities in selfcare on a long-term basis [1, 12]. Daily activities are comprised of activities of daily living (ADLs), such as getting dressed or eating, as well as instrumental activities of daily living (IADLs), such as doing housework or preparing meals [19, 20]. The type of caregiver determines if LTC is either informal or formal. Informal LTC is described as unpaid support from, e. g., family or community members, or friends. In contrast, formal LTC is described as paid assistance from, e. g., a professional nurse or household support.

In Germany, individuals in need of LTC have free choice of which type of LTC they would like to receive [17]. However, specific determinants, such as living arrangements, sex, disability, and multimorbidity levels, are associated with the type of LTC used [21]. To encourage community-based informal LTC, Germany's LTC insurance financially supports informal caregivers to provide LTC to their family or friends through (1) cash benefits ("Pflegegeld"). Another possibility is (2) in-kind benefits ("Pflegesachleistung") for formal community-based LTC, or a combination of (1) and (2). If community-based LTC is not possible (e. g., due to severity of impairments or lack of a caregiver) or not desired, financial support for institution-based LTC is provided [17].

Since 2017, the extent of LTC dependency, and thus the amount of benefits, has been expressed by five care degrees (“Pflegrade”) [17, 22, 23]. Up to 2016, three care levels (“Pflegestufen”) existed. They were converted into the new and more need-oriented care degree system that considers certain characteristics, e. g. cognitive impairments, in a more detailed way than before [24]. For the assignment to one of the care degrees, the individual in need of LTC has to apply for benefits through the LTC insurance. After that, the Medical Service conducts a needs assessment. It evaluates if the individual is in need of care according to the 11th book of the Social Code of Germany [25]. If applicable, the Medical Service further evaluates the degree of ability to manage life independently within six domains (see Table 1). The points received in each domain are combined into a single score between 0 and 100 points, with lower points leading to a lower care degree and thus lower benefits than higher points [24, 26].

Table 1: Domains and their respective weights for long-term care needs assessment

#	Domain	Weight of domain
1	Mobility	10%
2	Cognitive and communication skills	15% ^a
3	Behaviour and psychological issues	
4	Self-care	40%
5	Coping and dealing independently with illness and treatment-related demands and stresses	20%
6	Planning day-to-day living and maintaining social contact	15%

^a the highest points of either domain 2 or domain 3 build the basis to calculate the final score for the care degree

Care degree 1 (“Pflegrad 1”) is assigned to individuals with a score between 12.5 and < 27.0, expressed by a high degree of ability to manage life independently [24, 26]. Care degree 5 (“Pflegrad 5”) is the most severe degree and is assigned to individuals with a score ≥ 90.0 , characterized by having no ability or a low degree of ability to manage life independently (see Table 2) [17, 24, 26].

Table 2: Explanation of care degrees and their respective range of scores

Care degree	Explanation of care degrees	Range of scores
1	Few limitations in independence or skills	12.5 to < 27.0
2	Significant limitations in independence or skills	27.0 to < 47.5
3	Severe limitations in independence or skills	47.5 to < 70.0
4	Extremely severe limitations in independence or skills	70.0 to < 90.0
5	Extremely severe limitations in independence or skills with special demands on care provision	90.0 to 100.0

1.5 Settings in long-term care

LTC is either community-based or institution-based. Community-based LTC covers services for community-dwelling individuals, e. g., in their private homes (also called home-based LTC) or at day care centers [12, 27]. Institution-based LTC covers services and accommodation for individuals living permanently or for a longer period of time in, e. g., nursing homes or residential care facilities [28].

In 2019, 68.2% of individuals ≥ 65 years with utilization of LTC across OECD countries received community-based LTC [1]. Based on the German legal definition of being in need of care, 4.1 million people were defined as such with individuals ≥ 65 years comprising approximately 80.0% of them in Germany in 2019. Out of those, around 80.2% received community-based LTC, with around two-thirds of individuals being exclusively supported by informal caregivers [22, 23, 29]. In contrast, only 19.8% received institution-based LTC [23, 29]. In addition to the individuals officially determined to be in need of care, a large number of older adults with utilization of informal LTC remain undetected, as they do not apply for a care degree [21].

The distribution illustrates that the majority of people in need of LTC receive community-based LTC. This meets the demand of the German LTC Insurance Act of 1995 to favor community-based LTC over institution-based LTC [17, 30]. Furthermore, it is in line with older adults' preference to live in their familiar surroundings for as long as possible [1].

1.6 Necessity for need-based approaches for community-dwelling older adults

In view of the individual, societal, and economic impact of LTC and its developments to date, as well as projected trends for the future, pressure for need-based and cost-effective approaches to ensure the provision and affordability of LTC services is growing [12, 31]. Furthermore, approaches that prevent utilization of LTC are requested [31].

To facilitate positive changes for society, highly relevant subpopulations must be identified, analyzed, and targeted through promising interventions [31]. In our societies, community-dwelling older adults make up a large proportion of the entire population. This subpopulation can be defined as individuals ≥ 65 years of age residing outside of institution-based LTC facilities [32]. Of the 18.0 million individuals ≥ 65 years in Germany in 2019, only 818,000 lived in facilities providing institutional LTC. This means that the vast majority lived in community-based settings [33]. Thus, this subpopulation should be located and analyzed in

detail. Necessary details to consider when setting up need-based approaches would be, e. g., sex differences or health-related factors [34, 35]. In addition to gathering details about characteristics of the community-dwelling individuals themselves, it is important to gain further knowledge about their circumstances (e. g., living arrangements) [34, 35]. Furthermore, different community-based LTC settings (e. g., individuals' homes, day care centers) and their particularities should be analyzed [31].

1.7 Objectives and contents of this thesis

The overall objective of this thesis is to examine relevant needs and approaches for target-oriented LTC in the highly relevant subpopulation of community-dwelling older adults in Germany. To reach this objective, the thesis included an analysis of determinants for utilization of informal and formal LTC in females and males (Article 1). Furthermore, the association of various types of physical activity (PA) with LTC in relevant subgroups was analyzed (Article 2). The cost-effectiveness of a non-pharmacological approach for appropriate LTC which addresses older adults with cognitive impairments in day care centers was analyzed (Article 3). All articles aimed to identify or address vulnerable groups with respect to utilization of LTC in the community setting.

In the following paragraphs, the research questions of all articles included in this thesis are outlined and a short summary of each chapter is given.

Chapter 2 focuses on the identification of relevant determinants for utilization of LTC in community-dwelling females and males ≥ 65 years from the KORA-Age study. Determinants for utilization of informal or formal LTC were identified using cross-sectional generalized estimating equation (GEE) logistic models at two timepoints (2011/12 and 2016). A longitudinal logistic regression model identified determinants for a transition to LTC between 2011/12 and 2016. Andersen's Behavioral Model of Health Services Use was used to select potential determinants [35, 36]. The results demonstrated that in both females and males, there were associations of utilization of and transition to LTC with the following determinants: higher age, multimorbidity, and disability. In addition, the determinant living alone was statistically significantly associated with utilization of LTC in females and males. However, its effect was twice as strong in males. In other words, males living alone were identified as a highly vulnerable group that should be taken into consideration for need-based LTC approaches.

Chapter 3 examines the association of PA with utilization of LTC in community-dwelling females and males ≥ 65 years from the KORA-Age study. Associations of relevant types of PA in old age (walking, exercise) were explored by applying GEE logistic models at two timepoints (2011/12 and 2016). Sex-specific associations were assessed using corresponding models stratified by sex. Descriptive analyses examined the proportion of individuals meeting the suggested minimum values in the German National Physical Activity Recommendations (GNPAR) for older adults. The results illustrate that every analyzed type of PA has a statistically significant association with non-utilization of LTC. However, GNPAR are only met by a low proportion of community-dwelling older adults. The proportion of older adults who meet the GNPAR is especially low among those with utilization of LTC. To conclude, older adults should be encouraged to engage in PA and there should be a focus on highly vulnerable groups, such as older adults with utilization of LTC or with disability, and their particular needs.

Chapter 4 investigates the cost-effectiveness of a multicomponent, non-pharmacological intervention versus care as usual in the community-based day care center setting. The target group was community-dwelling older adults with mild cognitive impairment or mild to moderate dementia. The intervention addresses *Motor stimulation*, *Activities of daily living stimulation*, *Cognitive stimulation*, and *Social functioning*; it is named MAKS. The data were analyzed from a societal perspective and alongside a cluster-randomized, multicenter trial with waitlist-group design. Measured effects were changes in scores of the “Mini-Mental Status Examination” and the “Erlangen Test of Activities of Daily Living in Persons with Mild Dementia or Mild Cognitive Impairment”. Incremental differences in effects and incremental cost differences were analyzed using generalized linear models. Cost-effectiveness acceptability curves and cost-effectiveness planes were used to examine cost-effectiveness. Six months after baseline, both effects were significantly better in the MAKS-group compared to the care as usual-group. Furthermore, lower costs were incurred for individuals in the MAKS-group as compared to their counterparts. Thus, the analyses showed that MAKS can be designated as a cost-effective intervention to stabilize cognitive abilities and the ability to perform ADLs for individuals with mild to moderate dementia in the day care center setting. These results helped to identify MAKS as a target-group specific and cost-effective approach to address the needs of individuals in need of LTC.

To finish this thesis, **Chapter 5** addresses practical implications and describes an outlook for future necessities.

1.8 Individual contribution of the author

The author of this thesis has contributed substantially to the concept of all three articles and the definition of the research questions. She wrote all three original manuscripts. She prepared and analyzed the data for Article 1 and Article 2. For Article 3, the author supported the data analysis and checked the analyses' results for plausibility. Furthermore, she completed all necessary publication-related tasks as the corresponding author for all articles and was the main contributor to editing and reviewing all articles.

2 Article 1

Gender-linked determinants for utilization of long-term care in community-dwelling adults 65+ in Germany: results from the population-based KORA-Age study

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Gender-linked determinants for utilization of long-term care in community-dwelling adults 65+ in Germany: Results from the population-based KORA-Age study

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ABSTRACT

Background: The number of people using long-term care (LTC) is increasing steadily, hence, demand for adequate services is rising. The purpose of this exploratory study was to identify relevant gender-linked determinants for utilization of LTC in community-dwelling older adults.

Methods: We examined 4077 females (52.7%) and males ≥ 65 years old (range: 65–97 years) between 2011/12 (t_1) and 2016 (t_2). Data originated from the population-based Cooperative Health Research in the Region of Augsburg (KORA)-Age study in southern Germany. A descriptive analysis assessed the amount of LTC used. Cross-sectional generalized estimating equation logistic models identified determinants for utilization of (in) formal LTC. Determinants for transition to LTC between t_1 and t_2 were examined using a longitudinal logistic regression model. Potential determinants were chosen according to Andersen's Behavioral Model of Health Services Use.

Results: At t_2 , 820 (20.1%) were LTC users with 527 (64.3%) being female. The average amount of informal LTC was higher in males, whereas the amount of formal LTC was higher in females. In both genders, higher age, multimorbidity, and disability were associated with utilization of and transition to LTC. Living alone was significantly associated with utilization of LTC in both genders, but its effect was two times stronger in males. Thus, it is considered the essential gender-linked determinant.

Conclusions: Gender-linked determinants must be considered when establishing demand-oriented policies. Future health programs should specifically target older individuals, especially males, living alone to improve their capabilities in activities of daily living to allow them to remain living longer and independently within community settings.

1. Background

In industrialized countries, females have a higher life expectancy and

live more years with non-fatal disability and frailty than males (Alexandre et al., 2012; Bélanger et al., 2002; Fried et al., 2001). In general, females have a higher rate of health care utilization, including medical

Abbreviations: ABMHS, Andersen's Behavioral Model of Health Services Use; ADL, activities of daily living; CI, 95% confidence interval; GEE, generalized estimating equation; HAQ-DI, Health Assessment Questionnaire Disability Index; IADL, instrumental activities of daily living; IQR, interquartile range; KORA, Cooperative Health Research in the Region of Augsburg; LTC, long-term care; OR, odds ratio; SD, standard deviation; SNCI, statutory nursing care insurance.

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and preventive services, whereas it is harder to get males involved in common health programs (Carroll et al., 2014; Ladwig et al., 2000; Redondo-Sendino et al., 2006). Gender differences exist not only in health status and utilization of health care, but also in the utilization of long-term care (LTC) services.

In 2017, 3.41 million people in Germany were in need of LTC. Of those, 2.15 million (63%) were females (Federal Statistical Office, 2018b). Comparing home-based versus institutional LTC, the majority (2.59 million, 76%) used home-based LTC. Of those using home-based LTC, 1.76 million (68%) used LTC exclusively from informal caregivers (informal LTC), whereas 830,000 (32%) used paid LTC from a skilled nurse (formal LTC) (Federal Statistical Office, 2018a). Generally, females and males use different types of LTC. Females tend to use institutional LTC (30%) more frequently than males (22%). In home-based LTC users, males more frequently (73%) use informal LTC than females (66%) (European Union, 2010; World Health Organization, 2008).

Differences between females and males play important roles in the utilization of health care services and LTC. The differences can be based on biological factors (e.g., anatomy, physiology) (“sex”) or on social constructs and cultural standards (e.g., behavior within society) (“gender”) (Alex et al., 2012; Krieger, 2003). Although gender and sex are important to distinguish, the utility of this differentiation is often lost at the empirical level due to the inability to capture the differences and its complexity (Alex et al., 2012; Jahn et al., 2014). Indeed, in many concepts the terms are intertwined, with gender usually seen as the broader concept (Alex et al., 2012; Krieger, 2003). This resulted in using the term “gender” in this study.

Gender-linked factors such as females' higher adherence to treatment regimens, support seeking attitude, willingness to adopt the sick-role, or higher frailty are important determinants for the utilization of, as well as for the transition to, different types of LTC and have been shown to interact with the development and management of health and disease (Geerlings et al., 2005; Green and Pope, 1999; Krieger, 2003; Lippa et al., 2009; Martikainen et al., 2009; Steinbeisser et al., 2018). Hence, gender-linked determinants (i.e., factors that influence the utilization of different types of LTC in females and males) need to be understood in order to prepare the health care system for increasing demand for LTC services and to meet the needs of people who use LTC (World Health Organization, 2015). Whereas previous studies have mainly focused on gender-linked determinants for the utilization of institutional LTC or exclusively on individuals with chronic conditions, little is known about the utilization of different types of LTC in older, community-dwelling (i.e., individuals living at home or in a community-based setting) individuals without specific diseases (Lo et al., 2015; Lippa et al., 2009). Considering that the majority of people receiving LTC are community-dwelling, detailed knowledge of this group might enable policy makers to plan and allocate resources adequately and set up corresponding political agendas (e.g., health promotional programs especially for males).

This study's main objective was to identify relevant gender-linked determinants for utilization of informal and formal LTC in older females and males in Germany. We also investigated gender-linked determinants for a transition to LTC over a time period of four years. Furthermore, we identified the differences between the average amount of received informal and formal LTC between females and males.

2. Materials and methods

2.1. Long-term care

LTC means support with daily activities for people who experience a decline in self-care on a long-term basis (World Health Organization, 2019, 2015). Daily activities consist of activities of daily living (ADLs) (e.g., washing, dressing, bathing) and instrumental activities of daily living (IADLs) (e.g., cooking, cleaning, grocery shopping). Depending on

the type of caregiver, LTC is composed of informal and formal LTC. Informal LTC consists of unpaid assistance from family members, neighbors, or friends and is provided mainly at home. Formal LTC is defined as paid care provided from a skilled nurse or institution, as well as paid services for household support, and can be provided at home, in the community, or in a skilled nursing facility (Organisation for Economic Co-operation and Development, 2018).

2.2. Germany's statutory nursing care insurance

To financially support the provision of both informal and formal LTC, Germany's statutory nursing care insurance (SNCI) was introduced in 1995. The SNCI provides partial reimbursement of costs for home-based and institutional LTC up to a pre-defined maximum amount. SNCI is based on the principle that home-based LTC should be preferred over institutional LTC to allow people to stay in familiar surroundings. Since institutional LTC is more expensive than home-based LTC, this principle also reduces the economic burden on the health care and insurance systems in Germany (Federal Ministry of Health, 2020).

People can apply for support and are evaluated to receive a “care level” based on the amount of assistance they need for (I)ADLs. The care level is determined by a needs assessment conducted by the Statutory Health Insurance Medical Service (Health Insurance Medical Service, 2020). People without a care level cannot file claims for support from nursing care insurance and have to pay LTC services completely out-of-pocket. As need for LTC varies over time, the care level can be re-evaluated when the individual's health status changes (Health Insurance Medical Service, 2020).

Based on the minimum amount of assistance needed in minutes per day, one out of four care levels (0, I, II, III) is assigned to the person applying for support. This process is based on legal guidelines used between 2012 and 2016 (after 2016: 5 care grades). Depending on the type of LTC, either cash transfers (mainly for informal LTC) or direct services (mainly for formal LTC) are provided (Bundesministerium der Justiz und für Verbraucherschutz, 1994; Health Insurance Medical Service, 2020).

2.3. Study population

Our data originated from the Cooperative Health Research in the Region of Augsburg (KORA)-Age study. The KORA-Age study is a part of KORA research, a platform of population-based surveys and their follow-up studies for health research in Germany (Holle et al., 2005). The KORA-Age study is a follow-up of four independent, cross-sectional samples that includes participants aged at least 65 years who completed health surveys between 1984 and 2001. Participants in these initial studies were randomly selected from population registries in the city of Augsburg and two adjacent counties (total population in 2016: 668,500) in the federal state of Bavaria (Statistische Ämter des Bundes und der Länder, 2020).

In 2008 (Age1/ t_0), 5986 individuals born before 1944 were considered the eligible study population. Of those, 4127 people participated in a standardized computer-assisted telephone interview (response rate: 68.9%) (Holle et al., 2000). The interview included detailed questions on sociodemographic characteristics, morbidity, and utilization of health care services. If the participant was unable to answer the questions, proxies (e.g., informal caregivers) were interviewed ($n = 185$, 4.5%). Of the 4127 participants, a stratified subsample ($n = 1079$) with 100 people per stratum (two strata divided by gender, each with five sub-strata divided by age) completed additional medical examinations.

The first follow-up in 2011/12 (Age2/ t_1) only included individuals from this subsample. Out of the 1079 eligible individuals, 822 participated in medical re-examinations and a further telephone interview (response rate: 76.2%); 257 were lost to follow-up.

The second follow-up took place in 2016 (Age3/ t_2). For this sample, the total sample of Age1 was re-invited. Additionally, individuals from

the initial four samples who were born before 1951, and thus were at least 65 years old in 2016, were invited to participate. Hence, 5986 individuals were considered the eligible study population at t_2 . Of those, 4083 completed telephone interviews and paper-based questionnaires (response rate: 68.2%). A total of 191 interviews were completed by proxies (4.7%).

Since only Age2 (t_1) and Age3 (t_2) included information about utilization of LTC, we considered these follow-up studies for analyses. For the main analysis, we used individuals from t_1 ($n = 822$) and t_2 ($n = 4083$) (see Fig. 1). A total of 567 individuals participated in both t_1 and t_2 and were therefore eligible for the longitudinal analyses.

Approval for the KORA-Age study was obtained by the Ethics Committee of the Bavarian Medical Association. Individuals agreed to participation with informed consent. Further details on data collection, sampling, study design and response rates can be found elsewhere (Grill et al., 2013; Holle et al., 2005).

2.4. Categorization of utilization of long-term care

Study participants were asked if they had used LTC due to their health status within the last three months (Holle et al., 2000). Types of LTC could be either the utilization of (1) a home nursing service (i.e., assistance with ADLs); (2) paid services for household support (i.e., assistance with IADLs); (3) assistance from family members, friends, or neighbors; or a combination of (1), (2), and/or (3). Using (1), (2), or both was considered to be utilization of formal LTC. Informal LTC was equivalent to using only (3). If individuals used both formal and informal LTC, they were categorized as using formal LTC (Geerlings et al., 2005).

Transition to LTC was defined as a change from no LTC at t_1 to the utilization of any type of LTC (informal or formal) at t_2 . The amount of LTC was based on respondent estimates and presented in minutes per day.

2.5. Determinants for utilization of and transition to long-term care

Andersen's Behavioral Model of Health Services Use (ABMHS) is a model commonly used to assess determinants for utilization of LTC (Andersen and Davidson, 2014; Andersen and Newman, 1973). ABMHS distinguishes predisposing, enabling and need factors. Predisposing factors describe sociodemographic characteristics, such as education or age. Enabling factors describe resources available to the individual which either allow or impede utilization of LTC (e.g., income, living arrangements). Need factors represent a person's physical and psychological health and functional status (Andersen and Davidson, 2014; Andersen and Newman, 1973; Babitsch et al., 2012). Relevant determinants for this study were identified through a detailed literature search. In KORA-Age, those determinants for utilization of and transition to LTC were collected through telephone interviews. According to ABMHS, they were classified as predisposing (age, gender, education), enabling (living arrangements, income, care level) and need (multimorbidity, disability) factors (Andersen and Newman, 1973; Babitsch et al., 2012). A commonly used predisposing factor within ABMHS is "marital status" (Andersen and Newman, 1973; Babitsch et al., 2012). Due to the high correlation between "marital status" and "living arrangement" ($|r| > 0.8$, multicollinearity) (Vatcheva et al., 2016), we chose "living arrangement" as the variable of interest since it represents accessibility of informal support.

Age referred to the individual's age based on the date of the telephone interview. Gender was dichotomized as "female" or "male". Education was expressed in years and included school education, education at university and vocational training. Living arrangements were dichotomized as either living "alone" or "not alone". Income was expressed by self-perceived income sufficiency (subjective income), a common approach in older adults to indicate individuals' evaluations of the relationship between objective income or wealth and their expenses (Cialani and Mortazavi, 2020). To categorize subjective income as either "sufficient" or "scarce/insufficient", participants were asked if, on

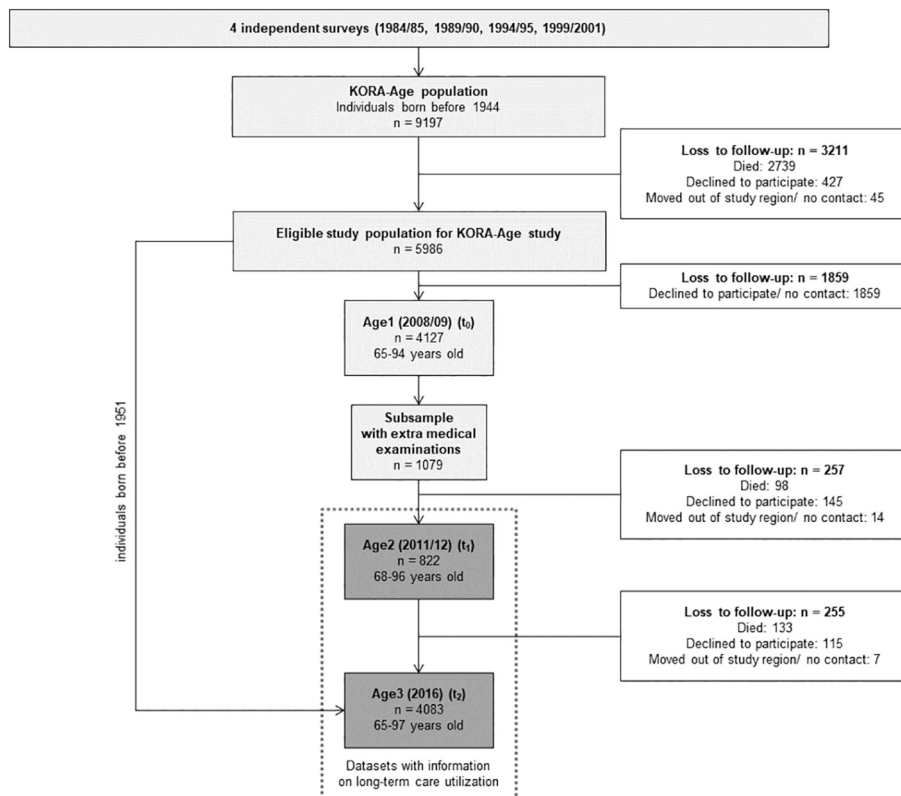


Fig. 1. Flow chart for KORA-Age population.

average, their income was enough to support them until the end of the month. Care level was categorized into “no care level” and the four care levels “0”, “I”, “II”, “III”. For regression analyses, the variable was dichotomized as “no care level” and “care level”. Multimorbidity reflects a sum score derived from self-reported conditions of the Charlson Comorbidity Index (Kirchberger et al., 2012). The index contains the following 13 conditions: heart disease, joint disease, lung disease, gastrointestinal disease, kidney disease, liver disease, Diabetes Mellitus, stroke, cancer, HIV, hypertension, neurological disease, and eye disease (Chaudhry et al., 2005). Disability was expressed by the Stanford Health Assessment Questionnaire Disability Index (HAQ-DI). This instrument assesses impairments in ADLs and IADLs and consists of 20 questions in eight domains: hygiene, dressing and grooming, standing up, eating, walking, reach, grip, and activities (Bruce and Fries, 2003; Fries, 2006). Domains range from 0 (no difficulty) to 3 (unable to perform). Each domain's score was built from the highest score in the current domain. The HAQ-DI was calculated using the mean of all eight domains. For this study, continuous values ranging from 0.000 to 3.000 were reported.

