KU LEUVEN

FACULTEIT SOCIALE WETENSCHAPPEN

PROACTIVE: A development and feasibility study on suPpoRting infOrmal cAregivers of older people with early CogniTIVe declinE

Shanshan WANG

Proefschrift aangeboden tot het verkrijgen van de graad van Doctor in de Sociale wetenschappen

Promotor: Prof. Dr. Anja Declercq
Copromotor: Dr. Johanna de Almeida Mello

Onderzoekseenheid: Centrum voor Sociologisch Onderzoek [CeSO]

2023

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“Though this be madness, yet there is method in’t.”
William Shakespeare



Image of ‘Good Company’ by Boris Kramer via Van Dop Gallery.com

De verantwoordelijkheid voor de ingenomen standpunten berust alleen bij de auteur.

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Summary/ Samenvatting

Background: In face of the increasing demand for healthcare resources due to the challenges of the ageing population and dementia, the Belgian government launched its second Flemish Informal Care Plan (Mantelzorgplan 2022-2024) and its third Dementia plan (Dementieplan 2021-2025). Families who care for people with early cognitive decline can experience a decline in their health and wellbeing due to the complexity of this disease in the early stage. Timely support for early informal caregivers has been proven beneficial for society, the economy and healthcare systems. This PhD thesis reports some findings about the feasibility of adapting an evidence-based psychosocial intervention in the context of Flanders, Belgium.

Objectives: As the goal of the PhD research is to adapt an evidence-based psychosocial intervention and evaluate its feasibility and acceptability in Flanders, Belgium, the following questions were explored:

- Q1: What is the randomized controlled evidence (RCT) on psychosocial interventions for informal caregivers of older people with early cognitive decline?
- Q2: Which factors affect the primary informal caregivers' ability to continue care across several degrees of cognitive decline and risk of burden?
- Q3: Is the PROACTIVE (suPpoRting infOrmal cAregivers of older people with early CogniTIVe declinE) intervention feasible, acceptable, and helpful in Flanders, Belgium?

Methods: Based on the recently updated Medical Research Council (MRC) framework, the PhD research covered the development and feasibility phases. In the development phase, existing RCT evidence was examined, and the PROACTIVE intervention was developed. In the feasibility phase, a cross-sectional study and a survey study were conducted to investigate the feasibility and acceptability of the intervention in Flanders, Belgium. A mixed-method approach was used throughout the research.

Results: The systematic review identified robust interventions for informal caregivers of people with early cognitive decline, the underpinning theories and effective intervention components. Informal caregivers of people with early cognitive decline perceived caregiving as a burden and are at risk of not being able to continue to provide care. Factors related to family and social support contribute to the informal caregiver's ability to continue to provide care. This applies especially to caregiver subgroups with lower levels of risk of caregiver's burden or lower levels of the care recipient's cognitive decline. Recruiting enough participants was found feasible and associated factors were identified. The intervention was considered acceptable, and most respondents perceived it as helpful.

Conclusion: This PhD thesis provided evidence that informal caregivers of people with early cognitive decline need timely support for their caregiving activities, and that proactively targeted support for this group can bring great benefits for the society (i.e., ageing well at home for a longer period). The study also added value about the feasibility, acceptability, and potential helpfulness of a Flemish adaptation of the NYUCI (i.e., PROACTIVE) on supporting informal caregivers of older people with early cognitive decline in Flanders, Belgium. The PROACTIVE intervention has great potential to improve the health and wellbeing of informal

caregivers who care for a person with early cognitive decline and a subsequent RCT evaluation study should be considered in future research.

Samenvatting

Achtergrond: In het licht van de toenemende vraag naar gezondheidszorgmiddelen als gevolg van de uitdaging van de vergrijzing en dementie, lanceerde de Belgische regering haar tweede Vlaams Mantelzorgplan (Mantelzorgplan 2022-2024) en haar derde Dementieplan (Dementieplan 2021-2025). Gezinnen die zorgen voor mensen met een vroege cognitieve achteruitgang kunnen een achteruitgang van hun gezondheid en welzijn ervaren als gevolg van de complexiteit van deze ziekte in een vroeg stadium. Tijdige ondersteuning van vroege mantelzorgers is gunstig gebleken voor de samenleving, de economie en de gezondheidszorg. Dit doctoraatsproefschrift rapporteert enkele bevindingen over de haalbaarheid van het aanpassen van een evidence-based psychosociale interventie in de context van Vlaanderen, België.

Doelstellingen: Om een evidence-based psychosociale interventie aan te passen, en de haalbaarheid en aanvaardbaarheid hiervan in Vlaanderen te evalueren, werden volgende vragen onderzocht:

- V1: Wat is het gerandomiseerde gecontroleerde bewijs (RCT) over psychosociale interventies voor mantelzorgers van ouderen met vroege cognitieve achteruitgang?
- V2: Welke factoren zijn van invloed op het vermogen van de primaire mantelzorgers om de zorg voort te zetten in verschillende gradaties van cognitieve achteruitgang en risico op belasting?
- V3: Is de PROACTIEVE (ondersteuning van informele zorgverleners van oudere mensen met een vroege cognitieve achteruitgang) interventie haalbaar, aanvaardbaar en nuttig in Vlaanderen, België?

Methoden: Op basis van het onlangs bijgewerkte Medical Research Council (MRC)-kader omvatte het promotieonderzoek de ontwikkelings- en haalbaarheidsfase. In de ontwikkelingsfase is bestaand RCT-bewijs onderzocht en de PROACTIEVE-interventie ontwikkeld. In de haalbaarheidsfase werden een cross-sectioneel onderzoek en een surveyonderzoek uitgevoerd om de haalbaarheid en aanvaardbaarheid van de interventie in Vlaanderen, België, te onderzoeken. Dit onderzoek maakte hiervoor gebruik van een mixed-method-benadering.

Resultaten: De systematische review identificeerde de robuuste interventies voor mantelzorgers van mensen met vroege cognitieve achteruitgang, de onderliggende theorieën en effectieve interventiecomponenten. Mantelzorgers van mensen met vroege cognitieve achteruitgang ervaren de mantelzorg als een last en lopen het risico niet in staat te zijn om de zorg aan de zorgontvangers thuis te blijven bieden. Factoren gelinkt aan familie en sociale steun dragen in grote mate bij aan het vermogen van de primaire mantelzorger om zorg te blijven verlenen, met name in subgroepen van mantelzorgers met een lager risico op last van de mantelzorger of een lager niveau van cognitieve achteruitgang van de zorgvrager. Het werven van voldoende deelnemers is haalbaar en bijbehorende factoren zijn geïdentificeerd. De interventie is acceptabel en wordt door de meeste respondenten als nuttig ervaren.

Conclusie: Dit doctoraatsproefschrift leverde bewijs dat mantelzorgers van mensen met een vroege cognitieve achteruitgang in België tijdige ondersteuning nodig hebben voor hun zorgactiviteiten. Proactieve gerichte ondersteuning voor deze groep kan grote voordelen opleveren voor de samenleving (d.w.z. langer goed thuis blijven wonen). De studie voegde ook waarde toe over de haalbaarheid, aanvaardbaarheid en potentiële bruikbaarheid van een Vlaamse aanpassing van de NYUCI (d.w.z. PROACTIVE) voor het ondersteunen van mantelzorgers van ouderen met vroege cognitieve achteruitgang in Vlaanderen, België. De PROACTIVE-interventie heeft een groot potentieel om de gezondheid en het welzijn te verbeteren van mantelzorgers die zorgen voor een persoon met vroege cognitieve achteruitgang en een daaropvolgende RCT-evaluatiestudie moet worden overwogen in toekomstig onderzoek.

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Chapter 1

General introduction

Background

Informal caregivers

In contrast to formal caregivers, informal caregivers provide unpaid and often without proper training, caring activities (e.g., help bathing, dressing, eating etc.) to a person with a chronic condition or disability [1]. They are family members (e.g., spouses, adult child), other relatives, friends or neighbors of the person cared for. Informal caregivers contribute substantially to the health care system, reducing public expenditure on formal care. In the United States, 95% of community-dwelling older people with long term service and support (LTSS) needs receive help from unpaid caregivers, diminishing public spending by governments [2]. In addition, family members often keep on providing regular informal care to their loved ones once they live in a residential care facility [3].

A study by Alzheimer's Disease International (ADI) addressed questions about the global societal economic impact of dementia. It reported that informal caregivers provided six hours of care and support per day to people with dementia living at home, which amounts to a total of 2,089 hours per year. This equals the economic value of more than 40 million full time workers in 2015 [4]. In Europe, more than 76 million informal caregivers (12.7% of the European population) provided care for a relative or friend. The time spent in care was 72.3 billion hours in 2016, which was valued at 576 billion euros, representing 3.63% of Europe's gross domestic product (GDP) [5]. The contribution of informal caregivers is considerable, but not for free. It is costly in the form of high opportunity cost.

According to the 2019 World Population Prospects, by 2050, one in six persons will be over the age of 65 in the world, and one in four of those persons will live in Europe and Northern America. The number of persons over 80 will increase from 143 million in 2019 to 426 million in 2050 [6]. Given the projected trends in population ageing, the world is experiencing a dramatic growth in the number of older persons with dementia in the population, which is projected to triple, from 57.4 million in 2019 to 152.8 million cases by 2050 [7]. Therefore, global spending on dementia is increasing. One study projected that the global healthcare spending on dementia will increase from 594 billion dollars in 2019 to 1.6 trillion dollars by 2050, which represents 11% of all expected health spending [8]. The increasing global burden of dementia poses a serious challenge to the sustainability of health care systems.