2.6. Statistical analyses

Characteristics of participants at both time points (t_1 : $n = 810$, t_2 : $n = 4077$, for information on missing values see below), dropouts, and the average amount of LTC in LTC users (longitudinal: $n = 563$, cross-sectional: t_1 : $n = 198$, t_2 : $n = 820$) were analyzed using descriptive statistics. Descriptive analyses included means and standard deviations (SD) for data with a normal distribution and additional information about median and interquartile range (IQR) for skewed data. Groups without LTC versus those with LTC utilization, as well as with formal versus informal LTC utilization, were compared using Pearson's chi-square or Fisher's exact tests ($\geq 25\%$ with $n < 5$ per cell) for independence for categorical variables and t -tests for continuous variables.

In order to find relevant gender-linked determinants for utilization of LTC at t_1 or t_2 (cross-sectional analysis with repeated measurements), we conducted two separate generalized estimating equation (GEE) logistic models based on an unstructured working correlation matrix in two stages. The model considers repeated measurements and their intra-subject correlation (Ballinger, 2004). Whereas mixed models mainly account for subject-specific effects, GEE models primarily account for population-averaged effects (Alencar et al., 2012). The latter were of interest in our study. First, we looked at determinants for utilization of LTC within the general study population. For these models, we assessed the interaction of gender with each independent variable through the calculation of the respective interaction terms. Then, we stratified the study population into females and males and analyzed determinants for females and males separately. We divided all GEE analyses into two stages: Stage 1 included all observations and compared utilization versus no utilization of any type of LTC. For stage 2, we conducted a subgroup-analysis with exclusively LTC users to compare utilization of formal versus informal LTC. All GEE analyses summed up observations from t_1 ($n = 802$) and t_2 ($n = 4024$) excluding observations in skilled nursing facilities ($n = 53$). At both time points, six independent variables (age, education, living arrangements, income, multimorbidity, disability score) were used. As “care level” represents an important enabling factor regarding the comparison of formal versus informal LTC, we additionally included this variable to all stage 2 analyses. As education and gender did not change between t_1 and t_2 , those variables were treated as fixed. All other variables were modelled as time dependent.

In order to find relevant determinants for a transition to LTC between t_1 and t_2 (longitudinal analysis), we conducted a separate regression model for each gender (Burgess, 2013). For the regression analyses, groups with a transition from LTC to no LTC, or informal LTC to formal LTC, or vice versa, were excluded. Thus, only individuals without LTC at both time points and those with a transition from no LTC to LTC remained in the final longitudinal sample ($n = 463$). Independent variables were the same as in the GEE models.

Since the outcomes of interest were determinants for utilization in community-dwelling individuals, we excluded individuals in skilled nursing facilities (t_1 : $n = 8$; t_2 : $n = 53$) in all analyses except the descriptive ones.

The dependent variable “utilization of LTC” had missing values in both informal and formal LTC for twelve individuals at t_1 and six at t_2 out of the total study population. We excluded those individuals using list-wise deletion, which reduced t_1 to 810 and t_2 to 4077 individuals (University of California, 2020; Yim, 2015). At t_2 , one individual had missing information about the utilization of a home nursing service and assistance of family members, friends, or neighbors. Another individual had missing information about paid services for household support. As they were a very small number of individuals in a subpart of the dependent variable, those missing values were imputed with single stochastic regression imputation using logistic regression through the fully conditional specification method (Liu and De, 2015). This imputation model assumes that missing values are missing at random, meaning that they are conditionally independent from the unobserved value and underlie an arbitrary missingness pattern (Berglund and Heeringa, 2014).

Relevant independent variables for the cross-sectional and longitudinal analyses also contained missing values. At t_1 , a total of 16 missing values (multimorbidity ($n = 9$, 1.1%), income ($n = 5$, 0.6%), disability score ($n = 1$, 0.1%), care level ($n = 1$, 0.1%)) were identified. At t_2 , a total of 96 missing values (income ($n = 49$, 1.2%), multimorbidity ($n = 35$, 0.9%), disability score ($n = 10$, 0.2%), education ($n = 2$, 0.1%)) were identified. Categorical values were imputed through single stochastic regression using the fully conditional specification method. For continuous variables, predictive mean matching was applied (Liu and De, 2015). Imputation of all missing values was based on identified auxiliary variables (correlation coefficient $> |0.4|$) and the models' independent variables (University of California, 2020).

Odds ratios (OR) and 95% confidence intervals (CI) were calculated. For all analyses in this study, variables with p -values ≤ 0.05 were considered significant. All statistical analyses were performed using SAS software, release 9.4 (SAS Institute, Cary, NC).

3. Results

3.1. Characteristics of the study sample

Table 1 gives an overview of female and male characteristics stratified by utilization of LTC at t_2 (Table A.1: time point t_1). The total sample's mean age was 75.1 years and ranged from 65 to 97 years. From 4077 individuals at t_2 , 820 (20.1%) received LTC. Of the non-LTC users, 1623 (49.8%) were females and 1634 (50.2%) males. Of the LTC users, 527 (64.3%) were females and 293 (35.7%) males.

Compared to male non-LTC users, female non-LTC-users were younger (mean years of age: 73.6 vs. 74.3), less educated (mean years of education: 10.7 vs. 12.1), more often living alone (37.5% vs. 14.9%), more often widowed (28.0% vs. 8.4%), and had a higher disability score (0.203 vs. 0.128). Similar trends could be seen when comparing female and male LTC users. The sample at t_1 showed similar characteristics (see Table A.1).

Out of the total study sample, 255 individuals dropped out between t_1 and t_2 (see Fig. 1). Dropouts were more likely to be older, live alone and have a higher multimorbidity and higher disability score.

3.2. Gender differences in the average amount of long-term care in long-term care users

The average amount of LTC per day in LTC users calculated via the longitudinal approach is shown in Table 2. Table A.2 shows the cross-sectional approach. Apart from formal LTC in males, the amount of LTC (expressed in mean minutes per day) increased between t_1 and t_2 . At both time points, both genders used informal LTC more frequently than

Table 1
Characteristics of females and males stratified by utilization of long-term care at t₂.

		N	Total n = 4077	No long-term care n = 3257 (79.9%)		p value	Long-term care ¹ n = 820 (20.1%)		p value
				Females (49.8%)	Males (50.2%)		Females (64.3%)	Males (35.7%)	
Predisposing factors									
Age in years	Total	4077	75.1 (6.7)	73.6 (5.8)	74.3 (6.1)	0.0007^a	80.1 (7.4)	79.6 (7.3)	0.4052 ^a
Education in years	Total	4075	11.3 (2.6)	10.7 (2.2)	12.1 (2.8)	<0.0001^a	10.2 (2.0)	11.7 (2.6)	<0.0001^a
Marital status	Marrried	4075	2708 (66.5%)	964 (59.4%)	1356 (83.0%)	<0.0001^b	193 (36.6%)	195 (66.8%)	<0.0001^b
	Single		173 (4.3%)	78 (4.8%)	59 (3.6%)		23 (4.4%)	13 (4.5%)	
	Divorced		260 (6.4%)	127 (7.8%)	81 (5.0%)		40 (7.6%)	12 (4.1%)	
	Widowed		934 (22.9%)	454 (28.0%)	137 (8.4%)		271 (51.4%)	72 (24.7%)	
Enabling factors									
Living arrangements	Alone	4077	1188 (29.1%)	609 (37.5%)	243 (14.9%)	<0.0001^b	258 (49.0%)	78 (26.6%)	<0.0001^b
	Not alone		2889 (70.9%)	1014 (62.5%)	1391 (85.1%)		269 (51.0%)	215 (73.4%)	
Living type	Community	4075	4022 (98.7%)	1623 (100%)	1632 (100%)	/	486 (92.2%)	281 (95.9%)	0.0398^b
	Residence		53 (1.3%)	0	0		41 (7.8%)	12 (4.1%)	
Income	Sufficient	4028	3336 (82.8%)	1361 (84.5%)	1384 (85.6%)	0.3764 ^b	374 (72.9%)	217 (75.1%)	0.5005 ^b
	Scarce/ insufficient		692 (17.2%)	249 (15.5%)	232 (14.4%)		139 (27.1%)	72 (24.9%)	
Care level	No care level	4077	3854 (84.5%)	1621 (99.9%)	1628 (99.6%)	0.2885 ^c	405 (76.9%)	200 (68.3%)	0.0222^b
	0		138 (3.4%)	2 (0.1%)	6 (0.4%)		72 (13.7%)	58 (19.8%)	
	1		67 (1.6%)	0	0		40 (7.6%)	27 (9.2%)	
	2		9 (0.2%)	0	0		7 (1.3%)	2 (0.7%)	
	3		9 (0.2%)	0	0		3 (0.4%)	6 (2.1%)	
Need factors									
Multimorbidity in no. of chronic conditions	Total	4042	2.3 (1.6)	2.1 (1.4)	2.0 (1.4)	0.6446 ^a	3.4 (1.7)	3.6 (1.6)	0.0987 ^a
Disability score (HAQ-DI)	Total	4067	0.372 (0.6)	0.203 (0.3)	0.128 (0.3)	<0.0001^a	1.223 (0.9)	1.134 (0.9)	0.1648 ^a
Care level	Hospital stays within last year	4076	877 (21.5%)	249 (15.3%)	301 (18.4%)	0.0300^b	199 (37.8%)	128 (43.7%)	0.3764 ^b
	No		3199 (78.5%)	1374 (84.7%)	1333 (81.6%)		327 (62.2%)	165 (56.3%)	

HAQ-DI: Health Assessment Questionnaire Disability Index. Bold numbers: significant at p ≤ 0.05.

Data presented as n (%)/mean (standard deviation). Any discrepancies in percentages due to rounding.

¹ Any type of long-term care (informal, formal, or a combination of informal and formal long-term care).

^a Based on t-test.

^b Based on chi²-test.

^c Based on Fisher's exact test.

Table 2
Average amount of long-term care per day in female and male long-term care users – longitudinal approach.

	t ₁				t ₂					
	N	Mean minutes	SD	Median minutes	IQR	N	Mean minutes	SD	Median minutes	IQR
Females (n = 273)										
Home based long-term care										
Informal long-term care	52	50.7	(74.5)	17.1	(8.6–55.7)	91	66.5	(123.8)	30.0	(8.6–75.0)
Formal long-term care	22	63.8	(200.6)	18.6	(10.0–32.9)	39	89.7	(224.7)	17.1	(8.6–45.0)
Of that ADL	8	137.3	(332.5)	20.0	(12.0–32.1)	19	139.2	(308.4)	12.9	(5.0–35.0)
Of that IADL	17	18.0	(12.8)	12.9	(8.6–21.4)	30	28.5	(65.0)	15.0	(8.6–17.1)
Skilled nursing facility ^a	3					7				
Males (n = 290)										
Home based long-term care										
Informal long-term care	26	93.4	(170.5)	45.0	(8.6–77.1)	63	158.0	(270.5)	42.9	(15.0–120.0)
Formal long-term care	11	29.1	(33.9)	17.1	(10.7–30.0)	22	28.5	(23.3)	25.7	(8.6–35.0)
Of that ADL	5	22.4	(23.5)	10.7	(10.0–30.0)	16	31.3	(25.8)	30.0	(8.6–52.5)
Of that IADL	7	29.7	(40.3)	17.1	(8.6–25.7)	8	15.8	(10.2)	12.9	(7.5–25.7)
Skilled nursing facility ^a	1					1				

ADL: activities of daily living. IADL: instrumental activities of daily living. SD: standard deviation. IQR: interquartile range.

Multiple answers for informal and formal long-term care (IADL, ADL) were possible; missing values were not imputed.

^a Amount of long-term care in skilled nursing facilities was not assessed in questionnaires.

formal LTC. Males used informal LTC in greater amounts of time than females. In contrast, females used formal LTC more frequently and when used, in greater amounts of time than males.

3.3. Determinants for utilization of long-term care

Table 3 shows the general determinants (i.e., those independent from gender) for utilization of LTC versus no utilization of LTC (stage 1) and of formal versus informal LTC in LTC users (stage 2). At stage 1, higher age (OR: 1.05; CI: 1.04–1.07), and higher education (OR: 1.05; CI: 1.01–1.10) increased the chance for utilization of LTC, whereas male gender (OR: 0.68; CI: 0.55–0.85) decreased the chance for utilization of LTC. Living alone increased the odds for utilization of LTC by a factor of 1.50 (CI: 1.21–1.85). Each additional chronic condition increased the odds for utilization of LTC by a factor of 1.32 (CI: 1.23–1.41). A higher disability score (OR: 9.88; 7.99–12.21) was strongly related to the utilization of LTC.

At stage 2, higher age (OR: 1.03; CI: 1.01–1.05), higher education (OR: 1.11; CI: 1.04–1.19), living alone (OR: 2.68; CI: 1.93–3.73), receiving a care level (OR: 4.16; CI: 2.76–6.26), and a higher disability score (OR: 1.47; 1.17–1.83) were associated with a higher chance for utilization of formal LTC in comparison to informal LTC.

3.4. Gender-linked determinants for utilization of long-term care

Determinants for utilization of LTC in females can be found in Table 4. At stage 1, higher age, higher multimorbidity and a higher disability score increased the odds for utilization of LTC in females. At stage 2, higher age, higher education, living alone, receiving a care level, and a higher disability score increased the odds for utilization of formal LTC in females.

Determinants for utilization of LTC in males can be found in Table 5. At stage 1, all factors except income could be detected as significant determinants for utilization of LTC in males. At stage 2, only living alone and receiving a care level were associated with a higher chance for utilization of formal LTC as compared to informal LTC in males.

Determinants for utilization of LTC (stage 1) and formal versus informal LTC (stage 2) between females and males differed to some extent (Table 4, Table 5). While females had 1.18 times higher odds (CI: 0.91–1.53) for utilization of LTC when they lived alone, the odds in males were 2.45 (CI: 1.74–3.45). The gender difference was significant (interaction term “living alone * gender”, OR: 2.06, CI: 1.35–3.16, reference: females).

Table 3

Influence of ABMHS factors on utilization of long-term care – GEE logistic model.

	Stage 1: LTC vs. no LTC ^a			Stage 2: formal vs. informal LTC ^b		
	Odds ratio	95% confidence interval	p value	Odds ratio	95% confidence interval	p value
Predisposing factors						
Gender (ref.: female)	0.68	[0.55; 0.85]	0.0008	0.94	[0.66; 1.34]	0.7490
Age in years	1.05	[1.04; 1.07]	<0.0001	1.03	[1.01; 1.05]	0.0116
Education in years	1.05	[1.01; 1.10]	0.0147	1.11	[1.04; 1.19]	0.0017
Enabling factors						
Living arrangements (ref: not alone)	1.50	[1.21; 1.85]	0.0002	2.68	[1.93; 3.73]	<0.0001
Income (ref: sufficient)	1.17	[0.91; 1.49]	0.2227	1.02	[0.72; 1.44]	0.9027
Care level (ref: no care level)	/	/	/	4.16	[2.76; 6.26]	<0.0001
Need factors						
Multimorbidity in no. of chronic conditions	1.32	[1.23; 1.41]	<0.0001	0.96	[0.87; 1.04]	0.3209
Disability score (HAQ-DI)	9.88	[7.99; 12.21]	<0.0001	1.47	[1.17; 1.83]	<0.0007

ABMHS: Andersen's Behavioral Model of Health Services Use (predisposing, enabling, need factors). GEE: generalized estimating equation. LTC: long-term care. HAQ-DI: Health Assessment Questionnaire Disability Index.

Bold numbers: significant at $p \leq 0.05$.

Sample for generalized estimating equation: sum of t_1 ($n = 802$) and t_2 sample ($n = 4024$).

^a Stage 1: Determinants for utilization of long-term care. Model includes all observations ($n = 4826$); observations divided by utilization of either long-term care ($n = 957$) or no long-term care ($n = 3869$).

^b Stage 2: Determinants for utilization of formal vs. informal long-term care. Model includes all observations with utilization of long-term care ($n = 957$); observations divided by utilization of either formal ($n = 332$) or informal long-term care ($n = 625$).

Regarding the need factor disability, the association for utilization of LTC was stronger in females (OR: 10.51, CI: 7.94–13.91) than in males (OR: 9.16, CI: 6.68–12.56). Other relevant determinants at stage 1 were similar in females and males. At stage 2, each year of education increased the odds for utilization of formal LTC by a factor of 1.19 (CI: 1.08–1.30) in females and 1.06 (CI: 0.96–1.16) in males. Living alone had a stronger association with utilization of formal LTC in males (OR: 3.85; CI: 2.23–6.65) than in females (OR: 2.06; CI: 1.38–3.09). The gender difference was significant (interaction term “living alone * gender”, OR: 1.95, CI: 1.01–3.77, reference: females). A higher disability score showed a significant association with utilization of formal LTC in females (OR: 1.76; CI: 1.33–2.32), but not in males (OR: 1.09; CI: 0.74–1.60). The gender difference was significant (interaction term “disability score * gender”, OR: 0.68, CI: 0.47–0.99, reference: females).

3.5. Gender-linked determinants for a transition to long-term care

Table 6 displays the gender-linked determinants for a transition from no LTC at t_1 to LTC at t_2 . In both females (OR: 1.17; CI: 1.09–1.26) and males (OR: 1.15; CI: 1.07–1.23), the odds for a transition from no LTC to LTC increased with age. Income had a significant influence on a transition to LTC only in females, not in males. Females who classified their income as “scarce/insufficient”, had 2.63 times (CI: 1.04–6.69) higher odds for a transition to LTC than those who classified it as “sufficient”. Multimorbidity in females (OR: 1.35; CI: 1.01–1.80) was significantly associated with a transition to LTC. For both females (OR: 5.06; CI: 1.72–14.90) and males (OR: 7.89; CI: 2.94–21.22), a higher disability score was strongly associated with a transition to LTC.

4. Discussion

This cohort study is among the first to reveal relevant gender-linked determinants for utilization of and transition to LTC in older, community-dwelling females and males. We found that in both genders, the determinants higher age, multimorbidity, and disability score increased the odds for utilization of and transition to LTC. In both genders, living alone was strongly associated with utilization of LTC. In males, this effect was even stronger. Thus, living alone is considered the essential gender-linked determinant for utilization of LTC.

Our study gives detailed insight into the average amount of LTC at two time points. Although research states the importance of measuring the amount of LTC, there is a lack of information about the actual amount of LTC used, especially for informal LTC (Bettger et al., 2012;

Table 4
Influence of ABMHS factors on utilization of long-term care in females – GEE logistic model.

	Stage 1: LTC vs. no LTC ^a			Stage 2: formal vs. informal LTC ^b		
	Odds ratio	95% confidence interval	p value	Odds ratio	95% confidence interval	p value
Predisposing factors						
Age in years	1.06	[1.03; 1.08]	<0.0001	1.05	[1.02; 1.08]	0.0035
Education in years	1.05	[0.98; 1.12]	0.1462	1.19	[1.08; 1.30]	0.0004
Enabling factors						
Living arrangements (ref: not alone)	1.18	[0.91; 1.53]	0.2220	2.06	[1.38; 3.09]	0.0004
Income (ref: sufficient)	1.15	[0.84; 1.59]	0.3793	1.18	[0.76; 1.82]	0.4594
Care level (ref: no care level)	/	/	/	3.24	[1.91; 5.50]	<0.0001
Need factors						
Multimorbidity in no. of chronic conditions	1.26	[1.16; 1.37]	<0.0001	0.97	[0.87; 1.08]	0.5946
Disability score (HAQ-DI)	10.51	[7.94; 13.91]	<0.0001	1.76	[1.33; 2.32]	<0.0001

ABMHS: Andersen's Behavioral Model of Health Services Use (predisposing, enabling, need factors) | GEE: generalized estimating equation | LTC: long-term care | HAQ-DI: Health Assessment Questionnaire Disability Index.

Bold numbers: significant at $p \leq 0.05$.

Sample for generalized estimating equation: sum of t_1 (n = 396) and t_2 sample (n = 2109).

^a Stage 1: Determinants for utilization of long-term care. Model includes all observations (n = 2505); observations divided by utilization of either long-term care (n = 610) or no long-term care (n = 1895).

^b Stage 2: Determinants for utilization of formal vs. informal long-term care. Model includes all observations with utilization of long-term care (n = 610); observations divided by utilization of either formal (n = 210) or informal long-term care (n = 400).

Table 5
Influence of ABMHS factors on utilization of long-term care in males – GEE logistic model.

	Stage 1: LTC vs. no LTC ^a			Stage 2: formal vs. informal LTC ^b		
	Odds ratio	95% confidence interval	p value	Odds ratio	95% confidence interval	p value
Predisposing factors						
Age in years	1.06	[1.03; 1.08]	<0.0001	1.00	[0.97; 1.04]	0.8041
Education in years	1.07	[1.01; 1.13]	0.0315	1.06	[0.96; 1.16]	0.2482
Enabling factors						
Living arrangements (ref: not alone)	2.45	[1.74; 3.45]	<0.0001	3.85	[2.23; 6.65]	<0.0001
Income (ref: sufficient)	1.22	[0.83; 1.80]	0.3097	0.83	[0.46; 1.50]	0.5363
Care level (ref: no care level)	/	/	/	6.39	[3.21; 12.72]	<0.0001
Need factors						
Multimorbidity in no. of chronic conditions	1.42	[1.28; 1.57]	<0.0001	0.93	[0.80; 1.09]	0.3887
Disability score (HAQ-DI)	9.16	[6.68; 12.56]	<0.0001	1.09	[0.74; 1.60]	0.6526

ABMHS: Andersen's Behavioral Model of Health Services Use (predisposing, enabling, need factors). GEE: generalized estimating equation. LTC: long-term care. HAQ-DI: Health Assessment Questionnaire Disability Index.

Bold numbers: significant at $p \leq 0.05$.

Sample for generalized estimating equation: sum of t_1 (n = 406) and t_2 sample (n = 1915).

^a Stage 1: Determinants for utilization of long-term care. Model includes all observations (n = 2321); observations divided by utilization of either long-term care (n = 347) or no long-term care (n = 1974).

^b Stage 2: Determinants for utilization of formal vs. informal long-term care. Model includes all observations with utilization of long-term care (n = 347); observations divided by utilization of either formal (n = 122) or informal long-term care (n = 225).

Table 6
Influence of ABMHS factors on transition to long-term care in females and males – logistic regression models.

	Determinants for transition in females ^a			Determinants for transition in males ^b		
	Odds ratio	95% confidence interval	p value	Odds ratio	95% confidence interval	p value
Predisposing factors						
Age in years	1.17	[1.09; 1.26]	<0.0001	1.15	[1.07; 1.23]	0.0001
Education in years	1.08	[0.91; 1.31]	0.3683	0.99	[0.86; 1.15]	0.9124
Enabling factors						
Living arrangements (ref: not alone)	0.83	[0.38; 1.81]	0.6374	1.80	[0.68; 4.77]	0.2349
Income (ref: sufficient)	2.63	[1.04; 6.69]	0.0416	1.44	[0.52; 3.97]	0.4855
Need factors						
Multimorbidity in no. of chronic conditions	1.35	[1.01; 1.80]	0.0407	1.22	[0.94; 1.59]	0.1349
Disability score (HAQ-DI)	5.06	[1.72; 14.90]	0.0033	7.89	[2.94; 21.22]	<0.0001

ABMHS: Andersen's Behavioral Model of Health Services Use (predisposing, enabling, need factors). GEE: generalized estimating equation. LTC: long-term care. HAQ-DI: Health Assessment Questionnaire Disability Index.

Bold numbers: significant at $p \leq 0.05$.

^a Determinants for transition to long-term care in females without long-term care at t_1 . Model includes all females (n = 205) with a transition from no long-term care (t_1) to either informal or formal long-term care (t_2) (n = 55) compared to individuals without a transition (n = 150).

^b Determinants for transition to long-term care in males without long-term care at t_1 . Model includes all males (n = 258) with a transition from no long-term care (t_1) to either informal or formal long-term care (t_2) (n = 40) compared to individuals without a transition (n = 218).

van den Berg and Spauwen, 2006). In our study, the amount of informal LTC used was higher than the amount of formal LTC used in both genders. This agrees with previous observations and emphasizes the importance of informal caregivers in compensating for the steadily increasing lack of skilled nurses in our society (Katz et al., 2000; Steinbeisser et al., 2018; Wimo et al., 2002). As shown in previous research, females received lower amounts of informal LTC than males (Katz et al., 2000; Noël-Miller, 2010; Wimo et al., 2002). The reason for this difference might be related to various gender-linked phenomena. First, about 80% of spouses are the main, or even sole, informal caregivers for community-dwelling older adults (Fuino et al., 2020; Lima et al., 2008). Females in our study, as well as in other studies (Feld et al., 2010; Katz et al., 2000), tend to live more frequently alone than males. The availability of a spouse as an informal caregiver is therefore limited and could result in the utilization of formal LTC as a substitute (Fuino et al., 2020). Second, remaining structural conditions and cultural expectations (i.e., gender role models) for females providing most of the household labor (i.e., unpaid work) and giving hands-on-care (e.g., raising children) result in females being more willing to provide informal LTC than males (Calasanti and Bowen, 2006). Third, learned skills in household work and caregiving influence whether a person is willing to provide LTC by her- or himself alone or to accept formal LTC services as a supplement or even substitute for informal LTC (Calasanti and Bowen, 2006). Due to historical behaviors and existing gender role models, males are more willing to accept formal assistance for the provision of LTC for their co-habiting spouse in need of LTC.