A globally recognized solution to this challenge is to achieve 'Healthy Ageing' proposed by the World Health Organization (WHO). 'Healthy Ageing' is defined as 'the process of developing and maintaining the functional ability that enables wellbeing in older age' [9]. Informal caregivers are mostly aged between 50 and 75 and experience decline in their health and wellbeing due to caregivers' burden, which impacts the achievement of 'Healthy Ageing' [10]. Informal caregivers often experience physical, emotional and financial burdens, such as reduced working hours, depression and anxiety, physical exhaustion, which impacts their own wellbeing and health, having a negative impact on their Healthy Ageing. [11-12]. This highlights the importance of timely care and support for informal caregivers, not only to provide care for their care recipients as well as to help maintain their own health and

wellbeing. Informal caregivers can play a key role in achieving the sustainability of health care through by receiving timely support in the form of training, education, emotional support, so that they can successfully manage their own health condition and sustain informal caring, improve care quality, and keep care recipients at home longer [13-14]. Well-established evidence supports timely intervention tailored for early-stage informal caregivers.

In most research, 'early cognitive decline' is defined as 'mild cognitive impairment' (MCI), which is an early stage of memory loss or other cognitive ability loss (such as language or visual/spatial perception) in individuals [15-18]. Other studies suggested the 'early cognitive decline' as the early stages of MCI [19] or most at risk of MCI [20]. Informal caregivers of early cognitive decline or early dementia struggle with acknowledging needs, actively seeking, or accepting help due to lack of knowledge on the disease, fear of stigma as well as feeling of guilt [21]. This group of informal caregivers are often hidden and receive no help or support at the beginning of their caregiving activities. They sometimes are left out of formal support services. Informal caregivers of people with dementia specifically experience more complex, costly, stressful, and demanding burden due to challenging dementia-related behavior compared to other caregivers [22]. For this reason, informal caregivers may discontinue care and older persons may be institutionalized due to failed adaptation of the caregiver to the new caregiving role with no preparation, prior caregiving experience or training [23]. There is a great need for more professional and skilled care from informal caregivers, even at the early stages of dementia, as the condition of people with cognitive decline often worsens faster because of improper informal caregiving [24]. A health care system that relies on untrained and unpaid informal caregivers to perform skilled tasks and professional caring should provide targeted support initiatives, which may be cost-effective [25] and improve care quality, provide rewards to caregivers, and increase wellbeing [26]. A systematic review also found that early psychosocial interventions for informal caregivers could improve caregivers' well-being and care quality for people with mild cognitive impairment or early dementia [27]. However, these early interventions are scarce and need to be developed and evaluated in future research.

Informal caregivers in Flanders

According to data from the Belgian statistical office (https://statbel.fgov.be/), the number of persons older than 65 in Belgium was 226,931,6 in 2022 or 19.59% of the country population. Moreover, the number of the oldest-old, aged 80 or over, was 643,298, or 5.55% of the country's population in 2022. A high proportion (20%) of people over age 50 report to be informal caregivers (9% daily and 11% on a weekly basis), which is one of the highest-ranking figures compared to other European countries [28]. The risk of dementia increases sharply with age, more than 40% of people over age 90 may have dementia [29]. The number of people with dementia (young-onset dementia included) in Flanders, Belgium was estimated to increase by more than 40% by 2035 compared to 2018, which was estimated at 131 818 [30-31]. A recent longitudinal cohort study highlights the problem of ageing population using a representative sample in general practice for the Flemish population, Belgium. This study showed a significantly increasing trend in the prevalence of registered dementia cases and of

registered multimorbidity (3+ comorbidities) in dementia patients over from 2000 to 2021 [32].

A recent study estimated the economic costs of dementia, including direct costs of medical and social care as well as indirect costs of informal care, in 11 European countries. Among the total costs (including direct costs of medical and social care as well as indirect costs of informal care), the proportions of informal care costs varied between 50% and 90%, and the proportion of informal care cost in Belgium was around 68% [33]. In Belgium, the general practitioner (GP) will perform a cognitive screening with a Mini Mental State Examination (MMSE) or a Clock drawing test, when a person shows some cognitive problems. But the referral by GPs to geriatrics, hospitals, memory clinics has not become a rule yet [34]. In Flanders, there is a gap of about 1 year between the first symptoms of dementia and reporting it to a friend or one's own partner. A formal diagnosis of dementia usually comes 3–4 years after the first signs of cognitive problems and it takes twice as long in the case of a young early-onset dementia [29]. In Flanders, about 70% of people with diagnosed dementia are cared for by informal caregivers at home [29]. A Belgium nationwide, cross-sectional study found that informal caregivers who cared for a relative with dementia experienced more vulnerability [35]. The high reliance on informal dementia care and corresponded high informal care cost in Flanders, Belgium highlights the importance of ensuring that informal caregivers should receive timely support. Studies showed that the probability of institutionalization may increase due to informal caregivers' physical, emotional, and financial burden without timely support received [21, 36-37]. This will lead to further direct and hidden costs increase.

Policy, the informal care plan, and the dementia plan in Flanders

Healthcare policy in Belgium supports informal caregivers mainly through financial compensation, an extension of legal and social rights, and some training opportunities. The healthcare policy emphasizes 'ageing in place', and reduction of hospitalizations and nursing home admissions, thus reducing the public spending on the LTC system. The Belgian LTC system can be characterized as a system with formal care services which are publicly financed, complemented by a significant amount of informal care. Formal LTC services are well developed and diversified, including nursing homes, semi-residential settings (i.e., service flats), day care and 'short stay' care centers, home nursing and non-medical home care services. Day care and 'short stay' care centers provide nursing or personal care to older people when the home care is temporarily unavailable, or as a complement to care at home. These formal services have an impact on allowing informal caregivers to care for their loved ones at home longer. The direct support services for informal caregivers include access to information and service (mantelzorgers.be), access to education and training, financial allowances for carers, access to respite care and carer's leave. Informal caregivers can get different carer allowances at the level of local authorities when they meet the eligibility requirements. Informal caregivers can apply for respite care from residential care facilities and from other initiatives, such as at home-respite care provided by insurance funds. Information about respite care can be obtained from different regional and local organizations and institutions (social services of the insurance funds, informal carer associations, social services of the hospitals, public municipal welfare centers, etc.). Regarding carers' leave, people who

are in paid employment (i.e., employees and civil servants) have access to a well-established system of paid leave schemes to care for a seriously ill family member up to the second generation [38].

In Flanders, a project called “Flanders in Transition 2025” states that sustainable healthcare should be achieved with financial viability as the ageing population will put more pressure on healthcare resources [39]. After the first Informal Care Plan (2016-2020), an updated new Flemish Informal Care Plan (Mantelzorgplan 2022-2024) was published in 2021 by the Flemish Council WVG [40]. This new plan highlights the affordability and availability of care and support and the prevention of overload and quality of life for informal caregivers. It focuses on acknowledging and recognizing informal caregivers, supporting informal caregivers, and improving their quality of life and wellbeing. The new plan emphasizes the importance of more and better professional care that supports informal caregivers. Improving the capacity of informal caregivers is also a spearhead of the new plan, such as psychological counseling, training courses and informal care café.

Regarding dementia care, the government also launched its third dementia plan (Dementieplan 2021-2025), which encourages dementia experts to help family caregivers through extending their knowledge and support to home care [41]. This new dementia plan focuses on improving home care for people with dementia (e.g., care quality, life quality etc.), and optimizing the specific informal care support through the facilitation of a diverse range of support initiatives (e.g., training, meeting groups etc.). This dementia plan also highlighted the importance of healthcare professionals in timely supporting people with dementia and their family caregivers.

Initiatives for informal dementia care in Flanders

Local support initiatives in Flanders are diverse for informal caregivers of people with dementia. ‘Dementie en Nu’ is an integrated psycho-educational service package developed to support informal caregivers (https://www.dementieennu.info/). The aim of this package is to increase the capacity of informal caregivers shortly after the medical diagnosis of dementia of their relatives. It first started in Bruges, in 2014. The rest of Flanders will follow to implement this program and health insurance funds, hospitals and local service centers are responsible for the implementation. ‘Dementie en Nu’ covers 10 sessions guided by a qualified coach who will provide psychoeducational topics, including knowledge about dementia, coping skills, referral information, self-care tips, self-efficacy training. The target group are informal caregivers of a person with dementia, regardless of relationship with the person, irrespective of age, gender, level of education, regardless of the type or the stages of dementia.

The Flemish Alzheimer Liga created a network of peer groups called family groups (Familiegroep Dementie en Jongdementie), which offers meeting opportunities for family members whose relatives have (early-onset) dementia. The peers are family members who are going through the same situation and who can easily gain common ground and recognition. The family group is an open self-help group for informal caregivers of people with dementia or young dementia. The focus of the family group meeting is to exchange information and tips,

and share experience among peers, approaching a main theme under the guidance of a trained mentor. Peers will also do some relaxation activities together and make social contacts in the family group meeting to improve emotional support. The Flemish Alzheimer Liga aims to reach as many informal caregivers of people with dementia as possible. Currently, there are 64 active groups in Flanders, including 48 dementia family groups, 13 young dementia family groups and 3 Flemish peer groups. The 3 Flemish peer groups focus consist of groups dealing with specific forms of dementia, such as frontotemporal dementia and Lew Body dementia. Some training courses, workshops and symposiums are also organized, and a free 24/7 listening & info line service is also available for families with dementia.

The 'Walk-in-House for Dementia' ('t moNUment inloophuis dementia, www.mechelen.be/tmonument-inloophuis) is a contact point for people with dementia and their informal caregivers in Mechelen. People who come to this house can ask any questions they have or seek emotional support. They can just drop by without having to make an appointment in advance during opening hours. Beyond the information function of the house, people with dementia and their caregivers can also meet their peers there and share stories, or just do some activities together in a relaxed way. Buddy activities bring together (young) people with dementia, informal caregivers, and volunteers in the community to do some business or relaxation activities. The aim of this activity is to help people understand more about dementia and to have a balanced image of dementia, thus establishing a dementia friendly society.

'De Sociale kaart Dementie' (www.desocialekaart.be) is an online tool for the healthcare professionals who are the first points of contact with families in search of help and support after a formal diagnosis of dementia. The first points of contact are often the general practitioner, the social work department of a person's health insurance fund, social service of the hospital or residential setting, the OCMW (Openbaar centrum voor maatschappelijk welzijn, Public Centre for Social Welfare) in the municipality. This tool can help them to refer people with dementia to available services, helping them to get timely information.

In addition, a website (www.huisartsendementie.be) was created to help healthcare professionals find all information about the approach to dementia according to the best available scientific evidence. This website offers general practitioners and other care providers tools for the detection and diagnosis of dementia, based on the guideline: 'Diagnosis of dementia in primary care'. The trust of the informal caregivers in the skills of the GPs to provide and plan care confirms the GPs in this important role. The most recent Dementia Plan (2021-2025) also gives the GP an important role. Proper psychoeducation of the informal caregiver contributes to the quality of life of both patient and informal caregivers.

Focusing on supporting early informal caregivers and reducing their burden has shown great benefits to the sustainability of healthcare reported in well-established evidence. In Flanders, little support is provided to this hidden informal caregiver group. Early informal caregivers are often left out of formal help while they are struggling at the beginning of their caregiving activities. Some consequences of receiving no help or support are informal caregivers' worsening health and wellbeing, lower care efficiency and care quality, worsening condition of care recipients and institutionalization, increasing healthcare expenses. An internationally

validated and comprehensive assessment, the interRAI Home Care (HC) instrument, is currently being mandated for Belgium routine care in nursing homes [42-43]. Recently, the BelRAI Screener instrument was fully implemented in Flanders containing 5 modules to assess a person's need for care and support at home. One of these modules contains items about cognitive functioning. After the assessment is filled out, the interRAI Cognitive Performance Scale (CPS2) is automatically generated using one item about short-term memory, making self-understood, daily decision-making, management of finances, medication management and walking. Compared to the original CPS (range 0 to 6), a study demonstrated that the CPS2 scale (range 0 to 8), when used in repeated assessments, is sensitive to detect changes particularly in early levels of cognitive decline [44]. In contrast, no systematic needs assessment tool is provided for informal caregivers in Flanders, Belgium. The needs of informal caregivers should be put on the similar emphasis to the needs of care recipients, as needs-matched and direct support for informal caregivers are more efficient and cost-effective.

Study aims

The New York University Caregiver Intervention (NYUCI), a multicomponent psychosocial intervention for informal caregivers of people with all stages of dementia, has proven great efficacy and sustained benefits over the past 30 years. The main aim of the NYUCI is to improve informal caregivers' wellbeing and to keep the care recipients at home longer. Proved effects included improved self-efficacy and social support, greater positive appraisal of stressors, and a large reduction of healthcare costs [45-49]. Key outcomes have been found after tests in other countries, such as Israel, England, and Australia [50-51]. The NYUCI consists of first individual counselling, four family counselling sessions, then another individual counseling session for four months, encouragement of participation in a weekly support group and ongoing telephone-based availability of counsellors to caregivers and families (called ad hoc counselling) during the whole journey of disease. Beyond basic counseling, counsellors also provide informal caregivers with information about available resources, referrals for auxiliary help, financial planning, and needed education.

The unique emphasis of the NYUCI is to leverage the social support in community for informal caregivers through the involvement of other family members, peer groups and on-going support from a professional counselor. The main mechanism of the NYUCI for improving caregivers' wellbeing is to improve social support, largely through helping the primary caregiver and other family members to interact in positive ways, but also by providing referrals to appropriate resources in the community [52]. By improving the physical and emotional wellbeing of informal caregivers through maximization of social support, NYUCI undoubtedly achieved additional healthcare cost savings. In Belgium, a national study sample analysis showed that perceived greater social support from family and friends can reduce informal caregivers' burden and improve their wellbeing [53].

In this perspective, the main objective of this study is to develop and evaluate a Flemish adaptation of the NYUCI for the target group of informal caregivers of older people with early cognitive decline, following the Medical Research Council (MRC) framework [54]. The Flemish NYUCI, which is named suPpoRting infOrmal cAregivers of older people with early CogniTIVe declinE (PROACTIVE), is the first adaptation of the NYUCI to be conducted in the context of

caregiving for relatives with early cognitive decline. This study will promote health and well-being for informal caregivers at the early stage of caregiving, and for care recipients who are at risk of adverse outcomes, by leveraging the power of social support. The first aims of the study were:

- To develop the PROACTIVE intervention to the context of Flanders, Belgium.
- To evaluate the effectiveness of the PROACTIVE intervention in Flanders, Belgium.
- To delineate the causal mechanism of health and well-being in early informal caregivers' caregiving process.
- To clarify the potential functioning mechanism of the PROACTIVE intervention through the method of process evaluation.
- To evaluate the usefulness, feasibility, and validity of the interRAI Carer Needs Assessment (Renamed as interRAI Self-Reported Carer Needs (SCaN) and recently published) in Flanders, Belgium.

To achieve the study aims, the following research questions were proposed:

Q1: What is the randomized controlled evidence on psychosocial interventions for informal caregivers of older people with early cognitive decline?

Q2: Which factors affect the health and well-being of early informal caregivers during their caregiving process and how?

Q3: Process evaluation: What is the potential functioning mechanism of the PROACTIVE intervention?

Q4: Does the PROACTIVE intervention enhance the health and well-being of informal caregivers (and care recipients)?

Q5: Is the interRAI Family Carer Needs Assessment (Renamed as interRAI Self-Reported Carer Needs (SCaN) and recently published) useful, feasible and validated in Flanders, Belgium?

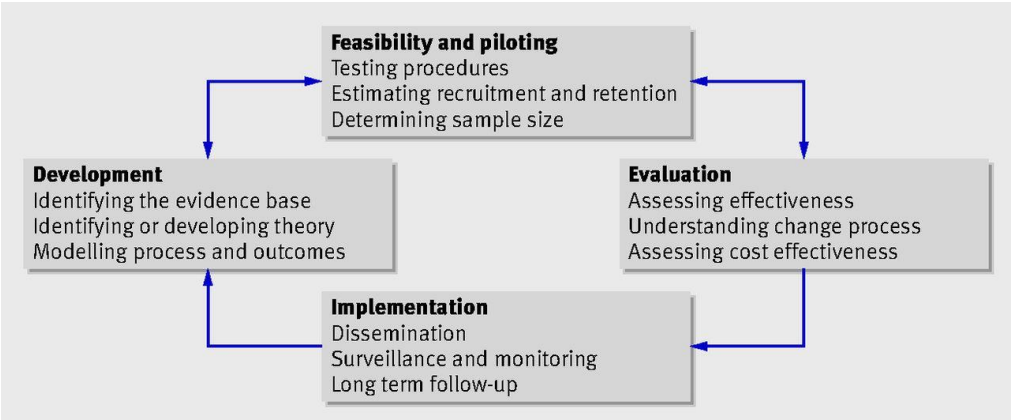

Figure 1: MRC Framework, 2008

In February 2020, when COVID 19 reached Belgium, the PhD proposal and protocol had just been published [55]. As the epidemic lasted for almost 2 years, it impacted the data collection,

as the target participants of my PhD study are informal caregivers of older people with cognitive decline. We had no access to this target group and were unable to involve them in the study, by means of delivering an intervention to them. Meanwhile, an updated MRC framework was published in October 2021, replacing the previous version which was published in 2008 [56]. The new MRC framework addressed some remaining weaknesses and gaps of the previous one. The new MRC framework updated the definition of complex interventions and especially emphasizes the dynamic relationship between the intervention and the context. Considering the new MRC framework and the impact from COVID 19, the original PhD proposal was adapted, and new research questions were proposed.

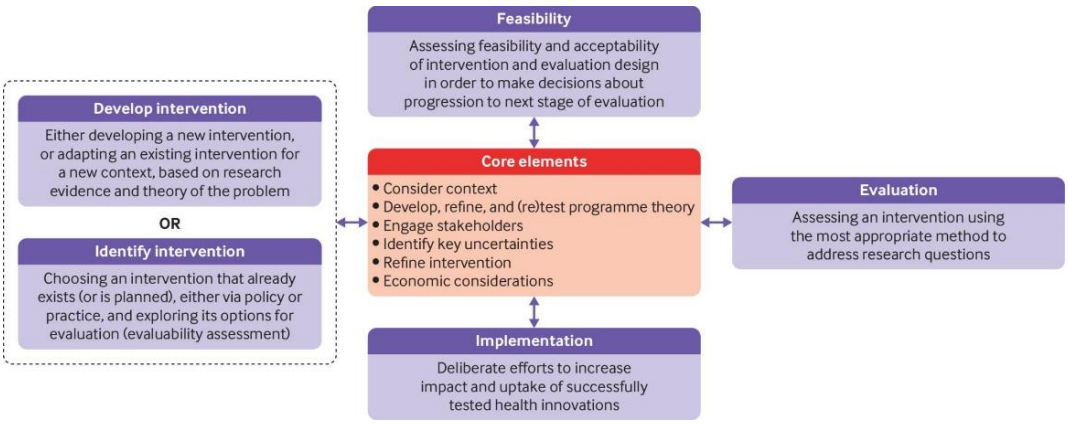

Figure 2: MRC Framework, 2021

Figure 1 and Figure 2 show the four main phases of the MRC frameworks: intervention development or identification, e.g., from policy or practice, feasibility, evaluation, and implementation. In the previous MRC framework, different research phases had different key elements. In the new MRC framework, there are also six core elements (e.g., consider context etc.) which should be considered in each research phase. The effects of a complex intervention might often be highly dependent on the context in which the intervention will take place. The value of feasibility testing also shows the importance of understanding the interaction between the intervention and its context. The feasibility phase in the new MRC framework also highlights the assessment of the feasibility and acceptability of the intervention and its evaluation design, to decide if it can progress to the next evaluation phase.