In contrast, females received a higher amount of formal LTC than males. One explanation might be that older females tend to have a more severely impaired health status (e.g., higher disability score) (Fu et al., 2017; Katz et al., 2000).

General determinants for utilization of home-based LTC were discussed in former studies and are similar to our results (Steinbeisser et al., 2018; Wong et al., 2010; Wu et al., 2014). It has to be pointed out that higher age, higher multimorbidity and a higher disability score were associated with utilization of LTC regardless of gender. The mentioned factors were also significant predictors for a transition to LTC.

Differences become apparent when examining determinants for utilization of and transition to LTC for each gender separately. First, there are determinants like education and income that are only significant in one gender. Literature states that higher education is associated with a higher utilization of formal health services (Dunlop et al., 2000). After stratifying by gender, our study shows that higher education is associated with utilization of formal LTC in females, but not in males. This result is in line with Fu et al. (2017), who analyzed factors associated with older individuals' needs for LTC and stratified their sample by gender. Higher education showed a significant association with the utilization of formal LTC in females, but not in males (Fu et al., 2017). It is interesting that for utilization of LTC, "scarce/insufficient" income was not a relevant determinant, whereas for transition to LTC it played a significant role in females, but not in males. One reason could be that self-perceived income insufficiency can indicate low socioeconomic status, which has a stronger association with utilization of LTC in females than in males (Cialani and Mortazavi, 2020; Fu et al., 2017; Wang et al., 2020). However, gender-specific information on socioeconomic status linked with transition to LTC could not be found in the literature and therefore should be part of future research.

Second, there are determinants like disability, care level, and living arrangements that are significant in both genders but have stronger associations in one gender. In females, disability score had a stronger association with utilization of LTC than in males. Regarding formal versus informal LTC, a higher disability score was only significantly associated with utilization of LTC in females, not in males. The interaction term between gender and disability score was significant. This result might be explained by the higher burden of morbidity or frailty in older age for females that is associated with the incidence of disability (Alexandre et al., 2012; Bélanger et al., 2002; Fried et al., 2001). In

contrast, the determinant "disability score" in our study showed a stronger association with a transition to LTC in males than in females. Whereas females who use LTC tend to be more severely impaired, males who use LTC range from being mildly to severely impaired; this could be a driving factor behind the willingness to accept support (Calasanti and Bowen, 2006). Another determinant that was significant in both genders but had a stronger association in males was "care level". In both genders, receiving a care level was strongly associated with utilization of formal LTC. If an individual receives a care level, financial support from SNCI through cash transfers or direct services is provided. As formal LTC results in high costs for the individual, the care level can serve as a financial support and thus lead to the decision to use formal rather than informal LTC. This is consistent to mentioned trends of countries where state responsibility or subsidiary schemes are in place (Fuino et al., 2020). In males, the association of receiving a care level with utilization of formal LTC was substantially stronger than in females. To the knowledge of the authors, appropriate literature about "receiving a care level associated with utilization of LTC in different genders" is missing. Additionally, care level systems vary substantially in different countries and underlie continuous changes. These facts lead to the need for further investigation regarding our mentioned result. Additionally, due to the small number of individuals with a care level in our community-dwelling cohort, this result ought to be researched in a larger cohort.

Another result to point out was that living alone was strongly associated with utilization of LTC in general, and particularly with formal LTC. This effect estimate for both utilization of LTC and utilization of formal LTC was substantially higher in males. Thus, we considered living alone the essential gender-linked determinant for utilization of LTC in males. Historically, males receive support in ADLs and IADLs from their female spouse and tend to have lower skills in household work (Calasanti and Bowen, 2006; Feld et al., 2010; Fuino et al., 2020; Katz et al., 2000). If they live alone, lack of support in the household results in a need for LTC and if informal caregivers are not available, there is a need for formal LTC (Calasanti and Bowen, 2006; Fuino et al., 2020). To further understand the gender differences in individuals living alone, more research is needed to address assumptions such as unmet needs of LTC.

In the future, the proportion of older individuals in our communities around the world will increase dramatically, whereas the number of potential informal caregivers other than spouses (e.g., children) will decrease. Furthermore, the predominant living arrangements will be "living alone". As these trends are strongly associated with utilization of expensive, formal LTC, the demand for skilled nurses in community settings will steadily increase and costs will rise (World Health Organization, 2015).

4.1. Strengths and limitations

Strengths of this study are various ones. First, KORA-studies are based on standardized assessments and use stringent quality-control, which ensure high data quality. We conducted a detailed analysis of the amount of LTC divided into ADLs and IADLs, which are associated with gender-linked attributes. This allowed the needs of each individual to be adequately addressed by the appropriate party (e.g., skilled nurses for ADL support, household maintenance for IADL support). It also has to be acknowledged that the operationalization of "utilization of LTC" instead of "need of LTC" enabled us to open a highly relevant research field. Furthermore, the methodological approach using the GEE logistic model allowed us to consider repeated measurements. The longitudinal analysis reinforced our cross-sectional results.

Additionally, our study sample's proportions for utilization of different types of LTC were similar to the ones in Germany, which might reflect generalizable results (Federal Statistical Office, 2018b). However, it has to be mentioned that the federal statistics are limited to individuals with a confirmed care level (i.e., "in need of LTC") and hence only report a subsample of all LTC users.

Nevertheless, there are limitations which deserve mentioning. First, female LTC users outnumbered male LTC users, which resulted in an imbalance of power between the two gender-strata. However, in comparison to other identified questionnaire studies addressing determinants for utilization of informal and formal LTC in older community-dwelling adults (e.g., (Fu et al., 2017; Geerlings et al., 2005; Wu et al., 2014), $n < 4000$), our study cohort was large.

Another caveat to consider is the potential for information bias due to self-reports based on recall-methods. However, literature has proven that self-reports remain as a valid method to collect data on utilization of health care services (Leggett et al., 2016) and are common methods e.g. to assess amount of informal LTC (van den Berg and Spauwen, 2006). Additionally, a recall period of three months in questionnaires has previously been proven to be appropriate (Seidl et al., 2019).

Furthermore, attrition is a common problem in studies with older adults. An attrition analysis in a former study has shown that dropouts received more LTC and had a poorer health status at t_1 [14]. This fact might have resulted in diminishing the strength of some associations.

Another limitation that exists due to limited data was that we were unable to divide informal LTC by IADLs and ADLs. This is of great importance when identifying further details about gender-linked determinants (Katz et al., 2000). In future studies, this aspect, as well as major drivers for need of LTC (e.g., dementia) should be addressed.

Lastly, an important topic to critically address is that the gender-aspects discussed were limited to females and males. Future research should address a modern understanding of gender to allow adequate, gender-sensitive provision of LTC.

5. Conclusions

In summary, there are relevant general and gender-linked determinants for utilization of and transition to LTC in older, community-dwelling females and males that should be considered to precisely plan for future needs for LTC services. Living alone can be considered the essential determinant for utilization of LTC in general and for utilization of formal LTC in particular. Thus, individuals living alone should be the focus of prevention and health-promotion programs in order to improve their capabilities in ADLs and thus allow them to live independently in community-settings for as long as possible. Since living alone was the essential gender-linked determinant in males, and because they are a known “hard-to-reach” target-group, gender-specific health programs for males need to be implemented according to established good practice guidelines.

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Kathrin Steinbeisser: conceptualization, methodology, formal analysis, investigation, writing – original draft, writing – review and editing, visualization

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Hildegard Seidl: conceptualization, methodology, writing – review and editing, supervision.

Declaration of competing interest

None.

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Ethics approval

All investigations have been conducted according to the principles expressed in the Declaration of Helsinki.

Consent to participate

Written informed consent was obtained from all individual participants included in the study.

Availability of data and material

The data are subject to national data protection laws and restrictions were imposed by the Ethics Committee to ensure data privacy of the study participants. Therefore, data cannot be made freely available in a public repository. However, data can be requested through individual project agreements via the KORA-PASST tool under <https://epi.helmholtz-muenchen.de/>

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	0	0	0	0	0	0
	1	35 (4.3%)	0	2 (0.6%)	20 (15.5%)	13 (19.1%)
	2	10 (1.2%)	0	0	3 (2.3%)	7 (10.3%)
	3	3 (0.4%)	0	0	3 (2.3%)	0
Hospital stays	yes	208 (25.7%)	51 (18.8%)	79 (23.4%)	51 (39.2%)	27 (39.7%)
within last year	no	600 (74.3%)	221 (81.3%)	259 (76.6%)	79 (60.8%)	41 (60.3%)
				0.1658 ^b		0.9482 ^b

HAQ-DI: Health Assessment Questionnaire Disability Index | Bold numbers: significant at $p \leq 0.05$ | ^a any type of long-term care (informal, formal, or a combination of informal and formal long-term care)

Data presented as n (%)/ mean (standard deviation) | Any discrepancies in percentages due to rounding | ^a based on t-test | ^b based on chi²-test | ^c based on Fisher's exact test

Table A.2: Average amount of long-term care per day in female and male long-term care users – cross sectional approach

	KORA-Age2 (t ₁)					KORA-Age3 (t ₂)				
	Females (n = 130)					Males (n = 68)				
	N	Mean minutes	SD	Median minutes	IQR	N	Mean minutes	SD	Median minutes	IQR
Home based long-term care										
Informal long-term care	107	63.9	(112.0)	25.7	(8.6-25.7)	55	144.2	(229.0)	60.0	(12.9-150.0)
Formal long-term care	46	46.7	(139.9)	19.6	(10.7-19.6)	27	37.3	(48.7)	18.6	(12.9-18.6)
of that ADL	21	74.3	(205.3)	20.0	(9.3-37.5)	16	23.2	(22.6)	12.9	(9.3-37.5)
of that IADL	29	20.3	(15.8)	17.1	(8.6-25.7)	16	39.8	(60.4)	17.1	(12.9-30.0)
Skilled nursing facility^a	6					2				
Home based long-term care										
Informal long-term care	426	84.2	(161.4)	30.0	(8.6-90.0)	246	129.3	(224.1)	34.3	(8.6-137.1)
Formal long-term care	164	53.3	(132.9)	17.1	(8.6-35.7)	95	48.3	(132.9)	17.1	(8.6-30.0)
of that ADL	94	57.5	(162.7)	12.9	(7.0-30.0)	58	41.7	(125.8)	15.0	(5.0-30.0)
of that IADL	101	33.0	(54.7)	17.1	(8.6-25.7)	54	40.3	(107.2)	12.9	(8.6-25.7)
Skilled nursing facility^a	41					12				

ADL: activities of daily living | IADL: instrumental activities of daily living | SD: standard deviation | IQR: interquartile range
 Multiple answers for informal and formal long-term care (IADL, ADL) were possible; Missing values were not imputed

^a Amount of long-term care in skilled nursing facilities was not assessed in questionnaires

3 Article 2

Association of physical activity with utilization of long-term care in community-dwelling older adults in Germany: results from the population-based KORA-Age observational study

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RESEARCH

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Association of physical activity with utilization of long-term care in community-dwelling older adults in Germany: results from the population-based KORA-Age observational study

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Abstract

Background: Physical activity (PA) is a proven strategy to prevent chronic diseases and reduce falls. Furthermore, it improves or at least maintains performance of activities of daily living, and thus fosters an independent lifestyle in older adults. However, evidence on the association of PA with relevant subgroups, such as older adults with utilization of long-term care (LTC), is sparse. This knowledge would be essential for establishing effective, need-based strategies to minimize the burden on healthcare systems due to the increasing need for LTC in old age.

Methods: Data originate from the 2011/12 (t_1) baseline assessment and 2016 (t_2) follow-up of the population-based Cooperative Health Research in the Region of Augsburg (KORA-)Age study in southern Germany. In 4812 observations of individuals ≥ 65 years, the association between various types of PA (walking, exercise (i. e., subcategory of PA with the objective to improve or maintain one or more components of physical fitness), walking+exercise) and utilization of LTC (yes/no) was analyzed using generalized estimating equation logistic models. Corresponding models stratified by sex (females: 2499 observations; males: 2313 observations) examined sex-specific associations. Descriptive analyses assessed the proportion of individuals meeting the suggested minimum values in the German National Physical Activity Recommendations for older adults (GNPAR).

Results: All types of PA showed a statistically significant association with non-utilization of LTC in the entire cohort. "Walking+exercise" had the strongest association with non-utilization of LTC in the entire cohort (odds ratio (OR): 0.52, 95% confidence interval (CI): 0.39–0.70) and in males (OR: 0.41, CI: 0.26–0.65), whereas in females it was "exercise" (OR: 0.58; CI: 0.35–0.94). The proportion of individuals meeting the GNPAR was higher among those without utilization of LTC (32.7%) than among those with LTC (11.7%) and group differences were statistically significant ($p \leq 0.05$).

Conclusions: The GNPAR are rarely met by older adults. However, doing any type of PA is associated with non-utilization of LTC in community-dwelling older adults. Therefore, older adults should be encouraged to walk or exercise

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regularly. Furthermore, future PA programs should consider target-groups' particularities to reach individuals with the highest needs for support.

Keywords: Sports, Health care utilization, Nursing care, Elderly, Gender, Prevention, Health promotion, Active lifestyle, Generalized estimating equations, National guidelines

Background

The beneficial effects of regular physical activity (PA) on older adults' physical, psychological, and social well-being have been shown in various systematic reviews [1–3]. Furthermore, PA is a proven strategy to promote health, prevent chronic diseases, and reduce falls. It also improves or at least maintains performance of activities of daily living, and thus fosters an independent lifestyle in older adults [4]. Despite PA's health benefits, older adults rarely follow the World Health Organization's (WHO's) recommendation of 150 minutes of moderate PA (on a scale relative to an individual's personal capacity between 0 and 10: usually 5 or 6) per week or 75 minutes of vigorous PA (rating: usually 7 or 8) per week [5–8]. Most high-income countries report that 20–60% of adults ≥ 65 years follow WHO's recommendations [7, 8]. Regarding PA patterns (e. g., duration, type, frequency) and PA's effects, differences between sexes should also be considered [8–12]. For example, females are less likely to do PA regularly than males [8]. Also, older males tend to do more vigorous exercise than older females [9].

The current evidence about PA's health benefits for older adults and particularities of PA in relevant subpopulations (e. g., sexes), as well as the low proportion of older adults meeting WHO's recommendations, are important to consider as populations age worldwide. By 2030, one in six people will be 60 years of age or older [13]. This trend is linked to an increasing burden on health care systems caused by older adults' considerable need for health care and long-term care (LTC) services [13]. The increasing demand for LTC services in old age is one of the main cost drivers in health care; thus, it is advisable that politicians and public health professionals seek out potentially effective strategies, such as PA interventions, to reduce the need for LTC services in old age [14].

WHO states in its "Guidelines on physical activity and sedentary behaviour" that notable gaps in evidence regarding the behavior of specific subpopulations remain, thus inhibiting the development of target-oriented programs for them [5]. In old age, community-dwelling older adults with and without LTC make up a large proportion of the entire population, and are thus a highly considerable subpopulation in our societies [13]. However, comprehensive evidence about the role of PA with respect to utilization of LTC in this subpopulation is sparse.

Furthermore, deeper knowledge about the implications of distinct types of PA, which, in old age, might be, e. g., walking or exercise, as well as the consideration of sex-specific particularities in regard to utilization of LTC, is lacking [15–18]. Additionally, detailed analyses comparing older community-dwelling adults with and without utilization of LTC meeting PA recommendations are still missing. This inhibits the assessment of this subpopulation's vulnerability and the benefits of promoting PA in this group.

In light of the existing evidence and its gaps, it is highly important to gain further knowledge about PA, its implications on utilization of LTC in relevant subpopulations like community-dwelling older adults, and subpopulation particularities. This information would enable policy-makers to identify vulnerable target groups and set up need-based PA interventions, whose effects could mitigate the growing public health problem of increasing demand for LTC services.

To contribute to closing the existing research gaps, this study has the following objectives: 1) to determine the association of PA with utilization of LTC in community-dwelling older adults; 2) to detect differences regarding the sex-specific association of PA with utilization of LTC in females and males; 3) to determine the proportion of community-dwelling older adults with and without utilization of LTC meeting the suggested minimum values for distinct types of PA according to the "German National Physical Activity Recommendations" for older adults (GNPAR).

Methods

Study population

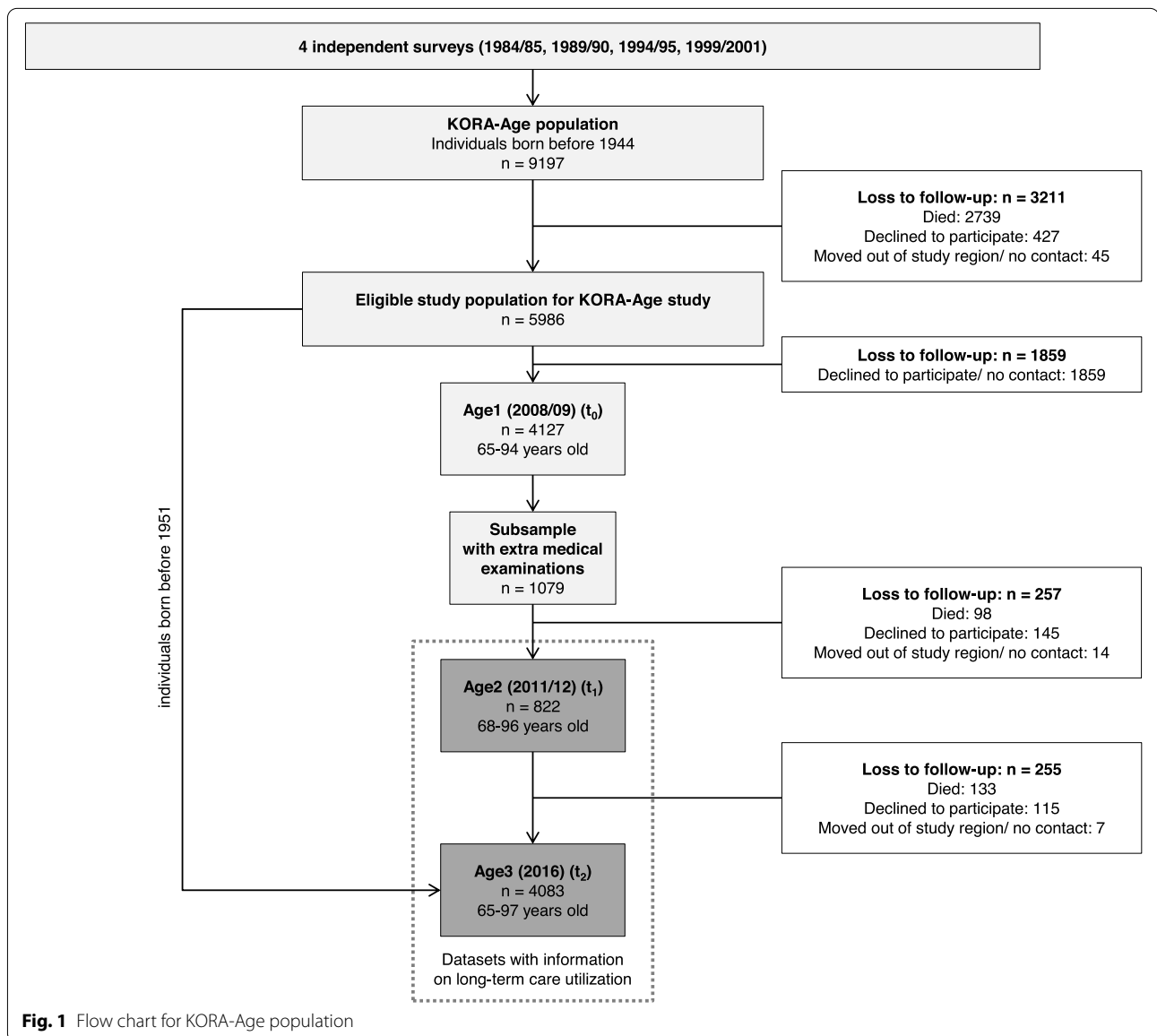
We used data from the Cooperative Health Research in the Region of Augsburg (KORA)-Age study, which is a part of the regional KORA research platform for population-based health research in Germany. The KORA research platform consists of population-based surveys and their follow-up studies. The KORA-Age study is a follow-up of participants ≥ 65 years from four independent cross-sectional samples who completed health surveys conducted between 1984 and 2001 [19]. A population-representative selection of participants from population registries in the city of Augsburg along with two adjacent counties (total population in 2016: 668,500) in the federal state of Bavaria took place [20].

At Age1 (t_0 , in 2008), the eligible study population consisted of 5986 individuals born before 1944. The first follow-up, Age2 (t_1 , in 2011/12), only included individuals from a sex- and age-stratified subsample of Age1 participants ($n=1079$) with 100 people per stratum (males and females in five age groups, i. e. ten strata). Of those, 822 participated in medical examinations and completed a telephone interview (response rate: 84.3%) consisting of validated questions on, e. g., sociodemographic characteristics, PA, morbidity, and utilization of health care services [21]. Proxies (e. g., informal caregivers) were interviewed if the participant was unable to answer the questions ($n=29$ [3.5% of participants]). For the second follow-up (Age3, t_2 , in 2016), the total sample of Age1

and individuals from the four cross-sectional samples who were born before 1951, and thus aged ≥ 65 years in 2016, were invited to participate. This resulted in an eligible study population of 6051 at Age3 (t_2). Of those, 4083 participated in telephone interviews and questionnaires (response rate: 67.5%; completed by proxies: $n=191$ [4.7% of participants]).

Since Age1 (t_0) did not assess information on utilization of LTC, only Age2 (t_1) and Age3 (t_2) were considered for analyses. For the main analysis, we used individuals from t_1 ($n=822$) and t_2 ($n=4083$) [see Fig. 1].

Approval for the KORA-Age study was obtained from the Ethics Committee of the Bavarian Medical Association. Individuals agreed to participation with informed



consent. Further details on data collection, study design, sampling, and response rates are described elsewhere [22, 23].

Measurement and operationalization of physical activity

According to the World Health Organization (WHO), PA is defined as “any bodily movement produced by skeletal muscles that requires energy expenditure” [5]. PA is an umbrella term for different forms of movement [24]. In this study, we investigated “exercise” and “walking” as types of PA. In the following lines, relevant information about PA according to the “Physical Activity Questionnaire Reporting Checklist” from Nigg et al. is reported [24].

“Exercise” is a planned, repetitive, purposeful, and structured subcategory of PA with the objective to improve or maintain one or more components of physical fitness [5, 7]. In our study, it was assessed with these two questions addressing duration of exercise: “How often do you exercise during winter?” and “How often do you exercise during summer?”. Response categories for those questions were (1) “regularly more than or equal to two hours per week”; (2) “regularly more than or equal to one, but less than two hours per week”; (3) “less than one hour per week”; and (4) “no exercise”. As operationalized by Karl et al. [25], the two responses for summer and winter were initially combined as one variable with the values “high exercise” (= (1) in both summer and winter), “moderate exercise” (= combinations for summer and winter of “(1)+(2)”, “(2)+(2)”, or “(1)+(3)”), “low exercise” (= combinations for summer and winter of “(1)+(4)”, “(2)+(3)”, “(2)+(4)”), and “no exercise” (= combinations for summer and winter of “(3)+(3)”, “(3)+(4)”, “(4)+(4)”). To facilitate the analyses and interpretation of results, we further dichotomized these values into “high or moderate exercise” (hereafter called “exercise”) and “no or low exercise” (hereafter called “no/low exercise”). Additional file 1 illustrates a detailed differentiation of the categories.

“Walking” was assessed with the following question addressing duration of walking: “On a typical weekday, how much time do you spend walking? For example, going for a walk, on the way to work or shopping?”. Possible response categories were (1) “more than or equal to one hour”; (2) “more than or equal to half an hour, but less than one hour”; (3) “more than or equal to a quarter of an hour, but less than half an hour”; (4) “less than a quarter of an hour”; or (5) “not applicable” (= no walking due to, e. g., using a wheelchair). To facilitate the analyses and interpretation of results, we further dichotomized these values into “high or moderate walking” (= (1) or (2), in the following: “walking”) and “no or low walking” (= (3), (4), or (5), in the following: “no/low walking”).

“Walking+exercise” was applied to individuals doing both “exercise” and “walking”.

The domain of PA – with the exception of walking while “going to work” representing occupational- or transport-based PA – was mainly leisure-time [24]. However, in Germany most people ≥ 65 years are retired, which allows focusing on “leisure-time PA”. Recall periods were “a typical (summer/winter) season” (exercise), and “a typical weekday” (walking) [26].