Based on the new MRC framework, a feasibility study should be designed to evaluate the evaluation design (e.g., reducing uncertainty around recruitment, data collection, retention, outcomes, and analysis) or the intervention itself (e.g., around optimal content, delivery, acceptability, adherence, capacity of intervention providers). A feasibility study is needed to minimize research waste and increase research cost-effectiveness, especially true for vulnerable hard-to-reach participants and expensive evaluations, such as randomized controlled trials. Therefore, the main aim of my new PhD plan is to in-depth explore the feasibility of the PROACTIVE intervention in Flanders, in preparation for a subsequent cost-effective randomized controlled trial. Such research may identify not only what needs

adaptation in the original proposal of intervention but also how changes might occur. Thus, the results of a feasibility study will establish the plausibility of the realization of the original research proposal, as well as help substantiate a RCT evaluation study proposal. The importance of the context of caregiving, healthcare system and policy should be recognized when an evidence-based intervention is implemented in Flanders, especially that the intervention will target at a special caregiver group, namely informal caregivers of older people with early cognitive decline. Feasibility research can help prepare the ground for subsequent RCTs, either improve the chances of success and reduce waste of resources, or answer the intended research questions which large studies are unlikely to do.

To attain the new goal of my PhD plan, the following research questions were proposed:

Q1: What is the randomized controlled evidence on psychosocial interventions for informal caregivers of older people with early cognitive decline?

Q2: Which factors affect the primary informal caregivers' ability to continue care across several degrees of cognitive decline and risk of burden?

Q3: Is the PROACTIVE intervention feasible, acceptable, and helpful in Flanders, Belgium?

Specially, the PhD study consisted of the following parts:

1. Protocol of the study

The study protocol provided a clear view of the whole research, including the background, research objectives, research questions, methods, development phase, evaluation design, sample size and recruitment, instruments, outcome measures, analyses, and discussion. This study aims to develop and evaluate a Flemish adaptation of the New York University Caregiver Intervention (NYUCI) in the context of informal caregivers of people with early cognitive decline in Flanders, Belgium. Using the MRC framework, this study covers two research phases: development phase and evaluation phase. In the development phase, we develop the PROACTIVE intervention in the context of Flanders. In the evaluation phase, we evaluate the PROACTIVE intervention with a pretest and posttest RCT design in one year. We evaluate the effectiveness of the intervention, and the validity and feasibility of the interRAI Carer Needs Assessment (Renamed as interRAI Self-Reported Carer Needs (SCaN) and recently published) in Flanders. We also conduct a process evaluation of the intervention to explore how and why the intervention could work and benefit our target population in Flanders, Belgium.

2. An overview of psychosocial interventions for informal caregivers of older people with early cognitive decline using randomized controlled trials

This is a systematic review on the interventions to effectively support informal caregivers of older people with early cognitive decline, and about why these interventions could work. Based on the MRC framework, we could identify evidence-based interventions through a systematic review, then adapt this identified intervention to the given context and evaluate the intervention. This way is more cost-effective than developing a complex intervention from the beginning. By critically assessing the current state of randomized controlled evidence, we can learn about (1) what psychosocial interventions are effective? What are the core

components of these interventions? (2) what are the underpinning theories of these effective psychosocial interventions? (3) what caregiver needs assessment were used and what needs were assessed before or during the interventions?

3. The identification of the determinants of informal caregivers' ability to continue care

This study was performed to identify factors associated with informal caregivers' ability to continue care for frail older people living in the community, across several degrees of care recipients' cognitive decline and risk of caregiver's burden. This was a cross-sectional study which collected national sample on frail older people and their informal caregivers. Instruments used were interRAI Home Care (HC), Zarit Burden Interview (ZBI-12) and informal caregiver questionnaire. Based on the combination of two frameworks, the Role Theory and Stress Process Theory, we performed a multivariate logistic regression to explore the associated factors. Moreover, the caregiver's risk of burden (CaRE) algorithm was applied to stratify the study population, so that we can perform a further regression analysis across subgroups stratified by levels of risk of caregivers' burden (CaRE) and levels of care recipients' cognitive performance (CPS). This was only possible because the CaRE algorithm and the CPS can be automatically calculated from the interRAI HC instrument, which has been mandatorily implemented for routine care in Flanders, Belgium.

4. The feasibility, acceptability, and potential helpfulness of the PROACTIVE intervention

The final study in this thesis explored the feasibility, acceptability, and potential helpfulness of the PROACTIVE intervention to reduce research waste and increase cost-effectiveness. A survey study was performed to investigate the feasibility of the PROACTIVE intervention in relation to the recruitment and intervention content for informal caregivers of people with early cognitive decline, and further analyses across different subgroups stratified by levels of care recipients' cognitive performance. This was only possible because we included the internationally validated CPS2-scale in our survey, so that we could assess the level of the care recipient's cognitive performance. The survey was constructed by the research team based on the comprehensibility of the benefits of the NYUCI components, and the NYUCI assessment materials.

5. Conclusion

This is the last chapter of the PhD thesis. In this chapter, we first summarize the whole PhD research, focusing on the main findings reported in each study. The main strengths and limitations of the study are also reported. Implications of the findings for practice, research and policy are discussed in this chapter, as well as suggestions for future research.

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Outline

The following chapters describe and answer each of the research questions of our study:

Chapter 2 – Protocol of research (background, methods, research questions and discussion)

Chapter 3 – Systematic review of psychosocial interventions for informal caregivers of people with early cognitive decline using randomized controlled trials

Chapter 4 – Factors associated with informal caregivers' ability to continue care: Subgroup analysis

Chapter 5 – Feasibility, acceptability, and potential helpfulness of the PROACTIVE intervention in Flanders, Belgium

Chapter 2

Development and evaluation of an intervention on suPpoRting infOrmal cAregivers of older people with early CogniTIVe declinE (PROACTIVE): a study protocol based on the Medical Research Council framework

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Wang S, de Almeida Mello J, Declercq ADevelopment and evaluation of an intervention on suPpoRting infOrmal cAregivers of older people with early CogniTIVe declinE (PROACTIVE): a study protocol based on the Medical Research Council framework BMJ Open 2021;11:e047529. doi: 10.1136/bmjopen-2020-047529

Introduction

This chapter consists of protocol of the original PhD research which aimed to develop and evaluate an evidence-based intervention for informal caregivers of older people with early cognitive decline using the Medical Research Council (MRC) framework (MRC, 2008). Due to the impact of 2-year epidemic on the original PhD research, a new PhD research goal was proposed using the recently updated MRC framework (MRC, 2021). The reason why the original PhD protocol is included as the Chapter 2, is the fact that the new PhD research plan was modified based on the original one. The original PhD research protocol also serves as a basis for this thesis.

In the original PhD research protocol, five research questions are described, as well as the methodology (e.g., evaluation design, participants, sample size, instruments etc.) used to answer these questions. Specifically, it covers two research phases: In the development phase, the suPpoRting infOrmal cAregivers of older people with early CogniTIVe declinE (PROACTIVE) intervention will be developed in the Flemish context through the identification of existing RCT evidence and program theories; In the evaluation phase, a pretest and posttest RCT design in one year will be conducted to evaluate the effectiveness of the intervention. The updated MRC framework (MRC, 2021) highlights the importance of understanding the interaction between the intervention and its context, and a feasibility study should be designed to evaluate the evaluation design (e.g., recruitment, data collection etc.) or intervention itself (e.g., acceptability, adherence of intervention etc.). A feasibility study is needed to reduce research waste and enhance the success chance, especially for hard-to-reach vulnerable participants, RCTs design. Therefore, the new PhD research aimed to develop and evaluate the feasibility (e.g., recruitment, feasibility, acceptability of intervention etc.) of an evidence-based intervention for informal caregivers of older people with early cognitive decline.

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Development and evaluation of an intervention on suPpoRting infOrmal cAregivers of older people with early CogniTIVe declinE (PROACTIVE): a study protocol based on the Medical Research Council framework

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ABSTRACT

Introduction Caring for people with cognitive problems can have an impact on informal caregivers' health and well-being, and especially increases pressure on healthcare systems due to an increasing ageing society. In response to a higher demand of informal care, evidence suggests that timely support for informal caregivers is essential. The New York University Caregiver Intervention (NYUCI) has proven consistent effectiveness and high adaptability over 30 years. This study has three main objectives: to develop and evaluate the Flemish adaptation of the NYUCI in the context of caregiving for older people with early cognitive decline; to explore the causal mechanism of changes in caregivers' health and well-being and to evaluate the validity and feasibility of the interRAI Family Carer Needs Assessment in Flanders.

Methods and analysis Guided by Medical Research Council framework, this study covers the development and evaluation phases of the adapted NYUCI, named PROACTIVE—suPpoRting infOrmal cAregivers of older people with early CogniTIVe declinE. In the development phase, we will identify the evidence base and prominent theory, and develop the PROACTIVE intervention in the Flemish context. In the evaluation phase, we will evaluate the PROACTIVE intervention with a pretest and posttest design in 1 year. Quantitative data will be collected with the BelRAI Screener, the BelRAI Social Supplement and the interRAI Family Carer Needs Assessment at baseline and follow-up points (at 4, 8 and 12 months). Qualitative data will be collected using counselling logs, evaluation forms and focus groups. Quantitative data and qualitative data will be analysed with SAS 9.4 software and NVivo software, respectively. Efficacy and process evaluation of the intervention will be performed.

Ethics and dissemination This study has been approved by the Ethics Committee of KU Leuven with a dossier number G-2020-1771-R2(MAR). Findings will be disseminated through community information sessions, peer-reviewed publications and national and international conference presentations.

Strengths and limitations of this study

- This is the first study to evaluate the Flemish adaptation of the New York University Caregiver Intervention following the Medical Research Council framework.
- This study addresses a suPpoRting infOrmal cAregivers of older people with early CogniTIVe declinE(PROACTIVE) intervention specifically working for an unrecognised but critical subpopulation, informal caregivers of older people with early-onset dementia or cognitive problems.
- This interdisciplinary study can systematically investigate the efficacy of the PROACTIVE intervention using the combination of instruments developed from the interRAI assessment systems.
- The sample of participants might not be entirely representative of the whole population in Flanders and 1-year intervention period may be relatively short.

INTRODUCTION

According to data from World Population Prospects, by 2050, one in six persons in the world and one in four persons living in Europe, will be aged 65 or older. The number of persons aged 80 years or over is projected to triple from 143 million in 2019 to 426 million in 2050.[1] These demographic changes put increasing pressure on healthcare resources. Dementia affects not only older people but also their informal caregivers. Literature shows that compared with other informal caregivers, people caring for persons with cognitive problems are more likely to be greatly impacted, as the caregiving is perceived to be more demanding.[2–6] Informal caregivers of people with early cognitive decline can experience a decline in health and quality of life because they have difficulties adapting

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to the caregiving role and acquiring caregiving coping skills.[7 8] A recent scoping review suggested that informal caregivers were more vulnerable when transitioning into the caregiver role, and experienced psychological distress and family conflicts.[9] A globally recognised solution to this problem is 'Healthy Ageing' proposed by WHO, which can contribute to a sustainable healthcare system. Healthy Ageing is mostly defined 'as the process of developing and maintaining the functional ability that enables well-being in older age.'[10]

All nations that wish to achieve sustainable development in their healthcare systems, face a similar problem. In Belgium, *Flanders in transition 2025*[11] states that sustainable healthcare should be achieved with financial viability as the ageing population will put more pressure on healthcare resources. A formal diagnosis of dementia, in Flanders, usually comes 3–4 years after the first signs of cognitive problems and about 70% of people with diagnosed dementia are cared for by informal caregivers at home.[12] Focusing on informal caregiver research, especially informal caregivers of older people with early-stage or probable dementia, shows to be important in a healthcare system.[13] However, little support is provided to this particular group, except for some basic guidance and information (eg, www.dementie.be) or by very local projects (eg, Foton, in Bruges). In addition, there is no systematic needs assessment tool and support plan for informal caregivers in Flanders.[14]

Well-established evidence is in favour of providing timely intervention for early-phase informal caregivers. Evidence showed that it is necessary to develop and validate psychosocial interventions focusing specifically on the earlier phases of dementia, when both people with dementia and their families have to adjust to the changing disease conditions.[15] Caregiver's burden varies in different stages of frail older people's impairment and providing early intervention for supporting informal caregivers is important.[16] One study showed that providing early support for informal caregivers may contribute to better adaptations to the caregiver's role and reduce caregiver's distress.[17] A Canadian psychoeducational individual programme for informal caregivers and a booster session on supporting caregiving transition proved to be effective.[18 19] In this psychoeducational programme, people in the experimental group were more confident and well prepared for care adjustment and future plan.[18 19]

Timely support interventions for early-phase informal caregivers of people with cognitive problems are scarce, although many studies evaluated a wide range of interventions to support informal caregivers. A recently performed systematic review found that only a few studies evaluated psychosocial interventions specifically focusing on informal caregivers of people with mild dementia or early cognitive problems.[20 21] Reviews of psychosocial interventions for supporting informal caregivers concluded that multicomponent interventions with tailored support to caregivers' needs are of great success.[22 23] Our review also found that the New York University Caregiver Intervention (NYUCI), a multicomponent psychosocial intervention for informal caregivers of people with all stages of dementia, had proven great efficacy and can play a preventive role in supporting informal caregivers.[24]

In Belgium, perceived greater social support from family and friends is related to lower informal caregiver burden.[25] In this perspective, the NYUCI, with its unique emphasis on the maximisation of social support for informal caregivers could also work well in the Flemish context. Therefore, we will develop a Flemish adaptation of the NYUCI for the target group of informal caregivers of older people with early cognitive decline. The Flemish NYUCI, which is named suPpoRting infOrmal cAregivers of older people with early CogniTIVe declinE (PROACTIVE), is the first adaptation of the NYUCI to be conducted in the context of caregiving for relatives with early cognitive decline.

This research will promote health and well-being for informal caregivers and care recipients who are at risk of adverse outcomes by leveraging the power of social support. The aims of the research are:

- To develop the PROACTIVE intervention in the Flemish context.
- To evaluate the efficacy of the PROACTIVE intervention in Flanders.
- To delineate the causal mechanism of health and well-being in early-phase informal caregivers.
- To clarify the potential causal mechanism of the PROACTIVE intervention under the conditions of high and low success.
- To evaluate the usefulness, feasibility and validity of the interRAI Family Carer Needs Assessment in Flanders.

To achieve the research aims, the following research questions will be answered:

Q1: What is the evidence on psychosocial interventions for informal caregivers of older people with early cognitive decline?

Q2: Which factors affect the health and well-being of early-phase informal caregivers and how?

Q3: Process evaluation: What is the potential causal mechanism of the PROACTIVE intervention?

Q4: Does the PROACTIVE intervention enhance the health and well-being of informal caregivers (and care recipients)?

Q5: Is the interRAI Family Carer Needs Assessment useful, feasible and validated in Flanders?

In this research, we hypothesise that the PROACTIVE intervention will be well developed in Flanders and will show efficacy on maintaining positive health and well-being outcomes (Healthy Ageing). To be specific, informal caregivers receiving support from the PROACTIVE intervention will most likely present improved outcomes, such as better relationship with care recipients and others, less or stable psychological health and enhanced well-being. Meanwhile, care recipients from the PROACTIVE group will show some ameliorations in their symptoms (eg, wandering, expression problems)

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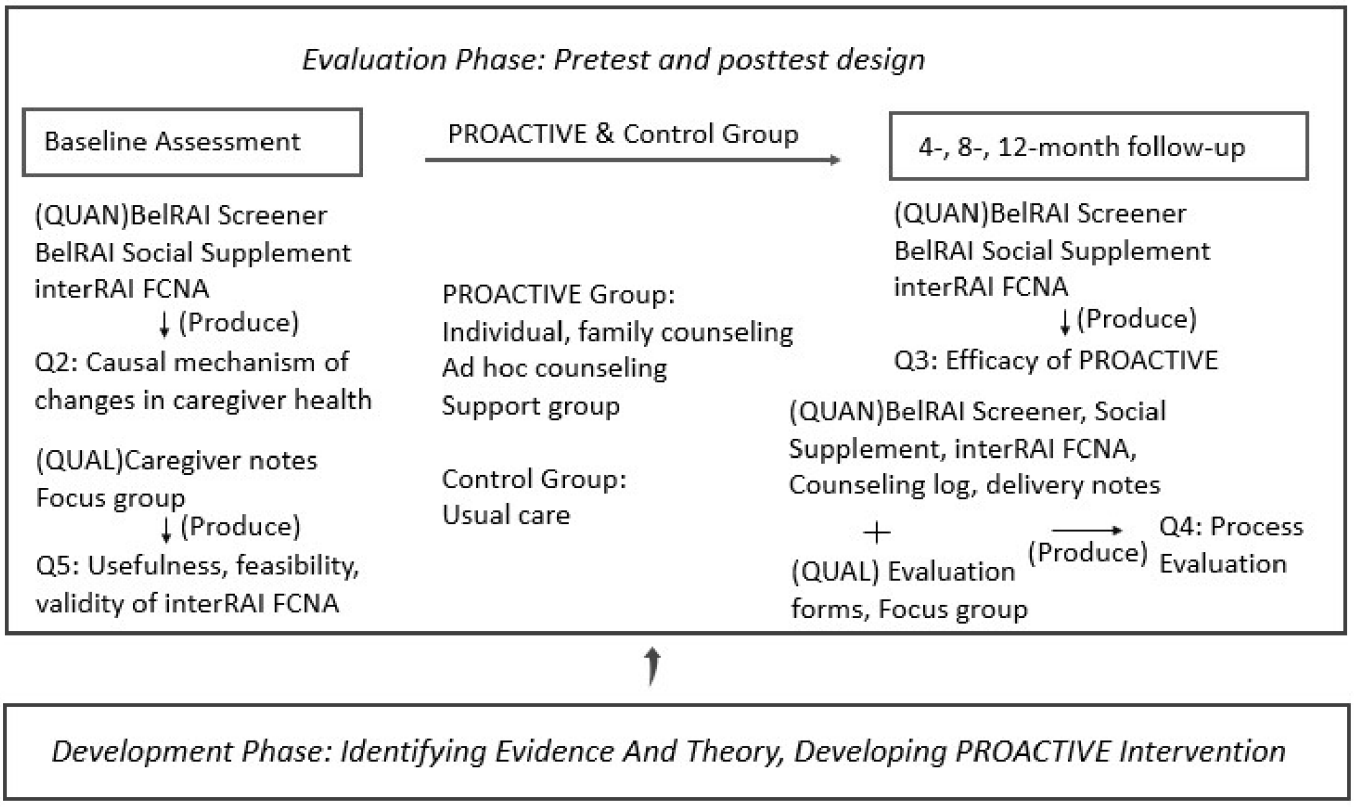

Figure 1 Study design based on Medical Research Council framework for developing and evaluating complex interventions. PROACTIVE: suPpoRting infOrmal cAregivers of older people with early CogniTIVe declinE, interRAI FCNA: interRAI Family Carer Needs Assessment, QUAL: qualitative analysis, QUAN: quantitative analysis.

as caregivers and caregiving can influence care recipients.[26] We also hypothesise that the interRAI Family Carer Needs Assessment will be useful and validated for informal caregivers of people with early cognitive decline in Flanders. Moreover, the potential benefit pathway of action of the PROACTIVE intervention will be clarified to better understand, which intervention elements are more amendable and effective.