To address important components of PA, frequency (number of sessions per week), intensity (walking, moderate-intensity exercise, vigorous-intensity exercise, strength training), and time (average duration of an individual session per week; unit of measurement: “minutes per week”) were assessed in the subpopulation at t_2 . Questions, response options, and the calculation of the amount of PA per week can be found in Additional file 2.

Measurement of utilization of long-term care

LTC is defined as support with daily activities for people who experience decline in self-care on a long-term basis (> three months) [27]. Daily activities consist of activities of daily living (ADLs) (e. g., dressing, bathing) and instrumental activities of daily living (IADLs) (e. g., cooking, cleaning) [28]. In Germany, there are three main forms of assistance in LTC for community-dwelling adults: formal support with ADLs, formal support with IADLs, and informal support with both ADLs and IADLs [29, 30]. Study participants were asked if they had received LTC due to their health status within the last three months [21]. Types could be (1) a home nursing service (i. e., formal support with ADLs); and/or (2) paid services for household support (i. e., formal support with IADLs); and/or (3) support from friends, family members, or neighbors (i. e., informal support with both ADLs and IADLs). If participants answered “yes” for at least one of the three types, the variable “utilization of LTC” (yes/no) was coded as “yes”. As all individuals were community-dwelling, settings for LTC were either community- or home-based.

Covariates

Covariates related to LTC and PA were identified based on Andersen’s Behavioral Model of Health Services Use (ABMHS) [18, 31–34], the GNPARG [35], and common correlates of PA in adults [36].

Identified sociodemographic factors were age, sex, education, living arrangement, and income. Age was the participant’s age on the interview date. Sex was defined as the biological distinction of “female” or “male”. Education was comprised of school education, education at university, and vocational training. It was expressed in years (8–17 years). Living arrangement was divided into living

“alone” or “not alone”. Income was defined as self-perceived income sufficiency (subjective income). In older adults, this is a common approach to express individuals’ personal evaluations of the relationship between wealth or objective income and their expenses [37]. Participants were asked if, on average, their income was enough to support them until the end of the month. The responses were divided into “sufficient” or “scarce/insufficient”.

Identified health-related factors were falls, multimorbidity, disability score, and Body Mass Index (BMI). Falls were reported as “ ≥ 1 fall” or “no falls/unknown” within the last year. We used participant self-reports to calculate their Charlson Comorbidity Index [38]. The index considers 13 types of chronic conditions: lung, heart, joint, kidney, gastrointestinal, liver, neurological, and eye diseases; stroke; diabetes mellitus; cancer; hypertension; and HIV [39]. In our study, multimorbidity was defined as the sum of reported chronic conditions ranging from 0 to 13. The Stanford Health Assessment Questionnaire Disability Index (HAQ-DI) was used to measure disability [40]. The HAQ-DI analyzes impairments in IADLs and ADLs. It consists of 20 questions about physical function in eight domains: dressing and grooming, hygiene, eating, standing up, walking, reach, grip, and activities [40]. Its responses range from 0 (no difficulty) to 3 (unable to perform). The highest score in a domain was taken as the domain’s score. The mean of all eight domains constituted the HAQ-DI, which was reported as a continuous value. Participants’ height and weight were measured at the study center through consistent and validated measurement methods (daily calibrated scales; stadiometer) at t_1 and were assessed using self-reports following detailed instructions from trained telephone-interviewers at t_2 . From these values, their BMI in kg/m^2 was calculated.

Statistical analyses

We assessed participants’ characteristics at both follow-up timepoints, dropouts, PA values, and comparisons with the GNPARG using descriptive statistics. To investigate the association of different types of PA (walking, exercise, walking+exercise) with utilization of LTC at t_1 or t_2 (i. e., cross-sectional analysis with repeated measurements), we applied a generalized estimating equation (GEE) logistic model with an unstructured correlation matrix. The model accounts for repeated measurements and their intra-subject correlation [41]. As the study focused on population-averaged effects and not individual, subject-specific changes, we did not apply mixed models, which would have been an alternative for examining intra-subject correlation [42].

In the first step, we analyzed the association of distinct types of PA with utilization of LTC in the entire cohort ($n=4812$ observations: sum of t_1 ($n=800$) and t_2

($n=4012$)). As the existence of differences between sexes for utilization of health care services and lifestyle habits is well-known [17, 18, 34], in the second step we applied two sex-stratified models: one for females ($n=2499$ observations: $t_1: n=395$, $t_2: n=2104$) and one for males ($n=2313$ observations: $t_1: n=405$, $t_2: n=1908$). As disability (expressed as, e. g., “poor health” or “impaired general physical functioning” [43–46]) is one of the major barriers to PA, we applied the sensitivity analysis (SA) SA1 to each model (entire cohort, females, males). The SA1 included only observations without disability, defined as an HAQ-DI < 0.5 [47, 48]. For the general model (entire cohort) and the observations without disability (SA1), we assessed the interaction of sex with types of PA through the calculation of the respective interaction terms.

In all models, we compared observations with utilization of LTC to those without utilization of LTC. The covariates sex and education did not change from t_1 to t_2 and thus were considered fixed variables. All other covariates were treated as time-dependent.

Individuals with either missing values in all types of LTC (= transformation variable “utilization of LTC” (outcome)) or in both “exercise” and “walking” (= transformation variable “PA” (exposure)) were excluded through listwise deletion [49, 50]. This resulted in a final sample size of $n=800$ at t_1 and $n=4012$ at t_2 . Missing values in subdomains of the variables “utilization of LTC” (t_2 : home nursing service and paid services for household support ($n=1$); assistance of family members, friends, or neighbors ($n=1$)) or “PA” (t_1 : walking ($n=2$); t_2 : exercise ($n=2$); walking ($n=8$)) were imputed through single stochastic regression imputation using logistic regression with the fully conditional specification method [51]. This imputation strategy is based on the assumption that missing values are missing at random, meaning that they are conditionally independent from the unobserved value, hence the underlying missing data pattern is arbitrary [52, 53]. To test our model’s robustness, we conducted SA2. It excluded observations with missing values in the above-mentioned subdomains of outcome or exposure.

Regarding covariates, twenty missing values (2.5%) at t_1 (multimorbidity ($n=9$), BMI ($n=7$), income ($n=4$)), and 126 missing values (3.1%) at t_2 (BMI ($n=53$), income ($n=35$), multimorbidity ($n=27$), falls ($n=5$), disability score ($n=2$), living arrangement ($n=2$), education ($n=2$)) were identified. We imputed binary variables using single stochastic regression with the fully conditional specification method and continuous variables using predictive mean matching [51]. We based imputation of all missing values mainly on the models’ covariates ($|\text{correlation coefficient}| > 0.4$) [49].

Table 1 Study sample characteristics stratified by utilization of long-term care and type of physical activity at t₂ (n = 4012)

	Total number of individuals per category	Individuals without long-term care n = 3250 (81.0%)				Individuals with utilization of long-term care n = 762 (19.0%)							
		Total	No physical activity ^a n = 334 (10.3%)	Walking only ^b n = 864 (26.6%)	Exercise only ^c n = 323 (9.9%)	Walking + exercise ^d n = 1727 (53.2%)	Total	No physical activity ^a n = 296 (39.3%)	Walking only ^b n = 247 (32.8%)	Exercise only ^c n = 54 (7.2%)	Walking + exercise ^d n = 157 (20.8%)		
Age in years	total	4002	75.0 (±6.6)	73.9 (±6.0)	76.1 (±6.3)	75.2 (±6.4)	73.6 (±6.1)	72.9 (±5.4)	79.5 (±7.3)	81.1 (±7.2)	79.9 (±7.3)	77.8 (±6.9)	76.5 (±6.5)
Sex	female	4002	2099 (52)	1621 (49)	178 (11)	444 (27)	166 (10)	833 (51)	478 (63)	180 (37)	158 (33)	33 (6.9)	107 (22.4%)
	male	1903 (47)	1627 (50)	156 (9)	420 (25)	894 (55)	157 (9)	894 (55)	276 (36)	116 (42)	89 (32.3)	21 (7.6%)	50 (18.1%)
Education in years	total	4000	11.3 (±2.6)	11.4 (±2.6)	11.0 (±2.5)	11.0 (±2.9)	11.8 (±2.9)	11.6 (±2.6)	10.8 (±2.4)	10.5 (±2.2)	10.7 (±2.4)	11.2 (±2.7)	11.3 (±2.5)
	alone	4002	1183 (29)	850 (26)	79 (9.3)	255 (30)	89 (10.5)	427 (50)	333 (44)	120 (36)	121 (36)	20 (6.0)	72 (21.6%)
Living arrangement	not alone	2819 (70)	2398 (73)	2744 (85)	271 (9)	715 (26)	277 (10)	1481 (54)	559 (75)	205 (36)	195 (34.9%)	43 (7.7%)	116 (20.8%)
	sufficient	3968	3303 (83)	2744 (85)	271 (9)	715 (26)	277 (10)	1481 (54)	559 (75)	205 (36)	195 (34.9%)	43 (7.7%)	116 (20.8%)
Income	scarce/not sufficient	665 (16)	479 (14)	479 (14)	60 (12.5)	139 (29)	43 (9.0)	237 (49)	186 (25)	85 (45.7)	49 (26.3%)	11 (5.9%)	41 (22.0%)
	≥ 1 fall last year	3997	575 (14)	331 (10)	50 (15.1)	103 (31)	37 (11.2)	141 (42)	244 (32)	113 (46)	65 (26.6)	17 (7.0%)	49 (20.1%)
BMI	no falls/unknown	3422 (85)	2913 (89)	2913 (89)	283 (9)	761 (26)	285 (9)	1584 (54)	509 (67)	183 (36)	181 (35)	37 (7.3)	108 (21.2%)
	total	3949	27.1 (±4.5)	27.0 (±4.3)	28.5 (±5.2)	27.4 (±5.1)	27.3 (±4.4)	26.5 (±3.9)	27.3 (±5.2)	28.2 (±6.0)	27.0 (±4.6)	27.3 (±5.0)	26.4 (±4.4)
Multimorbidity in no. of chronic conditions	total	3976	2.3 (±1.5)	2.0 (±1.4)	2.4 (±1.4)	2.3 (±1.4)	2.2 (±1.4)	1.8 (±1.3)	3.5 (±1.7)	3.7 (±1.7)	3.6 (±1.7)	2.9 (±1.5)	3.1 (±1.7)
	total	4000	0.3 (±0.6)	0.2 (±0.3)	0.4 (±0.5)	0.2 (±0.3)	0.2 (±0.3)	0.1 (±0.2)	1.1 (±0.8)	1.5 (±0.9)	0.9 (±0.7)	0.9 (±0.7)	0.7 (±0.6)

HAQ-DI Health Assessment Questionnaire Disability Index

Data presented as n (%)/ mean (± standard deviation) | any discrepancies to total N due to missing values | any discrepancies in percentages due to rounding

^a "no physical activity" = "no or low walking (≤ 15 min/weekday)" + "no or low exercise" (see Additional file 1 for more information)

^b "walking only" = "high or moderate walking (> 15 min/weekday)" + "no or low exercise"

^c "exercise only" = "high or moderate exercise" + "no or low walking (≤ 15 min/weekday)"

^d "walking+exercise" = "high or moderate walking (> 15 min/weekday)" + "high or moderate exercise"

Table 2 Association of physical activity with utilization of long-term care – GEE logistic model

	Main analysis: LTC vs. no LTC in all observations ^a			Sensitivity analysis: LTC vs. no LTC in observations without disability ^b		
	Odds ratio	95% confidence interval	p value	Odds ratio	95% confidence interval	p value
Physical activity (ref.: no physical activity) ^c						
Walking only	0.73	[0.56; 0.95]	0.0208	0.78	[0.51; 1.19]	0.2463
Exercise only	0.56	[0.38; 0.81]	0.0022	0.55	[0.31; 0.98]	0.0417
Walking + exercise	0.52	[0.39; 0.70]	<0.0001	0.44	[0.29; 0.66]	0.0001
Adjusted for:						
Sex (ref.: male)	1.41	[1.12; 1.76]	0.0031	1.49	[1.08; 2.06]	0.0157
Age in years	1.04	[1.03; 1.06]	<0.0001	1.07	[1.04; 1.10]	<0.0001
Education in years	1.05	[1.00; 1.09]	0.0296	1.08	[1.02; 1.13]	0.0063
Living arrangement (ref: not alone)	1.56	[1.26; 1.93]	<0.0001	1.80	[1.32; 2.45]	0.0002
Income (ref: sufficient)	1.16	[0.91; 1.49]	0.2375	1.26	[0.87; 1.82]	0.2280
BMI	0.98	[0.96; 1.00]	0.0666	0.98	[0.95; 1.02]	0.3883
Falls (ref.: no falls/unknown)	1.46	[1.14; 1.89]	0.0031	1.99	[1.38; 2.89]	0.0003
Multimorbidity in no. of chronic conditions	1.30	[1.22; 1.39]	<0.0001	1.46	[1.32; 1.61]	<0.0001
Disability score (HAQ-DI)	8.60	[6.85; 10.78]	<0.0001	/	/	/

GEE Generalized estimating equation | LTC Long-term care | HAQ-DI Health Assessment Questionnaire Disability Index

Bold numbers: significant at $p \leq 0.05$

Sample for generalized estimating equation ($n = 4812$): sum of t_1 ($n = 800$) and t_2 sample ($n = 4012$)

^a Model includes all observations ($n = 4812$); observations stratified by either utilization of long-term care ($n = 950$) or no long-term care ($n = 3862$)

^b Model includes all observations without disability (HAQ-DI < 0.5) ($n = 3504$); observations stratified by either utilization of long-term care ($n = 244$) or no long-term care ($n = 3260$)

^c Categories of physical activity defined as: “no physical activity” = “no or low walking (≤ 15 mins/weekday)” + “no or low exercise” (see Additional file 1 for more information) | “walking only” = “high or moderate walking (> 15 mins/weekday)” + “no or low exercise” | “exercise only” = “high or moderate exercise” + “no or low walking (≤ 15 mins/weekday)” | “walking+exercise” = “high or moderate walking (> 15 mins/weekday)” + “high or moderate exercise”

We tested for multicollinearity of covariates in all models (threshold: $|r| \leq 0.8$). We calculated odds ratios (OR) and 95% confidence intervals (CI). In all analyses, results with p -values ≤ 0.05 were considered statistically significant. We performed all statistical analyses using SAS software, release 9.4 (SAS Institute, Cary, NC).

Results

Characteristics of study sample

Table 1 characterizes the total study sample and the sample stratified by utilization of LTC and type of PA at t_2 . Out of 4012 individuals, 762 (19.0%) received LTC. Age in the entire cohort ranged from 65 to 97 years with a mean age of 75.0 years (standard deviation (SD): 6.6). The entire cohort (with missings) included 2099 females (52.5%), with 478 (22.8%) of them receiving LTC. Out of 1903 males, 276 received LTC (14.5%). In individuals without utilization of LTC, the most common type of PA was “walking+exercise” (53.2%), followed by “walking” (26.6%), no PA (10.3%), and “exercise” (9.9%).

Individuals with utilization of LTC did no PA most often (39.3%), followed by “walking” (32.8%), “walking+exercise” (20.8%), and “exercise” (7.2%).

Generally, individuals with no PA were older, had less education, and had a higher BMI, higher multimorbidity, and a higher disability score. Within individuals without utilization of LTC, those with “walking+exercise” (the most frequently completed type of PA) as compared to the other types of PA were the youngest (72.9; SD: 5.4); they had the second most years of education (11.6; SD: 2.6) after those who did “walking” (11.8; SD: 2.9), the lowest BMI (26.5, SD: 3.9), the lowest multimorbidity (1.8; SD: 1.3), and the lowest disability score (0.1; SD: 0.2). Looking at individuals with utilization of LTC, those with no PA (the most frequently completed type of PA) were the oldest (81.1; SD: 7.2); they had the fewest years of education (10.5; SD: 2.2), the highest BMI (28.2; 6.0), the highest multimorbidity (3.7; SD: 1.7), and the highest disability score (1.5; SD: 0.9) as compared to those with other types of PA. The sample at t_1 showed similar characteristics (see Table 6 in Appendix 1).

Table 3 Association of physical activity with utilization of long-term care in females – GEE logistic model

	Main analysis: LTC vs. no LTC in all observations ^a			Sensitivity analysis: LTC vs. no LTC in observations without disability ^b		
	Odds ratio	95% confidence interval	p value	Odds ratio	95% confidence interval	p value
Physical activity (ref.: no physical activity) ^c						
Walking only	0.72	[0.51; 1.02]	0.0620	1.24	[0.60; 2.56]	0.5550
Exercise only	0.58	[0.35; 0.94]	0.0288	0.82	[0.32; 2.07]	0.6666
Walking + exercise	0.62	[0.44; 0.89]	0.0094	0.95	[0.49; 1.86]	0.8906
Adjusted for:						
Age in years	1.05	[1.02; 1.07]	<0.0001	1.08	[1.04; 1.12]	<0.0001
Education in years	1.04	[0.98; 1.11]	0.1773	1.07	[0.99; 1.16]	0.0895
Living arrangements (ref.: not alone)	1.20	[0.92; 1.57]	0.1718	1.49	[1.00; 2.22]	0.0505
Income (ref.: sufficient)	1.14	[0.83; 1.56]	0.4128	1.16	[0.65; 2.05]	0.6162
BMI	0.99	[0.96; 1.01]	0.3857	1.00	[0.95; 1.04]	0.9063
Falls (ref.: no falls/unknown)	1.49	[1.09; 2.05]	0.0128	2.16	[1.31; 3.59]	0.0028
Multimorbidity in no. of chronic conditions	1.26	[1.15; 1.37]	<0.0001	1.43	[1.24; 1.66]	<0.0001
Disability score (HAQ-DI)	9.45	[7.02; 12.71]	<0.0001	/	/	/

GEE Generalized estimating equation | LTC Long-term care | HAQ-DI Health Assessment Questionnaire Disability Index

Bold numbers: significant at $p \leq 0.05$

Sample for generalized estimating equation ($n = 2499$): sum of t_1 ($n = 395$) and t_2 sample ($n = 2104$)

^a Model includes all observations ($n = 2499$); observations stratified by either utilization of long-term care ($n = 605$) or no long-term care ($n = 1894$)

^b Model includes all observations without disability (HAQ-DI < 0.5) ($n = 1669$); observations stratified by either utilization of long-term care ($n = 136$) or no long-term care ($n = 1533$)

^c Categories of physical activity defined as: “no physical activity” = “no or low walking (≤ 15 mins/weekday)” + “no or low exercise” (see Additional file 1 for more information) | “walking only” = “high or moderate walking (> 15 mins/weekday)” + “no or low exercise” | “exercise only” = “high or moderate exercise” + “no or low walking (≤ 15 mins/weekday)” | “walking + exercise” = “high or moderate walking (> 15 mins/weekday)” + “high or moderate exercise”

Table 4 Association of physical activity with utilization of long-term care in males – GEE logistic model

	Main analysis: LTC vs. no LTC in all observations ^a			Sensitivity analysis: LTC vs. no LTC in observations without disability ^b		
	Odds ratio	95% confidence interval	p value	Odds ratio	95% confidence interval	p value
Physical activity (ref.: no physical activity) ^c						
Walking only	0.76	[0.50; 1.15]	0.1930	0.49	[0.27; 0.86]	0.0140
Exercise only	0.52	[0.30; 0.93]	0.0274	0.34	[0.15; 0.77]	0.0098
Walking + exercise	0.41	[0.26; 0.65]	0.0002	0.19	[0.10; 0.35]	<0.0001
Adjusted for:						
Age in years	1.04	[1.01; 1.07]	0.0033	1.06	[1.02; 1.10]	0.0026
Education in years	1.06	[1.00; 1.12]	0.0611	1.08	[1.00; 1.16]	0.0390
Living arrangements (ref.: not alone)	2.64	[1.88; 3.72]	<0.0001	2.55	[1.57; 4.06]	0.0001
Income (ref.: sufficient)	1.24	[0.83; 1.85]	0.2852	1.41	[0.79; 2.51]	0.2414
BMI	0.96	[0.92; 1.00]	0.0458	0.96	[0.90; 1.02]	0.1847
Falls (ref.: no falls/unknown)	1.42	[0.94; 2.16]	0.0961	1.77	[0.94; 3.33]	0.0761
Multimorbidity in no. of chronic conditions	1.38	[1.24; 1.53]	<0.0001	1.52	[1.32; 1.75]	<0.0001
Disability score (HAQ-DI)	7.78	[5.53; 10.94]	<0.0001	/	/	/

GEE Generalized estimating equation | LTC Long-term care | HAQ-DI Health Assessment Questionnaire Disability Index

Bold numbers: significant at $p \leq 0.05$

Sample for generalized estimating equation ($n = 2313$): sum of t_1 ($n = 405$) and t_2 sample ($n = 1908$)

^a Model includes all observations ($n = 2313$); observations stratified by either utilization of long-term care ($n = 345$) or no long-term care ($n = 1968$)

^b Model includes all observations without disability (HAQ-DI < 0.5) ($n = 1835$); observations stratified by either utilization of long-term care ($n = 108$) or no long-term care ($n = 1727$)

^c Categories of physical activity defined as: “no physical activity” = “no or low walking (≤ 15 mins/weekday)” + “no or low exercise” (see Additional file 1 for more information) | “walking only” = “high or moderate walking (> 15 mins/weekday)” + “no or low exercise” | “exercise only” = “high or moderate exercise” + “no or low walking (≤ 15 mins/weekday)” | “walking + exercise” = “high or moderate walking (> 15 mins/weekday)” + “high or moderate exercise”

Dropouts between t_1 and t_2 with information about utilization of LTC and PA status ($n = 248$) used LTC (39.1%) more often, were older (81.2 years (SD: 6.4)), lived alone (55.7%) more frequently, had higher multimorbidity (3.0; SD: 1.6), and a higher disability score (0.8; SD: 0.8) than non-dropouts.

Association of physical activity with utilization of long-term care

Table 2 displays the association of distinct types of PA with utilization of LTC in all observations ($n = 4812$) and in observations without disability (SA1, $n = 3504$). Compared to no PA, all types of PA were associated with reduced odds of utilization of LTC in the main analysis and SA1. “Walking” reduced the odds of utilization of LTC by 27% (OR: 0.73; CI: 0.56–0.95) and “exercise” reduced it by 44% (OR: 0.56; CI: 0.38–0.81). The combination of “walking+exercise” achieved the highest reduction, with a 48% decrease (OR: 0.52; CI: 0.39–0.70). The covariate being “female” increased the odds of utilization of LTC by 41% (OR: 1.41; CI: 1.12–1.76). Other covariates that increased the odds of utilization of LTC to a statistically significant degree were older age (OR: 1.04; CI: 1.03–1.06), higher education (OR: 1.05; CI: 1.00–1.09), living alone (OR: 1.56; CI: 1.26–1.93), falls (1.46; CI: 1.14–1.89), higher multimorbidity (OR: 1.30; CI: 1.22–1.39), and a higher disability score (OR: 6.85; CI: 6.85–10.78). SA1 and SA2 (Table 7 in Appendix 2) confirmed those results.

Sex-specific association of physical activity with utilization of long-term care

Tables 3 and 4 illustrate the association of PA with utilization of LTC in females, and in males, respectively. As in the entire cohort, each type of PA reduced the odds of utilization of LTC when compared to no PA. Statistically significant covariates in both females and males were older age, higher multimorbidity, and a higher disability score. “Walking” reduced the odds of utilization of LTC by 28% in females (OR: 0.72; CI: 0.51–1.02) and by 24% in males (OR: 0.76; CI: 0.50–1.15). In females, “exercise” reduced the odds of utilization of LTC by 42% (OR: 0.58; CI: 0.35–0.94), and in males it reduced the odds by 48% (0.52; CI: 0.30–0.93). “Walking+exercise” reduced the odds of utilization of LTC by 38% (OR: 0.62; CI: 0.44–0.89) in females and by 59% (OR: 0.41; CI: 0.26–0.65) in males. Looking at SA1, no type of PA had a statistically significant association with utilization of LTC in females. In contrast, among males the association of all types of PA remained statistically significant and was even stronger than in the main analysis.

Tests of the interaction terms “types of PA*sex” (references: no PA, male) in the main analysis resulted in the following: “walking*female” (OR: 0.85; CI: 0.50–1.46), “exercise*female” (OR: 1.01; CI: 0.48–2.13), “walking*exercise” (OR: 1.31; CI: 0.75–2.28). Tests of the interaction terms in SA1 resulted in the following: “walking*female” (OR: 2.74; CI: 1.07–10.53), “exercise*female” (OR: 3.20; CI: 0.97–10.53), “walking*exercise” (OR: 5.03; CI: 1.99–12.70).

Individuals meeting suggested minimum values in German National Physical Activity Recommendations for older adults

Table 5 displays the number of individuals who met the GNPARG at t_1 . Almost a fourth (24.5%, $n = 196$) completed the suggested minimum of ≥ 150 minutes/week of “moderate-intensity exercise”, whereas only 6.5% ($n = 52$) completed ≥ 75 minutes/week of “vigorous-intensity exercise”. A total of 6.4% ($n = 51$) did strength training more than twice a week. For all types of PA, the proportion of individuals without utilization of LTC who met the GNPARG was higher than that of individuals with utilization of LTC. Group differences between individuals with and without utilization of LTC in relation to “moderate-intensity exercise” and “moderate- or vigorous-intensity exercise” were statistically significant.

Discussion

Our study is among the first to investigate the association of various types of PA with utilization of LTC in community-dwelling older adults in Germany. Compared to physically inactive individuals, those being physically active were less likely to utilize LTC. The combination of “walking+exercise” showed the strongest association with non-utilization of LTC in the entire cohort and in males. In contrast, among females, “exercise” had the strongest association with non-utilization of LTC. The proportion of individuals who completed the minimum values suggested by the GNPARG was higher among those without utilization of LTC than among those with utilization of LTC. In both individuals with and without utilization of LTC, the minimum values for “moderate-intensity exercise” were completed more often than the minimum values for “vigorous-intensity exercise” or “strength training”.

Our results suggest that being physically active is associated with reduced odds of utilization of LTC. Due to the lack of studies on the association of the outcome “utilization of LTC” with PA, and given that utilization of LTC is a complex construct, influenced by various determinants [18, 34], comparison with current evidence

Table 5 Individuals meeting suggested minimum values in German National Physical Activity Recommendations for older adults at t_1

	Total n = 800	No long-term care n = 612 (76.5%)	Long-term care n = 188 (23.5%)
Moderate-intensity exercise ≥ 150 min/week ^a	196 (24.5%)	174 (28.4%)	22 (11.2%)
Vigorous-intensity exercise ≥ 75 min/week	52 (6.5%)	52 (8.5%)	0 (0.0%)
Moderate-intensity ≥ 150 min/week or vigorous-intensity exercise ≥ 75 min/week ^a	222 (27.7%)	200 (32.7%)	22 (11.7%)
Strength training ≥ 2 times/week	51 (6.4%)	45 (7.4%)	6 (3.2%)

Multiple answers possible

Number and % of individuals completing each PA type were calculated based on the following:

1. Frequency: participants were asked "How often did you spend time doing [X] within the last 7 days?" per category (examples were given to specify the categories)
2. Time: if participants chose a category other than "not applicable/0 days", participants were asked: "How many hours have you spent on average doing [X] within the last 7 days?" (not applied for strength training)
3. Amount in min/week (lower bounds): frequency * time (not applied for strength training)
4. Number/% of individuals: all individuals with ≥ 150 min/week moderate-intensity exercise/ ≥ 75 min/week vigorous-intensity exercise/ ≥ 2 times/week strength training were counted

^a $p \leq 0.005$ | group differences "no long-term care" vs. "long-term care" and exercise intensity, analysis through χ^2 -tests

is limited. Until now, research mainly focused on the impact of PA on need factors (e. g., physical or cognitive problems) leading to utilization of health care services [32]. Evidence has demonstrated that various types of PA positively influence need factors [15, 54, 55]. This supports our results, although further studies with similar outcomes are needed to allow comparison of effects across studies.

Our results contribute to the evidence about the association of various types of PA with utilization of LTC in a subgroup of interest to policy-makers (i. e., older adults) [35]. WHO's "Guidelines on physical activity and sedentary behaviour" [5] strongly recommend that older adults do varied multicomponent PA addressing "functional balance and strength training at moderate or higher intensity" at least three times per week. Our results show that the combination of "walking+exercise" had a stronger association with non-utilization of LTC than "walking" or "exercise". Thus, that combination should be promoted more than "exercise" or "walking" alone in future PA programs for older adults. Still, to create evidence-based PA recommendations for community-dwelling older adults, specific subtypes (e. g., swimming, cycling), duration, and frequency of PA must be investigated in future longitudinal studies.

Comparing females with males based on the sex-stratified analyses, the association of "exercise" and "walking+exercise" with non-utilization of LTC was higher in males than in females. Older males prefer more vigorous exercise than females do [9] and the GNPARG assume that "increased energy expenditure at higher intensities 'counts' more" [35]. Therefore, we presume

that males' exercise was of higher intensity than females' and thus resulted in the larger effect on non-utilization of LTC. However, it must be considered that the interaction terms "types of PA*sex" showed statistically significant sex differences solely in the cohort without disability. Thus, we recommend further studies investigating sex-specific effects of PA intensities on utilization of LTC.

While the association of PA with non-utilization of LTC was even stronger in males without disability compared to the entire male cohort, for females no corresponding association was found. A possible explanation might be gender differences in household PA. Due to persistent social and cultural norms, older females complete most household chores. Murphy et al. [10] analyzed total moderate- to vigorous-intensity exercise in both sexes. After excluding domestic PA, the proportion of females meeting PA guidelines decreased, whereas in males it stayed almost equal [10]. As PA effects are curvilinear [35], i. e. PA in already physically active individuals has a lower impact than in inactive individuals, we suspect that the effect of leisure-time PA in our female cohort without disability is marginal [8]. However, one must consider that our group of females without disability was relatively small. Thus, further research regarding this finding is urgently needed.

With 27.7% following WHO's recommendations for moderate to vigorous PA, our sample falls within the documented range for countries worldwide (20–60%) [5, 7, 8]. The Robert Koch Institute (RKI), Germany's core institution for nationwide health monitoring [56], examined the German population (representative sample) ≥ 65 years in 2019/2020. It found that

38.2% were physically active ≥ 150 minutes/week [57]. In comparison, our cohort was less active. The lower proportion meeting the GNPARG in our cohort could be explained by the lack of detailed differentiation of PA intensities by the RKI, resulting in this German cohort probably also including some types of low-intensity exercise (e. g., riding a bike at low speed), or including a lower proportion of individuals with utilization of LTC than ours. In our cohort, almost a fourth (24.5%) met the suggested minimum of ≥ 150 minutes per week of “moderate-intensity exercise”, whereas only 6.5% met the minimum of ≥ 75 minutes/week of “vigorous-intensity exercise”. This aligns with previous research stating that in older age “moderate-intensity exercise” is done more often than “vigorous-intensity exercise” [7, 8]. As falls in older age are one of the leading causes of transitions to utilization of LTC, they should be prevented through verifiably effective interventions, such as strength training [5, 35, 58]. In our cohort, only 6.4% did strength training more than twice a week, whereas in the RKI’s cohort, 30.3% did strength training at least twice a week [57]. This large discrepancy may be due the KORA questionnaire using the time frame “> 2 times/week” instead of “ ≥ 2 times/week”, whereas the RKI questionnaire used an open question (“How often did you spend time doing strength-training in a typical week?”). Thus, KORA assessments probably underestimated the proportion of individuals meeting the GNPARG.

We detected that the proportion of individuals meeting the GNPARG was much higher in individuals without utilization of LTC than in individuals with utilization of LTC. Also, considering our finding that individuals with utilization of LTC were mostly physically inactive and that, according to Ruetten et al. [35], the “greatest health benefits occur when individuals who were entirely physically inactive become somewhat more active”, there is a clear need to encourage this group to do some PA rather than none at all.

Limitations and strengths

Our results must be interpreted with some caveats. First, we did not aim to assess causal relationships of PA with utilization of LTC. To investigate causal relationships, other study designs are needed. Our findings do suggest, however, that promoting PA in old age is associated with reduced odds of utilization of LTC.

Another limitation is the relatively small size of groups of individuals with LTC per subcategory of PA, which renders corresponding results less reliable. Still, as up to

now there is no comparable analysis regarding this topic, our study contributes relevant evidence. Furthermore, our questionnaire-based study of community-dwelling older adults is relatively large in comparison to other representative regional cohort studies addressing PA in older adults and included relatively even proportions of females and males [8].

As mentioned above, we may have underestimated the proportion of individuals meeting the GNPARG. Due to the assessment of time frames (e. g., 1–2 hours/week) rather than estimated mean duration/day, we could not calculate the exact mean duration/week for each type of PA. However, we took the lower bound of each time frame (e. g., 1 hour/week) to avoid the common problem of overreporting PA through self-reports [8, 59].

Our study has several strengths that improve upon limitations of previous studies of PA measurements and evaluations of PA’s effects. First, standardized assessment and utilization of quality management in KORA studies (e. g., plausibility checks of participants’ answers by independent interviewers and data analysts) ensured high data quality [19]. Moreover, we based our approach to detecting relevant covariates and controlling for them on factors explored in current literature on this topic. Additionally, the GEE logistic model allowed us to consider intra-subject correlation in repeated measurements. Furthermore, the detailed assessment of relevant types of PA in old age (walking vs. exercise) addresses a highly relevant topic and therefore reduces the current gap in evidence about the effect of various types of PA on older adults [60, 61]. Thus, our findings can help to create target-oriented, subtype-specific PA recommendations, as well as PA promotion programs for community-dwelling older adults.

Conclusions

Our results demonstrate an association between PA and non-utilization of LTC in community-dwelling older adults with sex-specific and disability-related particularities regarding distinct types of PA. Furthermore, they illustrate that the GNPARG are rarely met by older adults with and without utilization of LTC. To minimize or even partially prevent the public health issue of an increasing need for and thus higher utilization of LTC, policy-makers and health care workers should develop target-oriented PA promotion programs. For those programs, consideration of accessible and sustainable environments, as well as the target-groups’ needs, is indispensable for reaching this vulnerable group and fostering beneficial PA behaviors.

Appendix 1

Table 6 Study sample characteristics stratified by utilization of long-term care and type of physical activity at t₁ (n = 800)

		Total number of individuals per category	Individuals without long-term care n = 612 (76.4%)					Individuals with utilization of long-term care n = 188 (23.5%)					
			Total	No physical activity n = 63 (10.3%)	Walking only n = 184 (30.1%)	Exercise only n = 58 (9.5%)	Walking +exercise n = 307 (50.2%)	Total	No physical activity n = 70 (37.6%)	Walking only n = 56 (30.1%)	Exercise only n = 18 (9.7%)	Walking +exercise n = 42 (22.6%)	
Age in years	total	798	78.3 (±6.4)	77.1 (±6.0)	79.3 (±6.9)	78.9 (±5.6)	77.3 (±5.7)	75.5 (±5.6)	82.3 (±6.0)	85.0 (±4.7)	81.4 (±6.3)	78.8 (±5.5)	80.5 (±5.9)
Sex	female	798	394 (49.4%)	272 (44.4%)	22 (8.1%)	88 (32.4%)	25 (9.2%)	137 (50.4%)	122 (65.6%)	51 (41.8%)	36 (29.5%)	10 (8.2%)	25 (20.5%)
	male		404 (50.6%)	340 (55.6%)	41 (12.1%)	96 (28.2%)	33 (9.7%)	170 (50.0%)	64 (34.4%)	19 (29.7%)	20 (31.3%)	8 (12.5%)	17 (26.6%)
Educational years	total	798	10.9 (±2.6)	11.0 (±2.6)	11.3 (±2.7)	10.8 (±2.6)	11.2 (±2.5)	11.0 (±2.5)	10.5 (±2.5)	10.2 (±2.6)	10.5 (±2.6)	10.2 (±2.2)	11.1 (±2.5)
Living arrangement	alone	798	281 (35.2%)	183 (29.9%)	13 (7.1%)	65 (35.5%)	21 (11.5%)	84 (45.9%)	98 (52.7%)	37 (37.8%)	27 (27.6%)	8 (8.2%)	26 (26.5%)
	not alone		517 (64.8%)	429 (70.1%)	50 (8.2%)	119 (19.4%)	37 (6.1%)	223 (52.0%)	88 (47.3%)	33 (37.5%)	29 (33.0%)	10 (11.4%)	16 (18.2%)
Income	sufficient	794	632 (79.6%)	502 (79.4%)	49 (9.8%)	149 (29.7%)	48 (9.6%)	256 (51.0%)	130 (20.6%)	47 (36.2%)	41 (31.5%)	12 (9.2%)	30 (23.1%)
	scarce/not sufficient		162 (20.4%)	108 (66.7%)	13 (12.0%)	35 (32.4%)	10 (9.3%)	50 (46.3%)	54 (33.3%)	21 (38.9%)	15 (27.8%)	6 (11.1%)	12 (22.2%)
Falls within last year	≥ 1 fall	798	141 (17.7%)	77 (12.6%)	13 (16.9%)	31 (40.3%)	7 (9.1%)	26 (33.8%)	64 (45.4%)	29 (45.3%)	17 (26.6%)	7 (10.9%)	11 (17.2%)
	no falls/unknown		657 (82.3%)	535 (87.4%)	50 (9.4%)	153 (28.6%)	51 (9.5%)	281 (52.5%)	122 (65.6%)	41 (33.6%)	39 (32.0%)	11 (9.0%)	31 (25.4%)
BMI	total	791	28.1 (±4.2)	27.9 (±3.9)	27.9 (±3.5)	28.4 (±4.3)	28.5 (±4.3)	27.5 (±3.5)	28.7 (±5.2)	28.9 (±5.6)	28.7 (±5.2)	30.8 (±5.6)	27.3 (±4.1)
Multi-morbidity in no. of chronic conditions	total	789	2.5 (±1.5)	2.3 (±1.4)	2.6 (±1.6)	2.5 (±1.5)	2.2 (±1.5)	2.2 (±1.3)	3.3 (±1.6)	3.7 (±1.7)	3.3 (±1.5)	2.5 (±1.2)	2.9 (±1.6)
Disability score (HAQ-DI)	total	798	0.5 (±0.7)	0.3 (±0.4)	0.5 (±0.6)	0.3 (±0.4)	0.3 (±0.5)	0.2 (±0.3)	1.2 (±0.8)	1.7 (±0.8)	0.9 (±0.7)	1.2 (±1.0)	0.6 (±0.5)

Data presented as n (%) / mean (± standard deviation) | any discrepancies to total N due to missing values | any discrepancies in percentages due to rounding
 HAQ-DI Health Assessment Questionnaire Disability Index

^a “no physical activity” = “no or low walking (<= 15 min/weekday)” + “no or low exercise” (see Additional file 1 for more information)

^b “walking only” = “high or moderate walking (> 15min/weekday)” + “no or low exercise”

^c “exercise only” = “high or moderate exercise” + “no or low walking (<= 15 min/weekday)”

^d “walking+exercise” = “high or moderate walking (> 15min/weekday)” + “high or moderate exercise”

Appendix 2

Table 7 Association of physical activity with utilization of long-term care excluding observations with missing values in subdomains – GEE logistic model

	Main analysis: LTC vs. no LTC in all observations ^a			Sensitivity analysis: LTC vs. no LTC in observations without disability ^b		
	Odds ratio	95% confidence interval	p value	Odds ratio	95% confidence interval	p value
Physical activity (ref.: no physical activity)						
Walking only	0.72	[0.55; 0.94]	0.0173	0.78	[0.51; 1.19]	0.2488
Exercise only	0.56	[0.38; 0.81]	0.0021	0.55	[0.31; 0.98]	0.0417
Walking + exercise	0.52	[0.39; 0.69]	<0.0001	0.44	[0.29; 0.66]	0.0001
Adjusted for:						
Sex (ref.: male)	1.40	[1.11; 1.75]	0.0039	1.49	[1.08; 2.06]	0.0154
Age in years	1.04	[1.03; 1.06]	<0.0001	1.07	[1.04; 1.10]	<0.0001
Education in years	1.05	[1.00; 1.09]	0.0312	1.08	[1.02; 1.13]	0.0063
Living arrangement (ref.: not alone)	1.56	[1.26; 1.93]	<0.0001	1.79	[1.32; 2.44]	0.0002
Income (ref.: sufficient)	1.16	[0.90; 1.49]	0.2466	1.26	[0.87; 1.82]	0.2287
BMI	0.98	[0.96; 1.00]	0.0622	0.98	[0.95; 1.02]	0.3854
Falls (ref.: no falls/unknown)	1.47	[1.14; 1.89]	0.0027	1.99	[1.37; 2.89]	0.0003
Multimorbidity in no. of chronic conditions	1.30	[1.21; 1.39]	<0.0001	1.46	[1.32; 1.61]	<0.0001
Disability score (HAQ-DI)	8.53	[6.79; 10.71]	<0.0001	/	/	/

Bold numbers: significant at $p \leq 0.05$

Sample for generalized estimating equation ($n = 4799$): sum of t_1 ($n = 798$) and t_2 sample ($n = 4001$)

GEE generalized estimating equation, LTC long-term care, HAQ-DI, Health Assessment Questionnaire Disability Index

^a Model includes all observations ($n = 4799$); observations stratified by either utilization of long-term care ($n = 940$) or no long-term care ($n = 3859$)

^b Model includes all observations without disability (HAQ-DI < 0.5) ($n = 3503$); observations stratified by either utilization of long-term care ($n = 244$) or no long-term care ($n = 3259$)

^c Categories of physical activity defined as:

“no physical activity” = “no or low walking (≤ 15 mins/weekday)” + “no or low exercise” (see Additional file 1 for more information)

“walking only” = “high or moderate walking (> 15 mins/weekday)” + “no or low exercise”

“exercise only” = “high or moderate exercise” + “no or low walking (≤ 15 mins/weekday)”

“walking+exercise” = “high or moderate walking (> 15 mins/weekday)” + “high or moderate exercise”

Abbreviations

BMI: Body Mass Index; CI: 95% confidence interval; GNPAP: German National Physical Activity Recommendations for older adults; LTC: Long-term care; OR: Odds ratio; PA: Physical activity; RKI: Robert Koch Institute; SA: Sensitivity analysis; SD: Standard deviation; WHO: World Health Organization.

Supplementary Information

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Additional file 1. Title: Categorization of exercise. Description of data: Illustration explaining the transformation of the variable “exercise”.

Additional file 2. Title: Extract of questionnaire assessing type, frequency, and duration of physical activity at t_2 . Description of data: Questions used to assess types, frequency, and duration of physical activity at t_2 .

Additional file 3. Title: STROBE-checklist. Description of data: Checklist to determine quality, structure, and content of study.

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Authors' contributions

KS, HS, and LSa formulated the idea and study questions and devised the concept for this paper. LSe, and ML revised the concept critically. KS conducted the statistical analysis and the interpretation of the data and prepared the manuscript. LSe, EG, ML, CR, and AP revised the manuscript critically regarding the core intellectual content. All authors approved the final manuscript.

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Availability of data and materials

The data are subject to national data protection laws and restrictions were imposed by the Ethics Committee to ensure data privacy of the study participants. Therefore, data cannot be made freely available in a public repository. However, in reasonable cases data can be requested through individual project agreements via the KORA-PASST tool under <https://epi.helmholtz-muenchen.de/>.

Declarations**Ethics approval and consent to participate**

All procedures performed in studies involving participants were in accordance with the ethical standards of the institutional and/or national research committee (Ethics Committee of the Bavarian Medical Association, reference number 08064) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Written informed consent was obtained from all individual participants included in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Additional file 1: Categorization of exercise

		How often do you exercise during summer?			
		1	2	3	4
How often do you exercise during winter?	1	high exercise			
	2		moderate exercise	low exercise	
	3			no exercise	
	4				

- 1** “regularly more than or equal to two hours per week”
- 2** “regularly more than or equal to one, but less than two hours per week”
- 3** “less than one hour per week”
- 4** “no exercise”

According to:

Karl FM, Tremmel M, Luzak A, Schulz H, Peters A, Meisinger C, et al. Direct healthcare costs associated with device assessed and self-reported physical activity: results from a cross-sectional population-based study. *BMC Public Health*. 2018;18:966. doi:10.1186/s12889-018-5906-7

Additional file 2: Extract of questionnaire assessing type, frequency, and duration of physical activity at t₂

Walking	
How often did you spend time walking outside (e. g., to relax, to go shopping, to go to work, to walk with the dog) within the last 7 days?	<input type="checkbox"/> not applicable/0 days <input type="checkbox"/> 1-2 days ^a <input type="checkbox"/> 3-4 days ^a <input type="checkbox"/> 5-7 days ^a
Moderate-intensity exercise	
How often did you spend time doing moderate-intensity exercise (e. g., dancing, gymnastics, riding a bike at moderate speed, moderate swimming, nordic walking or other similar activities) within the last 7 days?	<input type="checkbox"/> not applicable/0 days* <input type="checkbox"/> 1-2 days ^a <input type="checkbox"/> 3-4 days ^a <input type="checkbox"/> 5-7 days ^a
High-intensity exercise	
How often did you spend time doing high-intensity exercise (e. g., running, intense swimming, riding a bike with high speed, hiking, aerobic, skiing or other similar activities) within the last 7 days?	<input type="checkbox"/> not applicable/0 days <input type="checkbox"/> 1-2 days ^a <input type="checkbox"/> 3-4 days ^a <input type="checkbox"/> 5-7 days ^a
Strength training	
How often did you spend time doing strength-training (e. g., lifting weights, push-ups) within the last 7 days?	<input type="checkbox"/> not applicable/0 days <input type="checkbox"/> 1-2 days ^a <input type="checkbox"/> 3-4 days ^a <input type="checkbox"/> 5-7 days ^a
Filter question for ^a	
How many hours on average did you spend doing [walking/moderate-intensity exercise/high-intensity exercise/strength training] on the mentioned days?	<input type="checkbox"/> less than 1 hour <input type="checkbox"/> more than 1, but less than 2 hours <input type="checkbox"/> 2 to 4 hours <input type="checkbox"/> more than 4 hours

Calculation of amount in min/week:

1. **Chosen number of days/week for frequency (i. e. the lowest value in the selected range):**
 - 0 days
 - 1 day
 - 3 days
 - 5 days

2. **Chosen number of minutes/chosen frequency for time spent:**
 - 30 minutes
 - 60 minutes
 - 120 minutes
 - 270 minutes

3. **Amount in minutes/week:**
frequency * time (not applied for strength training)

Additional file 3: STROBE Statement—Checklist of items that should be included in reports of cohort studies

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1-2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2
Objectives	3	State specific objectives, including any prespecified hypotheses	2
Methods			
Study design	4	Present key elements of study design early in the paper	2-7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	2-7
Participants	6	Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	2-4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4-6
Bias	9	Describe any efforts to address potential sources of bias	4-6
Study size	10	Explain how the study size was arrived at	2-4, 7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5-6
		(b) Describe any methods used to examine subgroups and interactions	5-6
		(c) Explain how missing data were addressed	5-6
		(d) If applicable, explain how loss to follow-up was addressed	5-6
		(e) Describe any sensitivity analyses	5-6, SA1, SA2
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Fig. 1, 2-4, 6-8
		(b) Give reasons for non-participation at each stage	Fig. 1, 2-4
		(c) Consider use of a flow diagram	Fig. 1
Descriptive data	14*	(a) Give characteristics of study participants (e. g., demographic, clinical, social) and information on exposures and potential confounders	6-8

Article 2

		(b) Indicate number of participants with missing data for each variable of interest	5-6
		(c) Summarise follow-up time (e. g., average and total amount)	6-9
Outcome data	15*	Report numbers of outcome events or summary measures over time	6-9
Main results	16	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e. g, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	2-4, 6-9, Tables
Other analyses	17	Report other analyses done—e. g analyses of subgroups and interactions, and sensitivity analyses	6-9, SA1, SA2
Discussion			
Key results	18	Summarise key results with reference to study objectives	9-11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9-11
Generalisability	21	Discuss the generalisability (external validity) of the study results	9-11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13-14

*Give information separately for exposed and unexposed groups.

4 Article 3

Cost-effectiveness of a non-pharmacological treatment vs. “care as usual” in day care centers for community-dwelling older people with cognitive impairment: results from the German randomized controlled DeTaMAKS-trial

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Cost-effectiveness of a non-pharmacological treatment vs. “care as usual” in day care centers for community-dwelling older people with cognitive impairment: results from the German randomized controlled DeTaMAKS-trial

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Abstract

Background Cognitive impairment in older adults causes a high economic and societal burden. This study assesses the cost-effectiveness of the multicomponent, non-pharmacological MAKS treatment vs. “care as usual” in German day care centers (DCCs) for community-dwelling people with mild cognitive impairment (MCI) or mild to moderate dementia over 6 months.

Methods The analysis was conducted from the societal perspective alongside the cluster-randomized controlled, multi-center, prospective DeTaMAKS-trial with waitlist group design. Outcomes were Mini-Mental Status Examination (MMSE) and Erlangen Test of Activities of Daily Living in Persons with Mild Dementia or Mild Cognitive Impairment (ETAM) of 433 individuals in 32 DCCs. Incremental differences in MMSE and ETAM were calculated via a Gaussian-distributed and incremental cost difference via a Gamma-distributed Generalized Linear Model. Cost-effectiveness was assessed via cost-effectiveness planes and cost-effectiveness acceptability curves (CEAC).

Results At 6 months, MMSE (adjusted mean difference = 0.92; 95% confidence interval (CI): 0.17 to 1.67; $p=0.02$) and ETAM (adjusted mean difference = 1.00; CI: 0.14 to 1.85; $p=0.02$) were significantly better in the intervention group. The adjusted cost difference was –€938.50 (CI: –2733.65 to 763.13; $p=0.31$). Given the CEAC, MAKS was cost-effective for 78.0% of MMSE and 77.4% for ETAM without a need for additional costs to payers.