METHODS AND ANALYSIS

The PROACTIVE Programme is structured following the Medical Research Council (MRC) framework[27] for development and evaluation of complex interventions to improve health. Figure 1 provides a diagram of the study design based on MRC framework.

Development phase

In this phase, we will develop the PROACTIVE intervention based on the adaptation of the NYUCI to the Flemish context.

Research question 1—What is the evidence on psychosocial interventions for informal caregivers of older people with early cognitive decline?

A systematic review was performed to identify the appropriate and effective psychosocial interventions for informal caregivers of older people with early cognitive decline. We found that the New York University Caregiver Intervention (NYUCI), among a few multicomponent interventions, has proven great efficacy and sustained benefits, including enhanced social support, reduced depressive symptoms, self-rated health, as well as greater positive appraisal of stressors.[28–30] The intervention also resulted in large healthcare cost savings over 30 years.[31–33] Additionally, the NYUCI proved high adaptability and transferability. Some adaptations of the NYUCI have been implemented in other areas in the USA,[34–37] as well as in Australia, England[38] and Israel[39 40] and similar and positive outcomes were replicated in other scientific studies.

The NYUCI consists of two individual and four family counselling sessions, encouragement of participation in a weekly support group and ongoing telephone-based availability of counsellors to caregivers and families (called ad hoc counselling). Beyond basic counselling, counsellors also provide resource information and referrals for auxiliary help, financial planning, and education for caregivers and family members.[24] Underpinning the NYUCI components, it is the stress process theory which has evolved steadily since 1981 and showed great power in caregiver stress research. The main concepts of this theory are: social and economic statuses; primary and secondary stressors; psychosocial resources and health outcomes.[41–43] Pearlin *et al*[41] conceived that the demands of caregiving, as encompassing primary stressors (ie, cognitive status, problematic behaviour, activities of

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daily living (ADL), instrumental ADL (IADL) dependencies), could in turn lead to secondary stressors (ie, family conflict, economic problems) and the emotional distress is likely to appear first in the stress process. Then eventually the physical health conditions will worsen. Moreover, the outcomes should cover mental and physical health of caregivers, their well-being and the sustainability of being a caregiver role. Together, this caregiver stress process theory shows how a mix of circumstances, stressors and resources (ie, coping, social support, appraisal) variably impact caregiver's health and well-being.

The original NYUCI includes six counselling sessions, and one NYUCI adaptation project in Minnesota defined the completion of intervention as 'participation in two-thirds or more of the programme sessions.'[34] In Flanders, we will reduce the total number of sessions and demands placed on participating informal caregivers in order to avoid fatigue and dropping outs. Basically, the adapted NYUCI called PROACTIVE will consist of wo individual and two family counselling sessions, at least monthly support group participation, and the ongoing availability of counsellors to caregivers and families (called ad hoc counselling). Then, in order to develop a successful Flemish adaption of the NYUCI, namely PROAVTIVE intervention, we will continue the following adaptation work: First, we will match the relevant theory from the stress process model with the intervention elements of the NYUCI. The stress process model shows how stressors have an impact on caregiver's health and well-being. We will examine each element (ie, individual, family counselling, support group, ad hoc counselling) of the NYUCI and explore their rationale and functions based on the corresponding parts of the stress process theory. Second, materials including programme manual,[44] implementation tools, worksheets, counselling summary forms and participant evaluation forms will be rigorously translated from English into Flemish/Dutch. Moreover, training and certification of counsellors will be made via an online video-based programme (http://www.hcinteractive.com/nyuci). Beyond the translation work, we will do the adaptation to (and thus the sociological study of) the cultural particularities of the Flemish healthcare system, care organisations, values and norms about informal care, as well as cultural views on dementia. The adaptation process of the intervention will follow a participatory approach, working with local stakeholders, including informal caregivers, counsellors, local organisations and policymakers. Moreover, international research networks (ie, Mittelman's research team, LUCAS and interDEM) and stakeholder meetings (ie, care recipients and their caregivers, counsellors, local organisations) will be motivated to ensure the success of the PROACTIVE development.

Evaluation phase

We will answer research question 2–5 during the evaluation phase with a pretest and posttest design in 1 year. Allocation will be concealed from participants and counsellors until after the baseline assessment, and it will be revealed as the counsellors open a sealed envelope in the caregivers' presence, allocating them to treatment or usual care conditions (control).

Caregivers assigned to the PROACTIVE group will receive the intervention over the course of 1 year. This intervention consists of a time-limited (within 4 months) counselling phase and an ongoing maintenance and support phase, namely ad hoc counselling and support group participation. The counselling sessions will motivate the participants to continue in the process and provide the basis for their ongoing support for each other.

Caregivers assigned to the usual care group will only receive services routinely provided to care recipients and their family, such as resource information and help on request, but they do not participate in the formal counselling sessions or in the support groups. These caregivers will not have any contact with the counsellors.

Instruments

Multiple instruments will be used in this research, including the interRAI Family Carer Needs Assessment, the BelRAI Screener, the BelRAI Social Supplement, evaluation forms for intervention elements and counselling logs.

The interRAI family carer needs assessment

The interRAI instruments are a suite of internationally standardised, validated assessment tools (http://www.interrai.org). The interRAI Family Carer Needs Assessment, as part of the interRAI integrated suite of assessment tools, was developed and tested in a longitudinal study across 11 countries in 2017.[45] The Family Carer Needs Assessment is a self-reported assessment, comprising many scale sections, including the role of the family carer, a carer health check, the required level of support, levels of care provided, caring effects on carers, social needs and life quality. This carer needs assessment tool can help identify carer needs and caregiving impact on carers, provide carer with support and advice, and identify caregiving difficulties.

The belrai screener

The BelRAI is an adapted version of the interRAI instruments in Belgium. These instruments are filled out in a secure web application, with an embedded BelRAIWiki site with an online manual.[46] A 7-year evaluation project for Belgian home care interventions called protocol 3 showed evidence that the interRAI Home Care (interRAI HC) is a valid instrument to be used in the community setting.[47] The BelRAI Screener was developed to be used in the Belgian home care setting consisting of four short modules from the interRAI HC, and one module from the interRAI Mental Health instrument. This short screening instrument determines whether a person should have a full interRAI HC assessment based on a certain cut-off value and is a tool for eligibility of home care services.

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The BelRAI social supplement

The BelRAI Social Supplement is a complementary tool for the BelRAI Screener. This tool can assess the social context variables of people living at home, including social engagement, social relationship, feelings of loneliness, communication and mood. Currently, the interRAI assessment instruments (BelRAI) are being mandatorily implemented in the daily care routine in Flanders.

Counselling log and evaluation form for intervention elements will be translated from the NYUCI original materials. Counselling log can collect data about the frequency and type of counselling, as well as frequency of support group participation. There are three types of evaluation forms: evaluation form for individual counselling, family counselling and support group. Each evaluation form includes review questions on whether the intervention element is helpful.

Target population

In this research, early cognitive decline means the early onset of dementia or early cognitive problems (eg, memory loss). Older people with early cognitive decline will be screened through the interRAI Cognitive Performance Scale (CPS2)[48 49] embedded in the BelRAI Screener. Older people must be at least 65 years old, live in the community and have a score of 1, 2 or 3 in the CPS2 scale (range 0–8). Participants are the informal caregivers of these older people with early cognitive decline and they are eligible if they (1) are recognised as the primary caregiver, (2) and if they are willing and able to participate. Caregivers may be spouses, children or other family members, either or not living with the care recipient. Caregivers are not eligible if they (1) have already received formal counselling or joined a peer-support group and (2) have insufficient cognitive capacity to complete the intervention.

Sample size

The minimum sample size for this research is 128 participants, calculated using GPower software with an effect size of 0.5, a two-sided significance level of 0.05 and a power of 0.8.