Conclusions MAKS is a cost-effective treatment to stabilize the ability to perform activities of daily living and cognitive abilities of people with MCI or mild to moderate dementia in German DCCs. Thus, MAKS should be implemented in DCCs.

Keywords Dementia · MCI · Cost-effectiveness analysis · MMSE · ETAM · Non-pharmacological treatment

JEL Classification I12 Health Behavior

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Abbreviations

ADAS-Cog	Alzheimer's Disease Assessment Scale—Cognitive Subscale
ADLs	Activities of daily living
ADCS-ADL	Alzheimer's Disease Cooperative Study—Activities of Daily Living Inventory
BSFC-s	Burden Scale for Family Caregivers, short version
CEA	Cost-effectiveness analysis
CEAC	Cost-effectiveness acceptability curve
CE plane	Cost-effectiveness plane
CG	Control group
CI	95% confidence interval
DCC	Day care center
DeTaMAKS-trial	German acronym for "Dementia in Day care (German "Tagespflege") with Motor stimulation, Activities of daily living stimulation, Cognitive (German "Kognitiv") stimulation, and Social functioning"
ETAM	Erlangen Test of Activities of Daily Living in Persons with Mild Dementia or Mild Cognitive Impairment
IG	Intervention group
ITT	Intention to treat
MAKS	Non-pharmacological treatment with four components—Motor stimulation, Activities of daily living stimulation, Cognitive stimulation, and Social functioning
MCI	Mild cognitive impairment
MMSE	Mini-Mental Status Examination
NOSGER	Nurses' Observation Scale for Geriatric Patients, social behavior subscale
NPI-Q	Neuropsychiatric Inventory Questionnaire
SA	Sensitivity analysis
SD	Standard deviation

Background

Demographic change leads to an aging population and is expected to increase the prevalence of disability and chronic conditions such as cognitive impairment [1]. Cognitive impairment in older people often begins with mild cognitive impairment (MCI), which can be a transition stage to dementia with a conversion rate of about 15% per year [2]. Over the last 10 years, the prevalence of MCI in Germany for people older than 65 years was 13.0 to 20.0% [3, 4]. In 2017, more than 1.7 million people older than 65 years in Germany suffered from dementia with an incidence of

300,000 cases per year [5]. Owing to rising life expectancy, the prevalence of dementia is estimated to increase to 3 million cases in Germany by 2050 [6]. Cognitive impairment causes high economic and societal burden due to the high costs of care, especially for institutionalization [7–10].

To prevent institutionalization and minimize costs resulting from deterioration of cognitive impairment, adequate treatments are necessary for community-dwelling people with cognitive impairment. Until recently, the literature has mainly focused on pharmacological treatments for effective management strategies for cognitive impairment (e.g., [11–13]). However, the literature states that non-pharmacological treatments are useful and potentially cost-effective approaches to improve and stabilize people's cognitive and functional abilities [14–17]. To affect multiple domains, a combination of cognitive and physical interventions (multimodal approaches) within non-pharmacological treatments is recommended [15, 18].

In Germany, different services exist for community-dwelling people with cognitive impairment. One service is the adult day care center (DCC), which is a regular service in many industrialized countries [19]. DCCs support the social, health, and daily living needs of people in need of care (including people with cognitive impairment) in a group setting during daytime hours and thus minimize informal caregivers' burden of care during the day. DCCs are facilities located in or close to a community where older adults live. They enable community-dwelling older adults or people with disabilities or chronic diseases to remain living at home through providing a supportive environment regarding social needs and activities of daily living (ADLs), such as eating or going to the toilet. Furthermore, people with cognitive or physical health needs receive support through different health and occupational programs (e.g., promotion of physical activity through balloon-games). "Care as usual" in German DCCs is normally considered as assistance with daily activities like eating or going to the toilet, managing medication, and the offer of different types of occupational programs, such as playing board games. The scope of assistance is individual to every DCC. Especially the offer of occupational programs can be different regarding the scope and types of activities provided in the DCCs [20, 21]. Support is provided by formal caregivers, such as skilled nurses and occupational therapists [20, 22, 23]. Germany's statutory nursing care insurance covers costs of day care including transportation for statutory-insured adults with a level of care (since 2017: "care grades"). Only costs for food and specific investments are not covered. The amount of financial support depends on the individual's level of care; one is the level for the lowest level of assistance needed, while three is the level for the highest assistance needed [22]. People applying for a level of care are evaluated for the amount of assistance they need by the statutory Health

Insurance Medical Service. The prerequisites for receiving day care depend on the individual’s need and the availability of a caregiver during day [22, 23]. Independent from financing day care, similar models as above described “care as usual” day care exist in other industrialized countries [19, 24, 25].

According to previous research [19, 26, 27], DCCs show a positive effect on the well-being of older adults who visit DCCs regularly. To date, mainly clinical effectiveness of non-pharmacological treatments for community-dwelling people with cognitive impairments and their caregivers was assessed (e.g., [14, 16, 19, 25, 27, 28]). However, literature states that cost-effectiveness analyses focusing on evidence-based, structured, non-pharmacological treatments in the setting DCC for community-dwelling people with cognitive impairments continue to be limited [16, 27, 29–31]. Researchers suggest that future trials should systematically include cost-related measures [14, 27, 29]. Furthermore, Nagy et al. recommend that economic evaluations should include analyses of cognitive, as well as functional, parameters of people with cognitive impairment [13].

The objective of this study is to assess the cost-effectiveness of a multicomponent, non-pharmacological treatment vs. “care as usual” in DCCs for community-dwelling people with cognitive impairment from the societal perspective.

Methods

Study design

We conducted a cost-effectiveness analysis (CEA) alongside the cluster-randomized, controlled, multicenter, prospective DeTaMAKS-trial (German acronym for “Dementia in Day care (German “Tagespflege”) with Motor stimulation, Activities of daily living stimulation, Cognitive (German “Kognitiv”) stimulation, and Social functioning”). The treatment is called “MAKS”. The DeTaMAKS-trial had a waitlist control group design and was applied within 34 German DCCs between April 2014 and March 2017 [32].

Individuals in DCCs were included if they had MCI, mild or moderate dementia, and if informed consent was given. Individuals who were blind, deaf, without a caregiver, not able to communicate, or had suffered more than one stroke, severe depression, schizophrenia, an addictive disorder, had concrete plans for institutionalization, or were attending DCCs less than once a week were excluded [20]. All DCCs were randomized into two groups (intervention vs. “care as usual”). Further details on the recruitment strategy of DCCs and the eligibility criteria of DCCs and participants are described in detail elsewhere [28, 32]. All procedures were approved by the Friedrich Alexander University

Erlangen-Nuremberg Ethics Committee. The trial’s registration number is ISRCTN16412551.

For the CEA, participants were assessed both at baseline (t_0) and at 6-month follow-up (t_1) of the intervention. Both the intervention group (IG) and the control group (CG) included only individuals who started the allocated treatment and did not die during the intervention phase (intention to treat (ITT)). A sensitivity analysis included all individuals in the IG and CG who completed the intervention as per protocol (complete cases).

Intervention

The IG underwent the treatment “MAKS”, whereas the CG continued with “care as usual”. MAKS is a non-pharmacological, multicomponent, group-based treatment developed for patients in DCCs. The treatment’s aim is to improve or at least stabilize the ability to perform ADLs and cognitive abilities of people with MCI or mild to moderate dementia in German DCCs. MAKS combines four components (social warm-up session (S) (sensori)motor activation (M), cognitive stimulation (K), activation of ADLs (A)). Oswald et al. [33, 34], Olazarán et al. [14] and Özbe et al. [15] found multicomponent-interventions to be more effective than single-component interventions and that they generate broader positive outcomes. Thus, MAKS includes more than one component. According to the German “S3-Leitlinie Demenzen” [18] and the British “NICE-SCIE Guideline Dementia” [31], activities to stimulate cognition (K), improve or stabilize ADLs (A) and physical activity (M) are effective strategies to minimize risk factors for dementia in patients with MCI or to delay the disease’s progress in patients with mild to moderate dementia. Furthermore, the “social warm-up session” (S) was added to MAKS, because of former research stating social participation to minimize the risk of dementia [35–37]. The importance of social interactions to minimize the risk of dementia was pointed out by the systematic review of Kuiper et al. [38]. Additionally, NICE-SCIE recommends that e.g., “people with mild-to-moderate dementia of all types should be given the opportunity to participate in a structured group cognitive stimulation” [31].

The four components of MAKS are always applied in the same order, thus forming an intervention unit that lasts approximately 2 h per day. The daily intervention begins with a social warm-up session, such as a discussion about various topics or a group meditation. After that, a sensorimotor activation session follows, which addresses gross and fine motor skills, sensory perception, and balance. The cognitive stimulation session consists of game-based exercises, such as knowledge quizzes and memory games. The last session addresses the activation of ADLs through social tasks (e.g., baking, doing handicrafts). Social interaction is important in all sessions (e.g., completion of tasks together)

[28, 32]. Further details of MAKS can be found elsewhere [32, 39].

MAKS' clinical effectiveness was proven in the described randomized, controlled DeTaMAKS-trial [28]. The trial's aim was to evaluate MAKS' effect on cognitive abilities and capabilities to perform ADLs in people with MCI or dementia in German DCCs.

"Care as usual" within the DeTaMAKS-trial was defined as above described "care as usual" in German DCCs.

Costs

The economic evaluation was performed from the societal perspective. All costs were calculated for the year 2014/2015 and reported in Euros.

Service utilization was assessed at t_0 and t_1 via proxy interviews with the participants' informal caregivers. The assessment was based on a modified version of the validated FIMA questionnaire [40]. The reference period for t_0

covered the 3-month period before t_0 . The reference period for t_1 was the 6-month intervention period.

Costs for informal and formal care, as well as for therapeutic services, were calculated by applying the German unit costs of Bock et al. [41] and using several updated sources for 2014/2015 (e.g., [42–45]). Costs for informal care were calculated according to the opportunity cost approach [46]. All caregivers were asked about their amount of informal care time and whether they reduced their work to undertake caregiving. If so, work productivity loss was calculated by average wage rates per hour. Additional hours were calculated by average rates for leisure time per hour [41]. Further details on unit costs and their data sources can be found in Table 1.

Intervention costs

Intervention costs consisted of personnel costs for the MAKS trainer for providing onsite training and phone-based support for questions regarding the implementation

Table 1 Cost categories of service utilization and unit costs in € for 2014/2015

Cost category	Unit	Unit costs in €	Source
Costs of service utilization			
Formal care			
Home nursing service	h	42.00	[41], updated
Paid service for household support	h	21.00	[41], updated
Service for supervision at home	h	31.44	[41], updated
Short-term care	day	55.35	[45]
Meal delivery	day	1.00	[43]
Informal care			
Care during leisure time	h	22.32	[41], updated
Work productivity loss due to caregiving	h	31.50	[41], updated
Services provided for informal caregivers			
Training in nursing skills	day	90.00	[47]
Consultation	h	40.00	[47]
Patient group supervision	Contact	25.00	[47, 48]
Self-help group sessions including patient supervision	Contact	14.33	[49, 50], average of salary and rental costs
Therapeutic services			
Physical therapy	Contact	17.45	[41], updated
Occupational therapy	Contact	39.34	[41], updated
Medical pedicure	Contact	29.75	[41], updated
Intervention costs			
MAKS training session	h	29.90	Wage/hour by University Hospital Erlangen
MAKS refresher course	h	29.90	Wage/hour by University Hospital Erlangen
Phone-based support	h	29.90	Wage/hour by University Hospital Erlangen
Travel costs of MAKS trainer	km	0.20	[51]
Hotel costs of MAKS trainer	Overnight stay	70.00	Average price of overnight stays at hotel [52]
Manual	Book	48.80	Retail price

MAKS non-pharmacological treatment (Motor stimulation, Activities of daily living stimulation, Cognitive stimulation, and Social functioning)

of MAKS. Additionally, the trainer's hotel and travel costs to the onsite sessions were considered. Furthermore, material costs for the manual provided to the DCCs were accounted for (see Table 1).

Effects

The effect of MAKS on cognitive abilities was operationalized by the Mini-Mental Status Examination (MMSE) [53]. The effect on capabilities to perform ADLs was operationalized by the Erlangen Test of Activities of Daily Living in Persons with Mild Dementia and Mild Cognitive Impairment (ETAM) [54, 55]. MMSE and ETAM were both assessed at t_0 and t_1 . Both tests have a range from 0 to 30 points with higher values indicating better performance.

Statistical analysis

The economic evaluation included a CEA with MMSE and ETAM as the intervention's effects. Both MMSE and ETAM were conducted on an ITT basis. All analyses were performed at an alpha-level of 0.05. To examine differences between IG and CG at t_0 , subject characteristics were compared using Pearson's Chi square tests for independence for categorical variables and Mann–Whitney U tests for continuous variables.

To calculate the incremental difference of MMSE and ETAM between the IG and CG at t_1 , we used Gaussian-distributed Generalized Linear Models. For this analysis, we controlled for age, gender, MMSE, and ETAM at t_0 .

Costs were calculated by multiplying the reported utilization figures by their respective unit costs. Here, single missing items were assumed to be true zeros. For therapeutic services not being assessed at t_0 , multiple imputation was performed within the ITT population. Total costs were derived by summing up the costs of each cost domain. To estimate the incremental cost difference, we used a Gamma-distributed Generalized Linear Model to consider the right-skewed nature of cost data [56]. We assigned a small value of €10.00 for individuals without costs (IG: $n = 2$ at t_0) to avoid them being excluded from the analyses. Cost differences adjusted for age, gender, and costs at t_0 were estimated based on recycled predictions with group assignment (IG vs. CG) as the coefficient of interest. Recycled predictions create an identical covariate structure for both the IG and the CG. First, costs are predicted under the assumption that all individuals are cases, i.e. all individuals are in the IG. Subsequently, costs are predicted under the assumption that all individuals are controls, i.e. all individuals are in the CG, and predict costs. Calculating the difference in the mean predictions for all individuals between these two scenarios then results in an estimate of the adjusted marginal difference in costs between IG and CG [57]. For the adjusted

cost difference, a 95% confidence interval (CI) was estimated from 1000 bootstrap replications using the percentile method. Similar to the previous analysis of MAKS' clinical effectiveness [28], costs and effects were calculated on an individual-, rather than cluster-based structure to allow comparability.

For ETAM and MMSE, we analyzed incremental cost-effectiveness ratios (ICERs) when applicable (not negative) [58]. Simultaneous bootstrapping ($n = 1000$) of incremental cost and incremental effect estimates addressed estimation uncertainty. Those replications were plotted on the cost-effectiveness plane (CE plane). Furthermore, we calculated cost-effectiveness acceptability curves (CEAC) based on the resulting bootstrap distribution. Those CEACs indicate the likelihood that the intervention is cost-effective for a given value of willingness to pay.

Missing values were assumed to be missing at random, which means that observed variables before dropout can be used to predict the missing value. It is supposed that there is no pattern of missingness and bias results to be small [59]. Missing values were imputed for those study participants with dropout reasons other than death (see Fig. 1). ETAM and MMSE were imputed using an expectation maximization algorithm. This method uses the variables that show the greatest correlation with the missing variable [28].

Sensitivity analyses

Finally, we performed three sensitivity analyses (SA).

For SA₁, we repeated all analyses within complete cases.

For SA₂, intervention costs were calculated within the ITT population by applying a real-world situation for all costs of MAKS' implementation.

As different approaches for costs for informal care exist, we also calculated costs for informal care according to the often-used proxy good method in the ITT population as SA₃ [60, 61]. For this approach, we used the minimum gross wage including incidental wage costs for skilled nurses. For 2015, this value was €12.03 [62, 63].

All analyses were performed with SAS (Version 9.4, SAS Institute Inc., Cary, NC, USA).

Results

Study sample

Figure 1 presents the flow chart of the study sample. At t_0 , 34 DCCs were randomized into two groups. Two out of the 34 recruited DCCs were excluded for analysis (DCC₁: terminated collaboration treatment, DCC₂: treatment was not performed according to the instruction manual). Thus, the final study sample resulted in the remaining 32 DCCs with

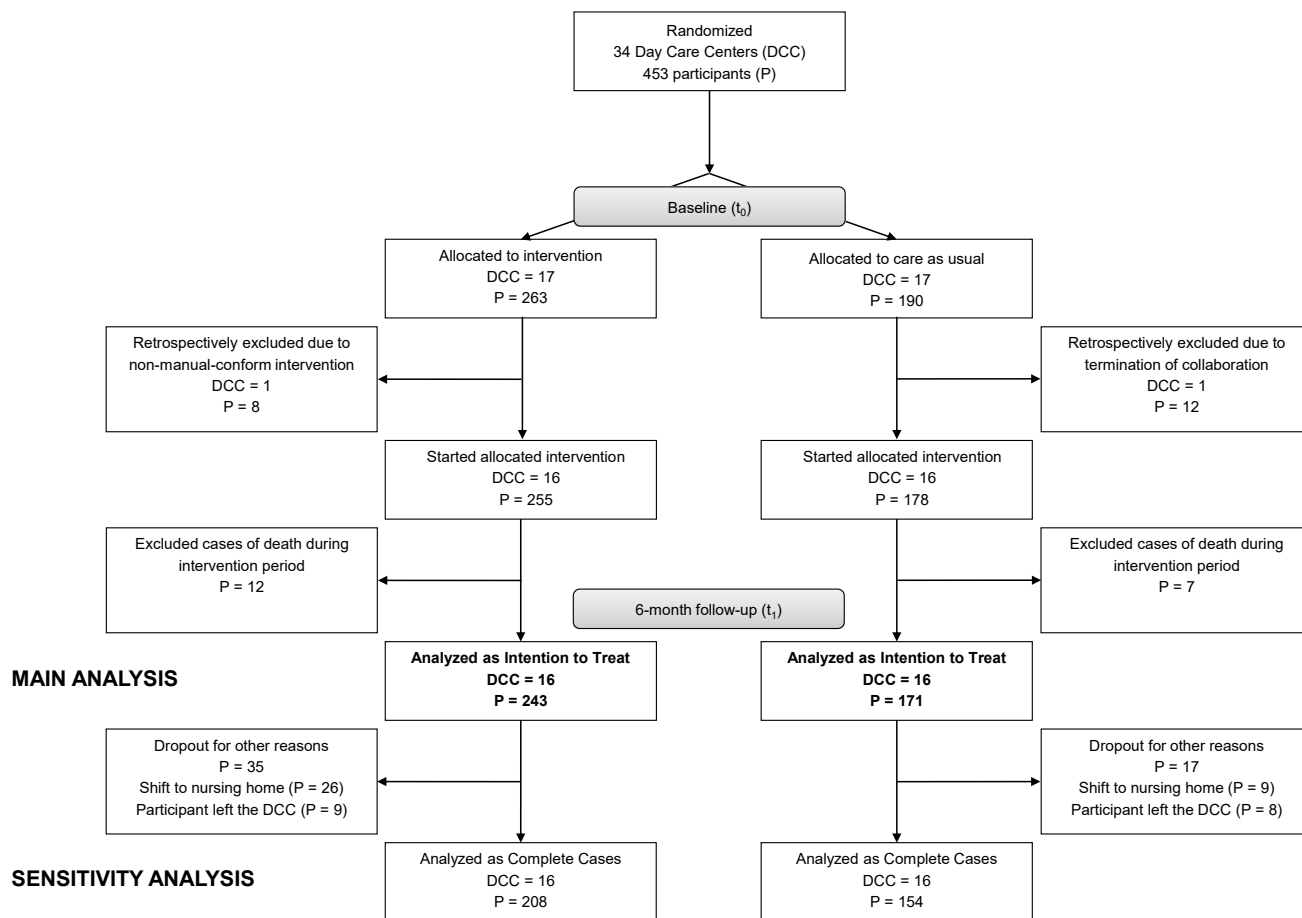


Fig. 1 Flow diagram of the DeTaMAKS-trial's study sample. DCC day care center, P participant

a total of 433 individuals (IG: $n = 255$, CG: $n = 178$). Owing to death between t_0 and t_1 , 19 individuals had to be excluded for the CEA based on ITT. Thus, the CEA included 243 individuals in the IG and 171 in the CG.

The 19 dropouts were significantly older than individuals who remained in the ITT analysis (86.3 versus 81.4 years). All other values of dropouts were similar to those in the ITT analysis.

The study sample's baseline characteristics are shown in Table 2. Mean age was 81.4 years. Of 414 individuals, 259 (62.6%) were women (see Fig. 2). Randomization produced relatively well-balanced samples (see Table 2).

For SA₁, we included 208 individuals in the IG and 154 individuals in the CG who completed the intervention. Similar to the ITT analysis, mean age was 81.3 years and 221 (61.0%) were women.

Effects

Whereas unadjusted MMSE values at t_0 were comparable between IG (19.51; SD=0.30) and CG (19.40; SD=0.36),

they differed at t_1 : MMSE in the IG remained almost at the same level (19.42; SD=0.37), MMSE in the CG declined (18.44; SD=0.46). The adjusted difference was significant (adjusted mean difference=0.92; CI: 0.17 to 1.67; $p=0.02$).

Similar, ETAM at t_0 started at a comparable level. The unadjusted value for the IG was 17.49 (SD=0.44) and for the CG 17.19 (SD=0.58). At t_1 , ETAM in the IG increased to 17.67 (SD=0.44). In contrast, ETAM in the CG declined to 16.48 (SD=0.63). The adjusted difference was significant (adjusted mean difference=1.00; CI: 0.14 to 1.41; $p=0.02$) (see Fig. 2).

Service utilization and costs

Mean service utilization at t_0 and t_1 and mean costs per patient are presented in Table 3. At t_0 , individuals in the IG (€8551.57; SD=5411.60) created similar unadjusted costs to those in the CG (€8089.63; SD=4872.46). Costs for informal care were the largest contributor to costs of service utilization (84.9%).