Recruitment

The following strategies for recruitment of participants will be used: contacting home care organisations, advertisement at community events and marketing to local agencies working with caregivers. The BelRAI Screener instrument will be used to initially screen older people with early cognitive decline (CPS2=1, 2 or 3) and then identify their primary caregivers who are eligible to participate in the intervention and are interested in enrolling. Informed consent will be obtained from all participants, including each caregiver, as well as from any other relatives who come to the family counselling sessions. Figure 2 provides a diagram of planned

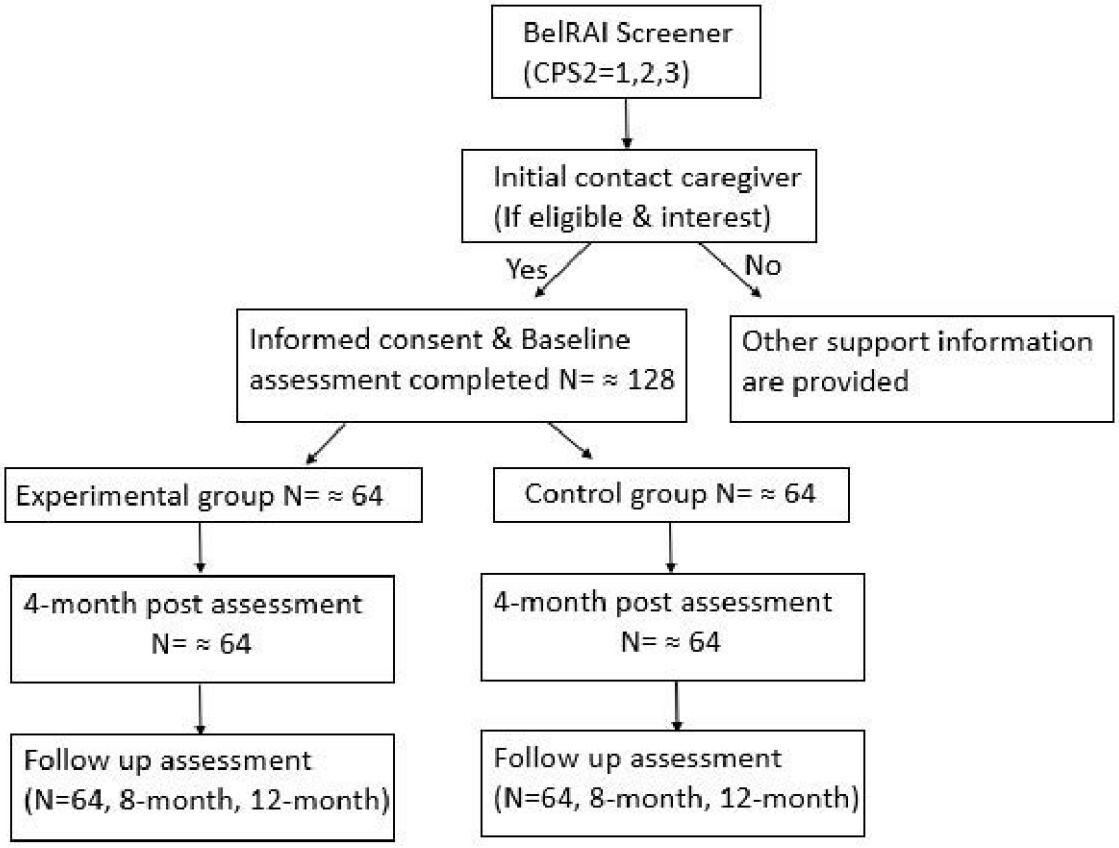

Figure 2 Planned flow of participants throughout the PROACTIVE study CPS2: interRAI Cognitive Performance Scale (CPS2) embedded in the Belrai Screener. PROACTIVE: suPpoRting infOrmal cAregivers of older people with early CogniTIVe declinE.

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flow of participants throughout the PROACTIVE study. The Ethics Committee of KU Leuven has approved this protocol with dossier number G-2020-1771-R2(MAR).

The PROACTIVE intervention consists of:

- Two individual and two family counselling sessions.
- At least monthly support group participation.
- Ongoing availability of counsellors to caregivers and families (called ad hoc counselling).

Outcomes

1. The causal mechanism of factors affecting informal caregiver health and well-being.
2. The effectiveness of the PROACTIVE intervention on the health and well-being of informal caregivers (and care recipients).
3. The benefit pathway of the action of the PROACTIVE intervention.
4. The usefulness, feasibility and validity of the interRAI Family Carer Needs Assessment in Flanders.

Data collection and analysis

Research question 2—Which factors affect the health and well-being of informal caregivers and how?

We will use stress process model to explain causal mechanism related to changes in caregivers' health and well-being. Stressors dataset will be collected using the BelRAI Screener instrument, resources variables and health outcomes dataset will be collected using the BelRAI Social Supplement and the interRAI Carer Needs Assessment in 4-month point.

Regarding the analysis of causal mechanism of direct, mediated and moderated effects, we will use hierarchical regression analyses to explore the associations among resource variables (age, gender, marital status, relationship to the care recipient, appraisals, coping responses, social engagement and relationship with others) and stressors (ADL, IADL, cognition status, behaviour problems) and health outcomes (mental health, life quality, self-rated health).Collected data will be analysed with SAS 9.4 software.

Research question 3—Process evaluation: What is the potential causal mechanism of the PROACTIVE intervention?

The process evaluation of the PROACTIVE intervention guided by MRC guidance,[50] aims to delineate the causal mechanism of the intervention under conditions of high and low success, identifying which intervention elements may be most appropriate and amenable for subsequent translation and implementation. In-depth qualitative data on deemed beneficial intervention elements will be collected by means of focus group discussions and delivery notes. Quantitative data on key process variables (frequency and types of counselling contacts, frequency of counselling contacts) will be collected with counselling log and list, as well as evaluation forms. Quantitative data on stressors and caregiver health outcomes will be collected with the BelRAI Screener, BelRAI Social Supplement and interRAI Family Carer Needs Assessment at baseline and at 4-month, 8-month and 12-month follow-up.

Qualitative data analysis will be conducted using the NVivo software. A thematic analysis will also be performed. Quantitative data will be analysed with SAS 9.4 software. We will integrate quantitative and qualitative analyses in a mixed-methods approach to clarify the causal pathway of the intervention.

Research question 4—Does the PROACTIVE intervention enhance the health and well-being of informal caregivers (and care recipients)?

Four time point (baseline, 4, 8, 12 months) quantitative data will be repeatedly collected using the BelRAI Screener instrument, the BelRAI Social Supplement and the interRAI Carer Needs Assessment. The specific health and well-being outcomes in informal caregivers will be: (1) IADL, health condition and cognition, and (2) life quality, self-rated health, mental health (depression, stress, anxiety) and (3) relationship with care recipients and others, social engagement and (4) appraisal of caregiving and support needs. The specific health and well-being outcomes in care recipients will be: ADL, IADL, behavioural problems and cognition.

Quantitative data will be analysed with SAS 9.4 software. Independent-sample t-tests and χ^2 tests will be used to compare the baseline subject characteristics between the experimental and control groups. To clearly compare change rates between experimental and control group, over the whole trial period (baseline, 4-month, 8-month and 12-month follow-up), a repeated-measures linear mixed model will be used incorporating the intention-to-treat principle.

Research question 5—Is the interRAI Family Carer Needs Assessment useful, feasible and validated in Flanders?

Psychosocial interventions for caregivers need to be as person-centred as for people with dementia.[51] We need to develop a validated instrument to assess the needs of informal caregivers of people with cognitive impairment and this instrument should be regularly used in healthcare.[52] Thus, it is of great significance to evaluate the usefulness, feasibility and validity of the interRAI Family Carer Needs Assessment for subsequent implementation.

Qualitative data will be collected with focus group discussions with informal caregivers. Caregivers will be asked after their baseline assessments on the following themes: whether items and scales are difficult to understand, lacking to cover carer needs and concerns, redundant, uncomfortable or unclear. These caregivers' answers will be used as information as well as input for focus group discussions. Meantime, we will develop a focus group question guide based on the experience of using interRAI instruments in BelRAI projects, so as to help guide the group discussion towards the topics that are to be examined. Qualitative data analysis will be conducted using the NVivo software.

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DISCUSSION

This paper describes a study protocol of developing and evaluating an intervention called PROACTIVE following the Medical Research Councul (MRC) framework. First, the study aims to develop and evaluate the PROACTIVE, which is a Flemish adaptation of the New York University Caregiver Intervention (NYUCI) in the context of caregiving for older people with early cognitive decline. Second, to explore the causal mechanism among stressors and caregiver's health and wellbeing. Third, to evaluate the validity and feasibility of the interRAI Family Carer Needs Assessment for informal caregivers of older people with cognitive problems.

To our knowledge, this is the first study to adapt the NYUCI to informal caregivers of older people with early cognitive decline or early dementia. Challenges during care transitions (eg, lack of preparedness in initial caregiving stage) contribute to negative health outcomes for people with cognitive decline and their family caregivers.[53] However, little attention is given to this critical subpopulation who are transitioning into the caregiver role of people with mild cognitive problems. Second, this study follows the methodology of MRC framework to develop and evaluate a complex intervention for informing future community implementation. The MRC framework fits the evaluation of complex interventions, guiding the process of translating research into practice, which can help address the gap between research and practice. Finally, this interdisciplinary study can systematically investigate the efficacy of the PROACTIVE intervention, beyond the scope of a single discipline, through using the combination of instruments developed from the internationally standardised interRAI assessment systems.

As the needs of informal caregivers can go unrecognised,[54] we believe that the PROACTIVE intervention can work as a preventive treatment contributing to sustainable healthcare. If caregivers' needs are not addressed timely, older people with cognitive problems and their caregivers may inadvertently undermine their health, and thus care recipients cannot remain at home for as long as possible. The PROACTIVE intervention can identify hidden caregivers' needs and provide them with timely, person-centred support, enhance their health and well-being, subsequently contribute to 'Healthy Ageing'. Limitations of this research should also be acknowledged. The sample of participants might not be entirely representative of the whole population in Flanders. Another limitation of the PROACTIVE intervention is that a 1-year experiment period may be relatively short to be able to measure all the effects of the intervention.

CONCLUSION

If the PROACTIVE intervention shows to be effective, findings will enhance the health and well-being of informal caregivers (and care recipients) and contribute to sustainable healthcare. If the validity of the interRAI Family Carer Needs Assessment is positively evaluated, this study will provide evidence for large scale implementation and provide a validated caregiver needs assessment for informal caregivers of people with cognitive problems. Process evaluation findings will facilitate subsequent community implementation. Additionally, findings may be transferable to other countries and other contexts, such as caregivers of people with chronic diseases other than cognitive problems.