At t_1 , adjusted total costs resulted in lower costs in the IG of -€938.50 (CI: -2733.65 to 763.13; $p=0.31$). Except for

Table 2 Baseline characteristics of individuals stratified by group (*n* = 414)

		<i>N</i>	Total (<i>n</i> = 414)	Intervention group (58.7%) (<i>n</i> = 243)	Control group (41.3%) (<i>n</i> = 171)	<i>p</i> value
Dementia patients						
Age in years	Total	414	81.4 (7.7)	81.7 (7.9)	81.0 (7.4)	0.26 ^a
Sex	Female	414	259 (62.6%)	152 (62.6%)	107 (62.6%)	1.00 ^b
Education	Low (≤ 9 years)	413	317 (76.6%)	185 (76.5%)	132 (77.2%)	0.63 ^a
	Middle (10–11 years)		51 (12.3%)	28 (11.6%)	23 (13.5%)	
	High (≥ 12 years)		45 (10.9%)	29 (12.0%)	16 (9.4%)	
Marital status	Married	414	169 (40.8%)	99 (40.7%)	70 (40.9%)	0.96 ^b
	Widowed		221 (53.4%)	129 (53.1%)	92 (53.8%)	
	Divorced		12 (2.9%)	7 (2.9%)	5 (2.9%)	
	Single		12 (2.9%)	8 (3.3%)	4 (2.3%)	
Cognitive impairment (MMSE)	Total	414	19.5 (4.7)	19.5 (4.7)	19.4 (4.8)	0.68 ^a
	24–30 (MCI)		89 (21.4%)	53 (21.8%)	36 (21.1%)	0.83 ^b
	18–23 (mild dementia)		170 (41.1%)	102 (42.0%)	68 (39.8%)	
	10–17 (moderate dementia)		155 (37.4%)	88 (36.2%)	67 (39.2%)	
Activities of daily living (ETAM)	Total	414	17.4 (7.2)	17.5 (6.9)	17.2 (7.4)	0.71 ^a
Care level	None	414	20 (4.8%)	8 (3.3%)	12 (7.0%)	0.27 ^b
	Limited abilities in ADLs		46 (11.1%)	28 (11.5%)	18 (10.5%)	
	1 (low)		218 (52.7%)	136 (56.0%)	82 (48.0%)	
	2 (middle)		126 (30.4%)	69 (28.4%)	57 (33.3%)	
	3 (high)		4 (1.0%)	2 (0.8%)	2 (1.2%)	
Antidementia drugs	Total		122 (2.5%)	72 (29.8%)	50 (29.2%)	0.91 ^a
Social behavior (NOSGER)	Total	414	15.6 (4.4)	15.5 (4.3)	15.7 (4.5)	0.48 ^a
Neuropsychiatric symptoms (NPI-Q)	Total	412	5.4 ()	5.3 (2.7)	5.4 (2.8)	0.83 ^a
Caregivers						
Age in years	Total	414	59.6	59.5 (11.7)	59.7 (11.4)	0.76 ^a
Sex	Female	414	303 (73.2%)	174 (71.6%)	129 (75.4%)	0.39 ^b
Education	Low	414	166 (40.1%)	96 (39.5%)	70 (40.9%)	0.36 ^a
	Middle		149 (36.0%)	83 (34.2%)	66 (38.6%)	
	High		99 (23.9%)	64 (26.3%)	35 (20.5%)	
Employment status	Employed	414	226 (54.6%)	133 (54.7%)	93 (54.4%)	0.94 ^b
Marital status	Married/long-term partnership	414	326 (78.8%)	187 (77.0%)	139 (81.3%)	0.04^b
	Widowed		15 (3.6%)	12 (4.9%)	3 (1.8%)	
	Divorced		38 (9.2%)	18 (7.4%)	20 (11.7%)	
	Single		35 (8.5%)	26 (10.7%)	9 (5.3%)	
Relationship to person cared for	Spouse	414	112 (27.1%)	63 (25.9%)	49 (28.7%)	0.54 ^b
	Daughter/son (in law)		277 (67.0%)	163 (67.1%)	114 (66.7%)	
	Other		25 (6.0%)	17 (7.0%)	8 (4.7%)	
Caregiver burden (BSFC-s)		414	12.7 (8.1)	12.2 (8.2)	13.4 (7.8)	0.08 ^a
Care status						
Main caregiver	Yes	414	365 (88.2%)	210 (86.4%)	155 (90.6%)	0.19 ^b
Main caregiver = only informal caregiver	Yes	414	186 (44.9%)	110 (45.3%)	76 (44.4%)	0.64 ^b
Living together in same home	Yes	414	253 (61.1%)	139 (57.2%)	114 (66.7%)	0.05^b
Duration of informal care in months	Total	413	59.8	58.7 (48.3)	61.2 (54.6)	0.79 ^a
No. of visits/week to DCC within first month	Total	414	2.27 ()	2.29 (1.3)	2.25 (1.2)	1.00 ^a
Informal care time in hours per day	Total	414	3.2 ()	3.1 (2.0)	3.3 (2.1)	0.40 ^a

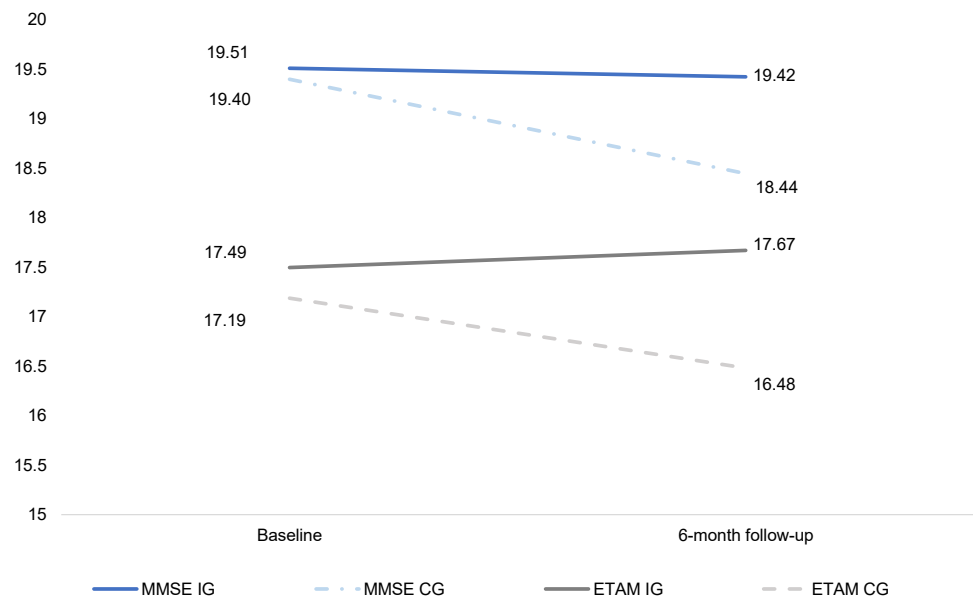
MMSE Mini-Mental Status Examination, *MCI* mild cognitive impairment, *ETAM* Erlangen Test of Activities of Daily Living in Persons with Mild Dementia or Mild Cognitive Impairment, *ADLs* activities of daily living, *NOSGER* Nurses’ Observation Scale for Geriatric Patients, social behavior subscale, *NPI-Q* Neuropsychiatric Inventory Questionnaire (number of symptoms), *BSFC-s* Burden Scale for Family Caregivers, short version, *DCC* day care center

Bold numbers: significant at *p* ≤ 0.05

Data presented as *n* (%) / mean (standard deviation) | any discrepancies in percentages due to rounding

^aBased on Mann–Whitney *U* test, ^bbased on Pearson’s Chi square test

Fig. 2 Changes in MMSE and ETAM between t_0 and t_1 . IG intervention group, CG control group, MMSE Mini-Mental Status Examination, ETAM Erlangen Test of Activities of Daily Living in Persons with Mild Dementia or Mild Cognitive Impairment



informal care, the IG incurred higher costs than the CG in all other categories. For informal care, we observed $-\text{€}1159.63$ (CI: $-\text{€}3078.81$ to $\text{€}786.73$; $p=0.25$) lower costs in the IG. However, in none of the categories was the cost difference statistically significant. Detailed information about adjusted costs can be found in Table 4.

Intervention costs

Four MAKS training sessions of 8 h for a pool of four DCCs with three participating employees per DCC were proposed (total costs: $\text{€}956.80$). The MAKS refresher courses were planned for a pool of four DCCs with a total of four sessions per course (total costs: $\text{€}478.40$). For every DCC, one manual was considered in the intervention's cost calculation (total costs: $\text{€}774.40$). A total of 3800 km (total costs: $\text{€}760.00$) and four hotel overnight stays (total costs: $\text{€}280.00$) were planned for the MAKS trainer. The ITT analysis resulted in total mean intervention costs of $\text{€}15.34$ per patient or $\text{€}233.00$ per DCC.

Cost-effectiveness

Figure 3a shows the CE plane of MMSE, Fig. 3b of ETAM. For both MMSE (76.7%) and ETAM (77.1%), most of the cost-effect pairs were located in the south-east quadrant of the CE plane. This quadrant suggests better effects and fewer costs. Although the intervention costs have been included, overall costs were lower in the IG (Table 4). In the north-east quadrant, 22.4% of MMSE and 21.8% of ETAM replications were located. This quadrant suggests better effects but higher costs.

Given the CEAC (Fig. 4a, b), MAKS was cost-effective for 78.0% of MMSE and 77.4% for ETAM replications in comparison with "care as usual" without a need for additional costs to payers (willingness to pay of $\text{€}0.00$). Probability of 95.0% of acceptable cost-effectiveness was reached for a maximum willingness to pay of $\text{€}939.66$ for MMSE and $\text{€}937.73$ for ETAM. All ICERs resulted in negative values and thus were not reported.

Sensitivity analyses

SA₁: complete case analysis

Similar to the ITT analysis, MMSE (adjusted mean difference = 1.08; CI: 0.25 to 1.91; $p=0.01$) and ETAM (adjusted mean difference = 1.14; CI: 0.19 to 2.10; $p=0.02$) in SA₁ showed significantly better results in the IG than in the CG. Owing to less intervention utilization, the SA₁ analysis resulted in slightly fewer total mean intervention costs than the ITT analysis ($\text{€}14.63/\text{patient}$, $\text{€}190.13/\text{DCC}$). Only two DCCs took advantage of the MAKS refresher course. Thus, only two instead of four sessions took place, and the costs for travelling and overnight stays, as well as for trainer wages, were lower. Furthermore, the phone-based support could be managed within approximately 0.5 h instead of the initially assumed 1 h per DCC.

Similar to the ITT analysis, adjusted total costs at t_1 resulted in lower costs in the IG of $-\text{€}492.29$ (CI: $-\text{€}3389.92$ to $\text{€}2465.11$; $p=0.65$). Equally, only informal care resulted in lower costs in the IG. None of the cost differences was statistically significant (see Table 4).

Within SA₁, 67.5% of MMSE and 65.1% of ETAM were located in the south-east quadrant of the CE plane (Fig. 5a,

Table 3 Mean service utilization in number of contacts and mean costs in € per individual for t_0 and t_1

Cost category	Unit	Intervention group (58.7%) (n = 243)				Control group (41.3%) (n = 171)			
		Mean service utilization (SD)		Mean costs (SD)		Mean service utilization (SD)		Mean costs (SD)	
		t_0^a	t_1^b	t_0	t_1	t_0^a	t_1^b	t_0	t_1
Costs of service utilization									
Formal care									
				1131.91	2513.83			906.83	2070.40
				(1466.13)	(3008.99)			(1198.01)	(2514.34)
Home nursing service	h	17.44 (2.96)	36.92 (64.49)	680.09 (1179.26)	1598.71 (2615.99)	11.31 (20.04)	26.72 (50.50)	479.13 (845.30)	1138.17 (2089.16)
Paid service for household support	h	10.15 (29.13)	21.47 (59.09)	221.80 (637.88)	484.62 (1222.10)	10.53 (22.38)	17.87 (41.63)	219.79 (464.11)	385.81 (849.87)
Service for supervision at home	day	1.78 (6)	4.35 (15)	75.92 (271.96)	146.10 (469.37)	2.53 (8)	6.05 (17)	56.48 (192.29)	176.84 (460.17)
Short-term care	day	2.75 (7)	4.67 (11)	146.73 (435.15)	241.96 (542.48)	2.56 (6)	7.45 (15)	146.13 (343.81)	388.56 (848.52)
Meal delivery	day	7.28 (20.49)	9.79 (31.80)	7.37 (20.22)	11.71 (32.25)	6.09 (18.89)	12.68 (34.35)	5.31 (17.49)	11.75 (32.62)
Informal care									
				6962.63	13,895.35			7499.85	16,200.71
				(4919.18)	(10,503.54)			(4952.01)	(11,330.74)
Care during leisure time	h	252.89 (179.15)	515.50 (439.87)	6187.17 (4113.42)	12,523.37 (9933.37)	264.29 (191.18)	554.23 (414.93)	6401.02 (3736.34)	13,974.66 (9244.08)
Work productivity loss due to care-giving	h	25.31 (69.51)	42.8 (122.86)	775.46 (2174.98)	1371.98 (3756.65)	33.62 (82.46)	67.74 (172.51)	1098.83 (2652.27)	2226.05 (5428.98)
Services provided for informal caregivers									
				53.27	169.78			52.68	97.45
				(143.01)	(430.78)			(157.10)	(237.06)
Training in nursing skills	day	–	0.02 (0.14)	–	2.34 (12)	–	0.03 (0)	–	3.26 (15.73)
Consultation	Contact	0.37 (1)	0.84 (3)	32.07 (108.61)	83.10 (239.12)	0.34 (1)	0.58 (2)	27.16 (121.66)	50.65 (188.05)
Self-help group sessions incl. patient supervision	Contact	0.23 (1)	0.53 (3)	3.57 (20)	9.51 (43)	0.88 (3)	0.97 (4)	2.83 (9)	13.30 (5)
Patient group supervision	Contact	0.68 (2)	2.63 (12)	17.63 (62.94)	74.83 (315.02)	0.19 (0)	0.86 (3)	22.69 (100.73)	30.32 (123.65)

Table 3 (continued)

Cost category	Unit	Intervention group (58.7%) (n=243)				Control group (41.3%) (n=171)			
		Mean service utilization (SD)		Mean costs (SD)		Mean service utilization (SD)		Mean costs (SD)	
		t_0^a	t_1^b	t_0	t_1	t_0^a	t_1^b	t_0	t_1
Therapeutic services				243.77	(527.41)			188.92	(447.63)
Physical therapy	Contact	–	7.13 (16.31)	–	132.81 (280.24)	–	6.30 (15.06)	–	113.78 (259.73)
Occupational therapy	Contact	–	2.42 (9)	–	110.68 (357.15)	–	1.64 (8)	–	74.24 (318.25)
Medical pedicure	Contact	–	0.00 (0)	–	0.00 (0)	–	0.04 (0)	–	0.90 (9.37)
Intervention costs				15.34					
MAKS training session	h	–			3.94	–			
MAKS refresher course	h	–			1.97	–			
Phone-based support	h	–			1.97	–			
Travel costs of MAKS trainer	km	–			3.13	–			
Hotel costs of MAKS trainer	Overnight stay	–			1.15	–			
Manual	Book	–			3.19	–			
Total costs^c				8089.63	16,359.44			8551.57	18,526.82
				(4871.46)	(10,333.29)			(5411.60)	(11,374.81)

Data presented as mean (standard deviation), any discrepancies due to rounding

Single missing items in resource utilization of complete cases not imputed, single missing items in cost calculation for complete cases assumed to be true zeros; thus, slightly different results due to multiplication of unit costs with mean service utilization

Bold numbers indicates summed costs of each category MAKS non-pharmacological treatment (Motor stimulation, Activities of daily living stimulation, Cognitive stimulation, and Social functioning)

^aReference period: 3-month period before t_0 , ^breference period: 6-month intervention period, ^cimputed values, summing of distinct cost categories yields slight deviation

b). In the north-east quadrant, 31.7% of MMSE and 33.0% of ETAM replications were located in the north-east quadrant.

Given the CEAC (Fig. 6a, b), MAKS was cost-effective for 68.5% of MMSE and 66.8% for ETAM replications in comparison with “care as usual” without a need for additional costs to payers.

SA₂: real-world situation

SA₂ based on the ITT population. Therefore, effects were expected to be similar to the ITT analysis. For SA₂, the

planned total mean intervention costs (€960.00/DCC) will be higher than in the ITT analysis. The higher costs will be caused by the extension of MAKS sessions from 8 h up to 16 h. Furthermore, the MAKS refresher course will be mandatory for every DCC (ITT and SA₁; voluntary) with a course fee of €290.00 and three required participants per DCC. Additionally, the printed manual will be converted into an online tool and has to be purchased for €90.00.

Similar to the ITT analysis, in SA₂ 74.7% of MMSE and 75.6% of ETAM of the cost-effect pairs were in the south-east quadrant of the CE plane (Fig. 7a, b). For MMSE,

Table 4 Adjusted costs and cost differences in € for t_1 per individual

	Intention to treat analysis			
	Intervention group [95% CI]	Control group [95% CI]	Cost difference [95% CI]	<i>p</i> value
Total costs	17,169.52 [15,938.52; 18,472.36]	18,108.01 [16,731.65; 19,642.09]	− 938.50 [− 2733.65; 763.13]	0.31
Formal care	2519.50 [2200.25; 2849.82]	2288.87 [1929.27; 2709.91]	230.63 [− 200.43; 654.13]	0.28
Informal care	14,636.34 [13,299.19; 16,229.85]	15,795.86 [14,441.91; 17,327.65]	− 1159.63 [− 3078.81; 786.73]	0.25
Services provided for informal caregiver	167.96 [115.44; 240.66]	114.65 [76.22; 181.20]	53.30 [− 2.69; 115.49]	0.06
Therapeutic services	239.59 [117.37; 308.27]	164.95 [111.80; 222.95]	74.63 [− 10.25; 156.16]	0.07
	Complete case analysis (sensitivity analysis 1)			
	Intervention group [95% CI]	Control group [95% CI]	Cost difference [95% CI]	<i>p</i> value
Total costs	17,755.30 [16,362.74; 19,399.73]	18,247.59 [16,759.36; 19,272.96]	− 492.29 [− 3389.92; 2465.11]	0.65
Formal care	2549.60 [2190.30; 2956.71]	2216.87 [1844.48; 2618.74]	332.73 [− 141.77; 789.61]	0.16
Informal care	15,145.71 [13,532.91; 16,830.79]	15,953.54 [14,360.91; 17,524.87]	− 807.28 [− 2880.75; 1408.10]	0.47
Services provided for informal caregiver	116.01 [113.37; 237.59]	115.44 [75.73; 167.81]	50.58 [− 12.49; 119.26]	0.12
Therapeutic services	258.13 [188.71; 336.05]	176.55 [121.32; 243.81]	81.58 [− 13.73; 174.60]	0.08

All cost estimates except for informal care based on two-part model
95% CI 95% confidence interval

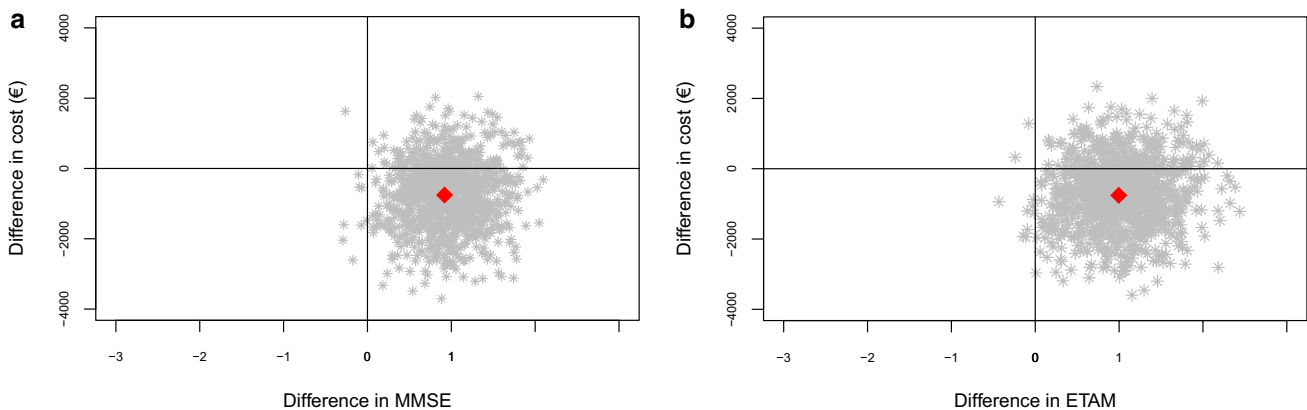


Fig. 3 **a** Intention to treat analysis: cost-effectiveness plane for the difference in MMSE at t_1 . **b** Intention to treat analysis: cost-effectiveness plane for the difference in ETAM at t_1 . *MMSE* Mini-Mental Sta-

tus Examination, *ETAM* Erlangen Test of Activities of Daily Living in Persons with Mild Dementia or Mild Cognitive Impairment

24.4% of the replications were in the north-east quadrant, and 23.4% for ETAM.

Given the CEAC (Fig. 8a, b), MAKS was cost-effective for 75.5% of MMSE and 76.4% for ETAM replications in comparison with "care as usual" without a need for additional costs to payers.

SA₃: proxy good approach for costs of informal care

Table 5 shows the adjusted costs and cost differences in € for t_1 per individual according to the proxy good approach. Similar to the opportunity cost approach, adjusted total costs

in SA₃ resulted in lower costs in the IG. For informal care, we observed − €661.21 (CI: − 1399.33 to 251.33; $p=0.2$) lower costs in the IG than in the CG. However, cost difference was not statistically significant.

Similar to the ITT analysis, in SA₃ 67.3% of MMSE and 66.3% of ETAM of the cost-effect pairs were in the south-east quadrant of the CE plane (Fig. 9a, b). For MMSE, 31.8% of the replications were in the north-east quadrant, and 32.7% for ETAM.

Given the CEAC (Fig. 10a, b), MAKS was cost-effective for 77.4% of MMSE and 78.0% for ETAM replications

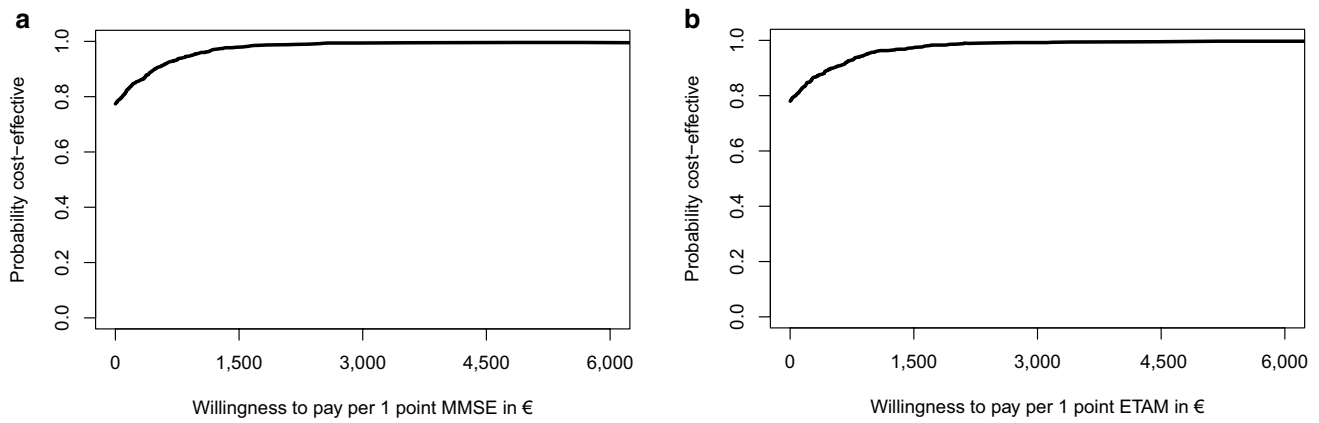


Fig. 4 **a** Intention to treat analysis: cost-effectiveness acceptability curve for the difference in MMSE at t_1 . **b** Intention to treat analysis: cost-effectiveness acceptability curve for the difference in ETAM at

t_1 . *MMSE* Mini-Mental Status Examination, *ETAM* Erlangen Test of Activities of Daily Living in Persons with Mild Dementia or Mild Cognitive Impairment

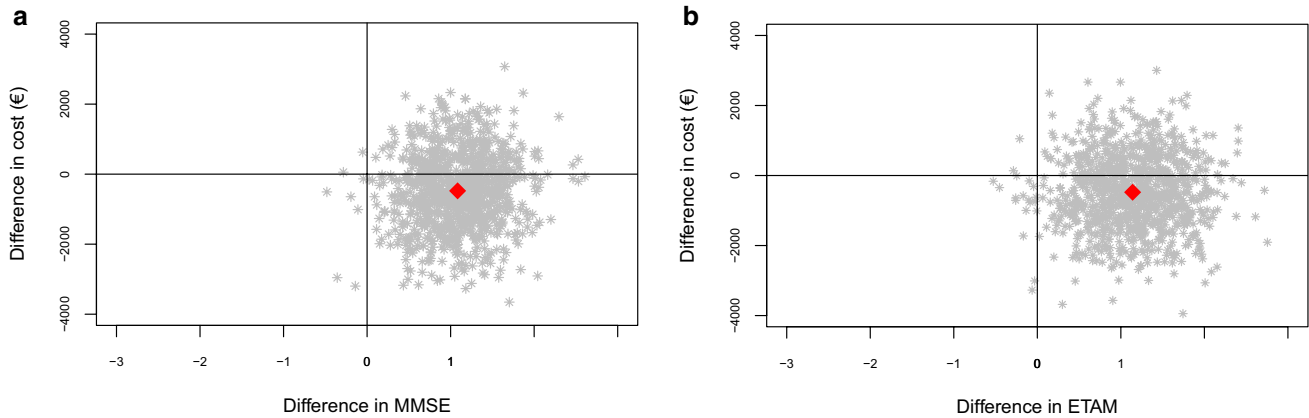


Fig. 5 **a** Sensitivity analysis 1: cost-effectiveness plane for the difference in MMSE at t_1 . **b** Sensitivity analysis 1: cost-effectiveness plane for the difference in ETAM at t_1

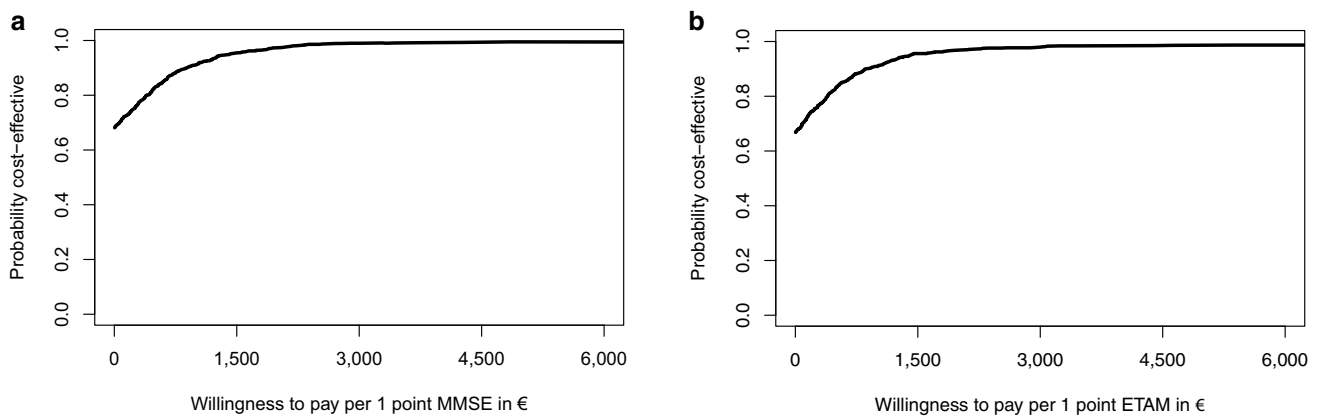


Fig. 6 **a** Sensitivity analysis 1: cost-effectiveness acceptability curve for the difference in MMSE at t_1 . **b** Sensitivity analysis 1: cost-effectiveness acceptability curve for the difference in ETAM at t_1

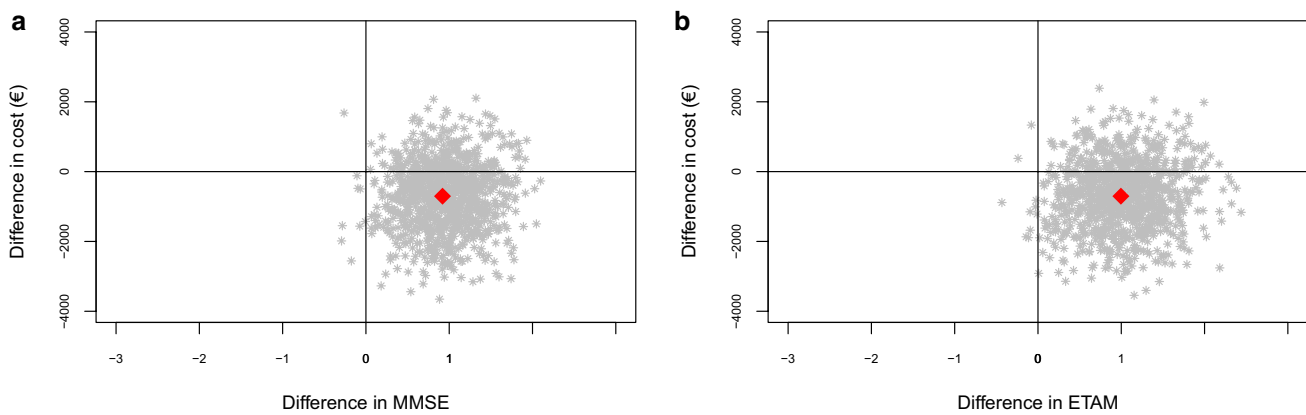


Fig. 7 **a** Sensitivity analysis 2: cost-effectiveness plane for the difference in MMSE at t_1 . **b** Sensitivity analysis 2: cost-effectiveness plane for the difference in ETAM at t_1

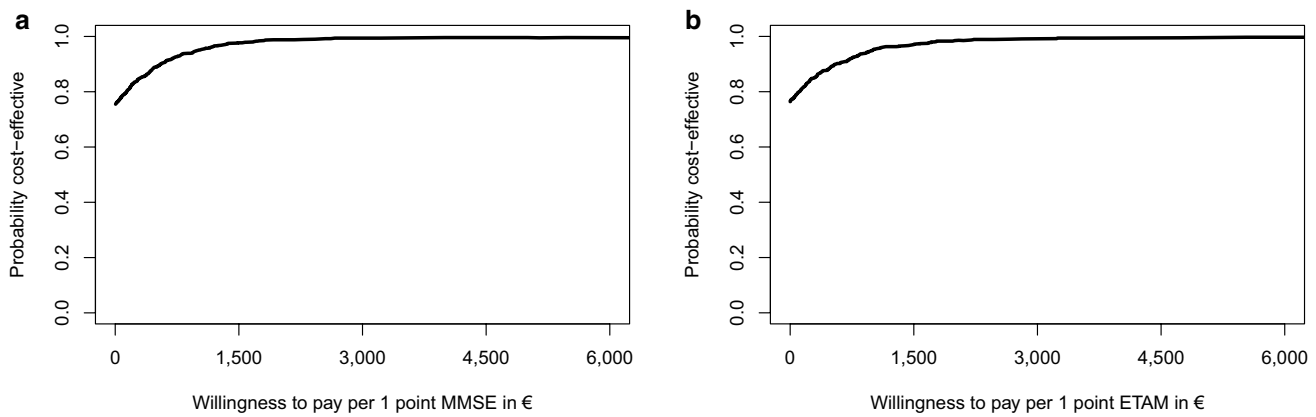


Fig. 8 **a** Sensitivity analysis 2: cost-effectiveness acceptability curve for the difference in MMSE at t_1 . **b** Sensitivity analysis 2: cost-effectiveness acceptability curve for the difference in ETAM at t_1

Table 5 Sensitivity analysis 3: adjusted costs and cost differences in € for t_1 per individual in the intention to treat population according to proxy good approach

	Intervention group [95% CI]	Control group [95% CI]	Cost difference [95% CI]	<i>p</i> value
Total costs	10,359.67 [9843.59; 10,730.98]	10,902.48 [9980.98; 11,787.83]	- 542.82 [- 1612.05; 585.14]	0.2
Informal care	7678.79 [7142.19; 8021.48]	8340.00 [7508.83; 8995.08]	- 661.21 [- 1399.33; 251.33]	0.2

95% CI 95% confidence interval. Costs for informal care were calculated with €12.03. Other cost domains equal to Table 4

in comparison with “care as usual” without a need for additional costs to payers.

Discussion

Main findings and interpretation

This study investigated the cost-effectiveness of a non-pharmacological treatment in DCCs over a 6-month

intervention period. To the knowledge of the authors, this is the first study to examine whether a structured non-pharmacological treatment in DCCs is cost-effective in comparison with “care as usual” in DCCs to improve or at least stabilize the ability to perform ADLs and the cognitive abilities of people with MCI or mild to moderate dementia. Adjusted costs at t_1 in the IG were estimated at €17,169.52 (CI: 15,938.52 to 18,472.36), and in the CG at €18,108.01 (CI: 16,731.65 to 19,642.09) per individual. CEACs show that the intervention was cost-effective for

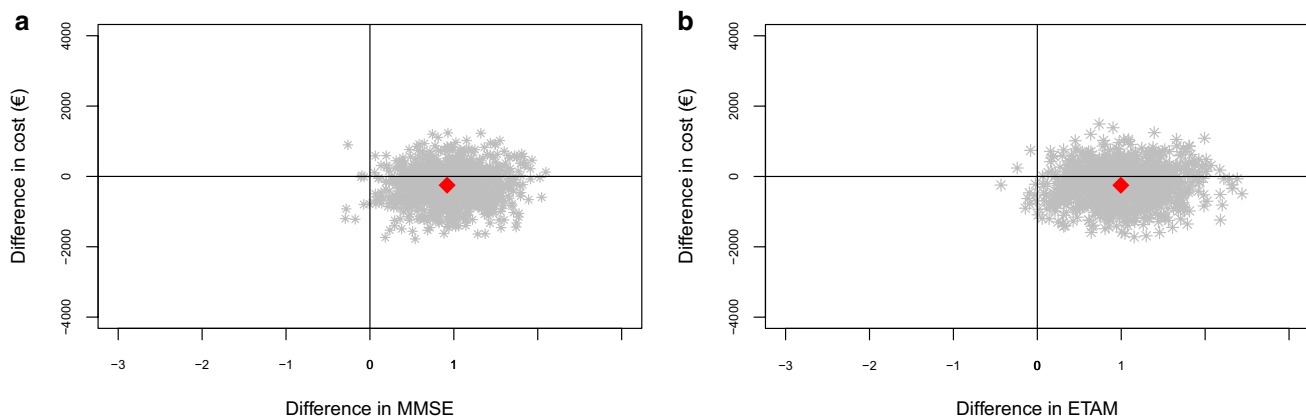


Fig. 9 **a** Sensitivity analysis 3: cost-effectiveness plane for the difference in MMSE at t_1 . **b** Sensitivity analysis 3: cost-effectiveness plane for the difference in ETAM at t_1

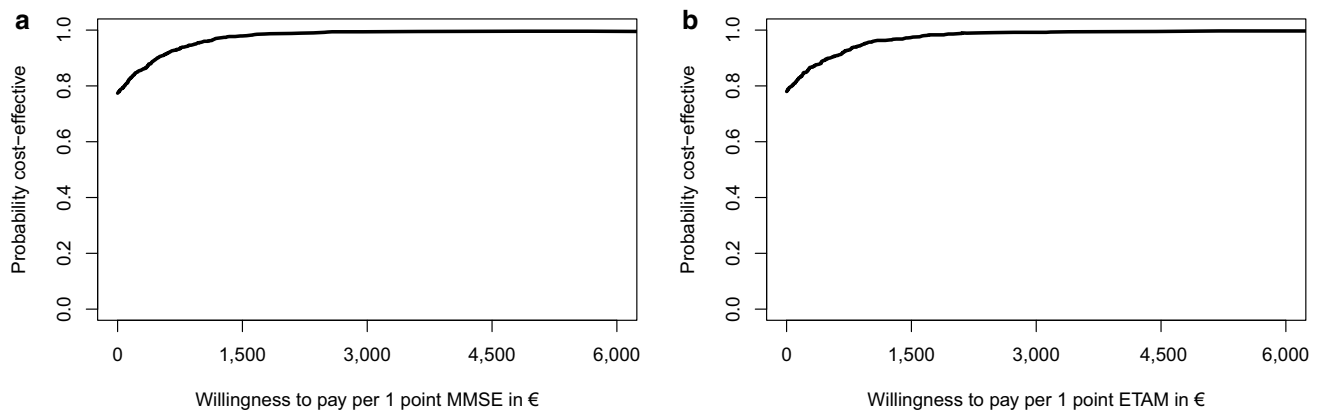


Fig. 10 **a** Sensitivity analysis 3: cost-effectiveness acceptability curve for the difference in MMSE at t_1 . **b** Sensitivity analysis 3: cost-effectiveness acceptability curve for the difference in ETAM at t_1

78.0% of bootstrapped MMSE and for 77.4% of bootstrapped ETAM replications in comparison with “care as usual” without a need for additional costs to payers. Sensitivity analyses supported our findings.

MMSE and ETAM both remained stable between t_0 and t_1 in the IG, whereas the values in the CG declined. Similar to other non-pharmacological treatments for older individuals with MCI or dementia, the slowing of decline in cognitive and physical functioning can be seen as effective [14, 64, 65]. This is also relevant in terms of clinical relevance. Without any intervention, a median decline of -2.8 MMSE points per year, thus -1.4 points in 6 months, in patients with dementia was observed in relevant studies and can be seen as a clinically meaningful decline [66, 67]. This is also confirmed by Howard et al. [68]. Andrews et al. [69] analyzed the “clinical meaningful decline” in people with dementia to lie between -1 to -3 MMSE-points. They additionally identified scores for “no meaningful decline” for different stages of disease severity. The researchers

concluded that for people with mild cognitive impairment, “no meaningful decline” is considered as a decline less than or equal to -0.19 , for mild dementia -0.40 , and for moderate to severe dementia -0.47 . For DeTaMAKS we analyzed a pooled sample consisting of several stages of severity. Thus, we considered the lowest threshold reported by Andrews et al. (i.e. -0.19) as the threshold for stable cognitive abilities [69]. The CG declined by -0.96 MMSE-points between t_0 and t_1 . Considering that individuals in the CG received some interventions and thus were more active than community-dwelling people without day care, this decline can be seen as a clinically meaningful decline. In contrast, the difference between t_0 and t_1 in the IG was only -0.09 MMSE-points. Thus, no clinically meaningful decline could be detected, which underlines the clinical effectiveness of MAKS.

Internationally accepted thresholds for ETAM-decline are still lacking. Since we observed an increase of 0.18 ETAM-points in the IG, we concluded that capabilities to

perform activities of daily living remained at least stable in the IG. This supports the thesis that MAKS is a clinically meaningful intervention. In contrast, the CG declined by -0.71 ETAM-points. This suggests a—potentially clinically meaningful—decline.

The most important cost driver in the DeTaMAKS-trial was informal care. It has to be stated that inconsistency exists about the assessment of informal care costs. It is difficult to measure the exact time caregivers spend on supporting those in need of care. Furthermore, various methods exist to calculate costs. Whereas D’Amico et al. [70] calculated costs using minimum wages per hour, we calculated costs using average rates per hour in our main analysis. This approach is a common one in Germany and is based on current evidence [41]. We also confirmed our results through SA₃, based on the proxy good method through using the minimum gross wage for skilled nurses. The different cost approaches have to be considered within comparison of the literature. However, studies on non-pharmacological treatments conducted from a societal perspective confirm that the main cost driver in community-dwelling people with cognitive impairment is informal care [8, 70, 71]. This is also in line with the assessment of general costs in health care caused by individuals with dementia [72, 73]. Regarding demographic change, interventions such as MAKS to stabilize older individuals’ health and thus reduce the burden on informal caregivers are highly recommended.

MAKS’ intervention costs of €15.34 per participant for the 6-month intervention period were cheap. Other non-pharmacological treatments with objectives similar to MAKS (comparison of £ with € for unit cost years adapted in studies) have higher intervention costs for the mentioned intervention periods [70, 74]. D’Amico et al. calculated €623.00 per participant for a 6-month intervention period, Knapp et al. [74] £220.50 per participant for a 7-week intervention period. Both the interventions of D’Amico et al. [70] (approximately £32.00/session per individual in community, 5 participants/session, costs for 2011) and Knapp et al. [74] (approximately £15.75/session per participant in care home or community, 5 participants/session, costs for 2001) were held twice per week. As the average number of DCC visits per week within the DeTaMAKS-trial’s IG was 2.29 times, intervention participation of twice per week per individual with an average of seven study participants per session was assumed. This was similar to the studies mentioned above. The low intervention costs resulted from its well-structured and sustainable approach. We trained skilled nursing staff to conduct the intervention within the DCCs. In contrast, the intervention sessions of Knapp et al. [74] and D’Amico et al. [70] were conducted by external researchers or facilitators with the assistance of skilled nurses at the community centers or care homes. This approach resulted in higher intervention costs due to higher personnel costs. Regarding the

costs and sustainability of the intervention, this is a disadvantage in comparison to MAKS due to higher costs and the difficulty of continuing the intervention after finishing the study. In contrast, MAKS could be conducted exclusively by skilled nurses after intense training. Skilled nurses are highly qualified professionals who have the knowledge and experience of how to treat people with cognitive impairment, how to conduct non-pharmacological treatments, and also how to consider the patients’ current health status. Furthermore, they are familiar with the day-to-day structure in the DCCs they work in and are able to integrate MAKS’ activities appropriately. Instead of conducting “care as usual”, trained nurses working in DCCs can conduct the cost-effective intervention MAKS. Therefore, MAKS’ intervention costs do not cause additional personnel costs in comparison to “care as usual” (sunk costs) [75]. To guarantee the sustainability of an intervention, it is of great importance that it can be easily implemented into normal day-to-day structures. Further explanations for the lower costs of MAKS are the setting “DCC” and the low material costs. Whereas D’Amico et al. [70] had to plan costs for participants’ transport to a community center for the community-dwelling individuals, participants in the DeTaMAKS-trial caused no intervention-related travel costs. Additionally, DCCs normally have materials provided for activities (e.g., beads, balloons) within “care as usual”. Materials needed for MAKS are similar. Therefore, alongside the manual, no additional material costs for MAKS were assumed in comparison to “care as usual”.

Overall, findings on the cost-effectiveness of non-pharmacological interventional studies in older community-dwelling individuals with MCI or dementia are inconsistent and there is still a lack of evidence [30, 76]. Possible explanations for the inconsistencies can be the focus on different outcome parameters, sample sizes, or intervention periods. Additionally, many studies have adopted the narrower perspective of the health care and social system, instead of the comprehensive societal perspective [30]. Moreover, generalizability is restricted on account of different health care systems in other countries [30]. Furthermore, for previous studies about similar multicomponent, non-pharmacological treatments, no cost-effectiveness analyses are available [14, 77, 78]. For these reasons, comparability of our study with others is limited.

Our results showed that MAKS is cost-effective in stabilizing cognitive abilities and capabilities to perform ADLs. To assess cognitive abilities, tests such as “MMSE” or the “Alzheimer’s Disease Assessment Scale—Cognitive Subscale” (ADAS-Cog) are common methods. Whereas ADAS-Cog in its original version is used to assess cognitive function for patients with dementia only [79], MMSE is also used for patients with MCI [80]. However, comparable studies assessing the cost-effectiveness of non-pharmacological treatments addressed patients with dementia only.

Therefore, it is likely that our results show slightly better cost-effectiveness because of the better health situations of individuals with MCI. The lack of studies examining the cost-effectiveness of non-pharmacological studies for individuals with MCI emphasizes the importance of our study.

Similar to our findings, D'Amico et al. [70] stated that cognitive stimulation therapy in comparison with "care as usual" assessed by MMSE was cost-effective at a low willingness to pay threshold. Similar to our study, the intervention period was 6 months. The main analysis was conducted from the health care and social perspective. However, a sensitivity analysis from a societal perspective could not confirm the results. It has to be noted that the study was conducted within nine care homes and nine community centers. The different settings cause different service utilization costs (e.g., no informal costs within care homes) than our study, which restricts comparisons to trends only. Knapp et al. [74] evaluated the cost-effectiveness of a cognitive stimulation therapy in 18 care homes and five DCCs. In line with our results, cost-effectiveness was shown for MMSE for a range of values of willingness to pay in a CEAC. However, detailed comparison is not possible because of a different perspective (health and personal social service), setting (majority: care homes), study participants (mild to moderate dementia only), and a shorter intervention period (7 weeks). As costs for individuals in community settings differ from those in care homes [8], we suggest conducting larger cost-effectiveness studies for each setting specifically. This would allow the detection of specific cost drivers and comparability with future cost-effectiveness studies.

To assess capabilities to perform ADLs, a variety of assessment tools exists. For example, the "Alzheimer's Disease Cooperative Study—Activities of Daily Living Inventory" (ADCS-ADL) [81] was developed to assess abilities to perform ADLs in people with dementia. In D'Amico [70], ADCS-ADL was cost-effective from a health and social care, as well as from a societal perspective. Our study revealed similar results. However, ADCS-ADL and other tests assessing abilities to perform ADLs (e.g., Bristol Activities of Daily Living Scale, Bayer Activities of Daily Living Scale) are mainly observer rating scales and focus on assessing dementia. One of the main disadvantages of observer rating scales is rater bias, which can result in underestimating deficits in ADLs [82]. Therefore, we assessed our outcome through ETAM. ETAM is a brief, validated performance test to determine capabilities to perform ADLs in MCI or mild to moderate dementia. It is based on the International Classification of Functioning and Health and—in contrast to other tests—shows only moderate correlation coefficients with cognitive abilities [54, 55]. ETAM allowed us to correctly assess capabilities to perform ADLs in our study group via blind testers. Thus, comparability in future studies with similar designs will be facilitated.

We are not aware of current evidence on health care decision makers' willingness to pay for non-pharmacological treatments such as MAKS. However, our results show that MAKS is cost-effective for a low willingness to pay. Still, further studies are needed to allow concrete comparability.

Strengths and limitations

Major strengths of our study are the randomized design and the relatively large sample size in comparison to former studies with similar designs [30, 70, 74].

The detailed coverage of relevant costs allowed us to estimate MAKS' impact from a societal perspective. This approach is recommended for cost-effectiveness analyses in dementia care by Wimo et al. [83] in order to include all relevant costs.

Unlike other cost-effectiveness studies, which mainly targeted individuals with dementia [30, 71, 74, 76, 84], we included individuals with MCI and dementia. MCI can often be a transition stage to dementia and should be targeted in more interventions in order to implement strategies to minimize the prevalence of dementia [2]. Furthermore, there is only sparse evidence about the cost-effectiveness of non-pharmacological treatments for individuals with MCI [30]. Therefore, our study contributed to an important topic.

Another strength of our study is the inclusion of three sensitivity analyses. The analyses support our findings and state that, even under different circumstances, MAKS is cost-effective for cognitive abilities and capabilities to perform ADLs.

According to the literature, external validity should be considered in interventional studies [85]. To address this issue, it is essential to mention that our study sample comprised 32 different DCCs all over Germany. Additionally, they were randomized into two groups. Therefore, MAKS is likely to be cost-effective in other German DCCs.

Some limitations of the present study have to be acknowledged. First, information on service utilization was based on self-reports. Therefore, it might be susceptible to recall bias. However, literature states that self-reports are a valid strategy to collect data on service utilization in the health care sector [86].

Another limitation of non-pharmacological studies is the restricted realization of blinding, which can lead to data collection bias. We could not blind therapists or participants as MAKS was a "visible treatment". However, the evaluation of the outcomes was done by external testers blinded for intervention.

Internal validity might be affected by attrition through "shift to nursing home" (IG: $n=26$, CG: $n=9$). Our imputation approach included the observed variables before dropout that had a significant influence on costs. Thus, differences between IG and CG which already consisted at t_0

were considered. If there was a decline in cognitive impairment caused by the intervention itself which would have led to "shift to nursing home", imputation would not have prevented bias.

Finally, our study is limited to a 6-month intervention period to ensure attractiveness for study participation of DCCs for both the IG, as well as waitlist CG. Pre-study negotiations with DCCs found that a longer intervention period would have been unattractive for DCCs allocated to the waitlist CG. Owing to the waitlist control group design, no long-term effects could be analyzed. However, in comparison with other economic evaluations with similar study designs, the intervention period of 6 months can be seen as average. According to the systematic review by Nickel et al. [30], out of nine randomized controlled trials primarily focusing outcomes on individuals with MCI or dementia, five had a period for cost analysis of 6 or fewer months. To examine the long-term effects on service utilization and costs, future economic evaluations should include longer periods for cost analysis.

Conclusions

In conclusion, our results emphasize that the non-pharmacological treatment MAKS is a cost-effective intervention to stabilize the ability to perform ADLs and the cognitive abilities of people with MCI or mild to moderate dementia in German DCCs. Evidence-based, non-pharmacological treatments are an effective addition to pharmacological interventions for individuals with cognitive impairment and help to improve the lives of these people. Owing to the limited resources in the health care system, decision makers can be supported by the knowledge of MAKS being a cost-effective intervention with low intervention costs. We recommend implementing MAKS as a regular non-pharmacological treatment in German DCCs. It can be supported financially in correspondence with the legal requirements of the German prevention law (§5, SGB XI) [87].

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Author contributions LS, HS, and EG were involved in study conception and design. EG prepared the material and collected the data.

HS was responsible for data management and quality assurance. LS analyzed the data. KS performed the literature research and interpretation of the data and wrote the manuscript. LS, HS, and EG revised the manuscript critically for the core intellectual content. All authors read and approved the final manuscript.

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Compliance with ethical standards

Conflict of interest Prof. Dr. Elmar Graessel is responsible for the content of the manual used in day care centers for the DeTaMAKS-trial. All other authors declare that no conflict of interest exists.

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5 Practical implications and outlook

The studies conducted in this thesis provide an extensive overview of LTC needs in community-dwelling older adults. They also detected sustainable and target group-specific approaches for this highly relevant subpopulation in view of the limited resources in the health care sector.

The knowledge gained through this thesis indicates several practical implications. Community-dwelling older adults are comprised of subgroups (e. g., females with disability, males living alone, older individuals being physically inactive) with complex characteristics and particularities associated with utilization of LTC. Therefore, health professionals and policy-makers should always identify the target groups they need to or would like to reach first. After that, a detailed analysis of the target group's needs should be conducted. In light of the limited resources in the health care sector, the focus should specifically be on identifying target groups with the highest needs for support.

To enable older adults to stay in the community setting for as long as possible, supportive policies and structures should be expanded. Day care centers make up one of those supportive structures. They allow older adults in need of LTC to spend the day together with a group in a safe environment with supervision and assistance from professional nurses. Day care centers help the individual in need of LTC to interact socially and be cognitively and physically stimulated. This has a positive impact on their mental and physical health. Additionally, the burden on informal caregivers is reduced. They can continue working and have time for other family members, as well as for themselves. Besides that, supportive structures like day care centers can result in cost reductions by minimizing the need for expensive institution-based LTC.

When developing approaches, a holistic view and the consideration of further aspects like sustainability and cost-effectiveness of interventions are essential. To address those aspects adequately, interdisciplinary networking in the community setting and expertise in this field are essential. Thus, some health professionals should be qualified and specialized in community-based practice. One type of professionals specialized in this way are community health nurses. These professionals are trained to identify vulnerable target groups and their needs, and to enhance health-promoting and preventive environments (e. g., walkability) and behaviors (e. g., healthier lifestyles). Moreover, community health nurses are familiar with the community

setting and a part of their job is to coordinate and cooperate with other disciplines (e. g., physicians, epidemiologists, economists) to achieve the best holistic outcomes for community-dwelling older adults. Thus, in countries like Germany, new, attractive professional training programs must be set up to prepare society for future needs in LTC.

Regarding the outlook for the future, the initial steps of understanding the needs and detecting sustainable approaches are the key to providing appropriate and sustainable LTC. This strategy will enable provision of LTC that is centered around the recipient's needs and that supports older adults' independence and dignity. Although highly necessary, scientific evidence in nursing remains an underappreciated research field in Germany. Target groups of interest and with a great impact on society, such as individuals residing in assisted-living arrangements or with specific health impairments, should be the focus of future studies completing longitudinal analyses with large cohorts. The future studies' primary objective should be to detect approaches enabling the provision of affordable, accessible, and high-quality LTC. As changes in LTC will be continuously ongoing, we should aim to gain new knowledge, and "*not to stop questioning*"!

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Ich, Kathrin Elisabeth Steinbeißer, erkläre hiermit an Eides statt, dass ich die vorliegende Dissertation mit dem Titel

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Ort, Datum

Kathrin Steinbeißer

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