Contributors All authors are involved in the study design and critically reviewed and approved the final manuscript. SW drafted the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

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Chapter 3

Assessing psychosocial interventions for informal caregivers of older people with early dementia: a systematic review of randomized controlled evidence

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Systematic Review

Assessing psychosocial interventions for informal caregivers of older people with early dementia: a systematic review of randomized controlled evidence

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1. Abstract

Dementia affects not only the patients, but also the caregivers. Timely targeted supporting for informal caregivers of people with dementia can improve their health and life quality, as well as contribute to sustainable healthcare. However, which interventions could efficiently support them and why still remains unclear. This systematic review aims to close this gap by critically assessing the current state of randomized controlled evidence concerning informal caregivers of older people with early dementia. We searched the electronic databases PubMed, CINAHL, Embase, Cochrane and Web of Science and assessed the methodological quality of the selected studies using the validated PEDro scale. A total of 2067 studies were identified in the initial searching, and 29 randomized controlled studies were finally selected based on the rigorous inclusion and exclusion criteria. Through completely assessing the methodological quality of studies, and the essentials and effectiveness of the 22 different types of interventions, we identified which interventions were effective and why. Timely targeted interventions for this caregiver group remains scarce. Furthermore, we highlight that there is a lack of systematic caregiver needs assessments prior to or when delivering the interventions.

2. Introduction

Cognitive decline and dementia affect not only older people but also their informal caregivers [1–3]. In the face of growing numbers of people living with dementia, ensuring that those who support them can remain healthy is a policy priority [4, 5]. Worldwide, around 50 million people have dementia, and there are nearly 10 million new cases every year [6]. People with dementia are mostly cared for by their family members, friends or neighbors, who are

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referred to as informal caregivers. The input from informal caregivers is a complex area, but regardless of how the input is calculated, it is estimated by Alzheimer's Disease International that the annual global number of informal care hours provided to people with dementia living at home was about 82 billion hours in 2015. This is equivalent to 2089 hours per year or 6 hours per day. This figure was equal to the input of more than 40 million full time workers in 2015, a figure that will increase to 65 million full time workers by 2030. This contribution is substantial for the health care system [7]. While the contribution is important, informal caregivers are often exposed to emotional strain, relationship deprivation, family conflicts and financial burden, which can impact their health and life quality [8]. Compared to other informal caregivers, those who care for older people with cognitive decline experience an even greater burden. This greater burden includes higher stress [9], increasing isolation and burden of care [10], higher levels of depression due to severe psychiatric and behavioral problems of the cared person [11, 12], lower quality of life [13], and poorer health [14]. A growing body of evidence points out that it is essential to develop effective interventions for this type of informal caregivers [15–20].

Informal caregivers of older people with cognitive decline bear increasing responsibility and burden with the progress of the disease. Even a newly acquired role as a caregiver affects other roles and often results in additional burden and emotional strain. This case will become worse especially when a caregiver has no prior experience in caregiving [8]. Moreover, family members often need to transition their relationship with the parent or spouse from that of a family member to that of a proactive caregiver. Early adjustment into this transition is needed because unprepared informal caregivers experienced frustration, resentment, grief, as well as relational deprivation [21].

Offering timely interventions for informal caregivers of people with dementia can help them better adapt to the transition, feel more competent to care and experience less psychological problems [22]. Timely supporting informal caregivers at risk of adverse outcomes showed an added value to the health care system [23]. Furthermore, this timely support can contribute to the caregiver's resilience to stress [24]. At this point, timely targeted supporting for informal caregivers of people with dementia can improve their health and life quality, as well as contribute to sustainable healthcare.

However, much remains unknown about how to best support informal caregivers of older people with early dementia. Most interventions developed focus on the persons who are affected by early dementia, but not on the informal caregivers. These interventions aim to improve the patients' physical and cognitive functions, quality of life, and the skills to perform activities of daily living [25]. A recent meta-review recommended that interventions should be developed to meet informal caregivers' changing needs in the course of dementia [26]. Scientific evidence shows that appropriate information and professional service for informal caregivers of people with early dementia are still lacking [27, 28]. Moreover, most systematic reviews focused on informal caregivers of people with moderate or advanced stages of dementia. These reviews assessed the effectiveness of interventions [29–33] concerning informal caregivers' outcomes, such as health-related quality of life [34], care burden, depression, disruptions in health and social support [35], and cost-effectiveness of the interventions [36], and the effects of content of the interventions [37]. The current state of randomized controlled evidence, particularly concerning informal caregivers of older people with early dementia, has not yet been systematically assessed. We aim to close this gap and explore which psychosocial interventions exist for informal caregivers of older people with early dementia. We also addressed the following questions: (1) What components of psychosocial interventions are effective for informal caregivers of older people with early dementia? (2) What theories underpin these interventions? (3) What caregivers' needs were assessed in these interventions?

3. Methods

A systematic review protocol was developed to identify and assess the intervention studies for informal caregivers of older people with early dementia. The review followed the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement [38]. Details of the protocol can be found in Appendix.

3.1 Initial search

We searched electronic databases PubMed, CINAHL, Embase, Cochrane and Web of Science using search terms in accordance with the following concepts: psychosocial interventions, evaluation, informal caregivers, older persons, dementia and cognitive problems. We did not impose data limits, and this review reflects the latest search through July 2021. Two independent reviewers constructed a comprehensive list of Medical Subject Headings (MeSH), which was designed for 5 explicit categories: (1) interventions; (2) evaluation; (3) informal caregivers; (4) older persons; and (5) dementia (Table 1). Terms were coupled with relevant MeSH terms and were truncated as appropriate. We hand-searched references in reviews and published literature to include more potential studies that could have been missed in the database searching.

3.2 Studies selection

After removing duplicates, abstracts were identified upon the initial search, and two independent raters se-

Table 1. Medical Subject Headings (MeSH) search terms*.

Search category	MeSH terms
Interventions	Counseling, education, support, problem solving, cognitive behavioral therapy, coping skills, art, singing, museums, music
Evaluation	Program evaluation, treatment outcome, evaluation study, health impact assessment
Informal caregivers	Family caregivers, spouse caregivers
Older persons	Aged
Dementia	Dementia, cognitive decline, mild cognitive impairment, memory disorders

* For a detailed table with MeSH terms, keywords and explosions of the search strategy, please contact the authors.

lected abstracts for full review based on inclusion/exclusion criteria. After each rater independently reviewed the abstracts, findings were reviewed to find a consensus producing a final list of studies for full-text examination. Full-text examination was also performed by the two raters independently.

All papers selected for final inclusion met the following criteria.

3.2.1 Inclusion criteria

• Only peer-reviewed journal articles written in English were included.

• Only randomized controlled trial designs were included.

• Interventions had to specifically focus on informal caregivers of people with early dementia delivered in the community setting. Studies were also included when people with early dementia were part of their care population, even when they also included more severe cases.

• Informal caregivers were viewed as those who are primarily responsible for the care and wellbeing of care recipients. They may be spouses, children or other family members, either or not living with the care recipient.

• Studies included efficacy evaluation of the interventions for informal caregivers intended to enhance their health and life quality (possibly also of the care recipient).

3.2.2 Exclusion criteria

• The intervention must primarily focus on informal caregivers. Interventions intended primarily for care recipients where the caregivers assisted with implementation were excluded.

•Studies were also excluded if the caregivers were professionals, and the care recipients were institutionalized.

• Descriptive studies such as protocol trials were excluded.

• Studies only focusing on older people with moderate or advanced stages of dementia were not the target of our review and were also excluded.

3.3 Data extraction

Two independent raters read the full text of each study included in the review, and extracted key content of the studies using an ad-hoc data collection form to record the following information: (1) author, year and country, (2) theoretical underpinnings, (3) caregiver needs assessment, (4) sample, (5) people delivering the intervention, (6) intervention duration, (7) intervention elements, (8) main outcomes of care recipients, (9) main outcomes of caregivers, (10) main findings, (11) study limitations. Studies were categorized based on the composing elements of an intervention (e.g., training, counseling) to facilitate synthesis of the studies.

Two independent raters selected the studies and rated them independently for their quality using a modified 11-item version of the PEDro scale [39, 40]. Differences in scoring were discussed and resolved collaboratively. According to the rating rule of PEDro scale, criteria 1 (i.e., Specification of eligibility criteria) is not included in the final score. Hence the PEDro scale consists of 10 quality ratings, each receiving either a yes (value 1) or no (value 0) score, which is based on the Delphi list developed by Verhagen *et al*. [41] PEDro score 9–10 is categorized as of excellent quality, PEDro score 6–8 is categorized as good quality, PEDro score 4–5 is categorized as of fair quality, and PEDro score $\leq$3 is categorized as of poor quality. The checklist identifies studies that are generalizable, internally valid, and contain interpretable data. Two raters followed the guidelines of PRISMA, so the consensus came after discussion and, when there was a doubt, once again raters assessed the paper to see whether they could come to an agreement. When the full text could not be located or when published articles did not present all necessary information, authors were contacted about the required information.

4. Results

As illustrated in Fig. 1, a total of 2067 studies were finally identified through online databases and handsearching. A total of 343 duplicates were removed. After full-text eligibility screening for 156 records, 29 randomized controlled studies were included based on rigorous inclusion and exclusion criteria. Raters then performed data extraction and quality of assessment on the included studies.

4.1 Quality assessment

The methodological quality of the included studies ranged from good to excellent (Table 2). Amongst the 29 studies [42–70], 9 studies [43, 53–57, 59–61] were categorized as of excellent quality (PEDro score = 9–10). As

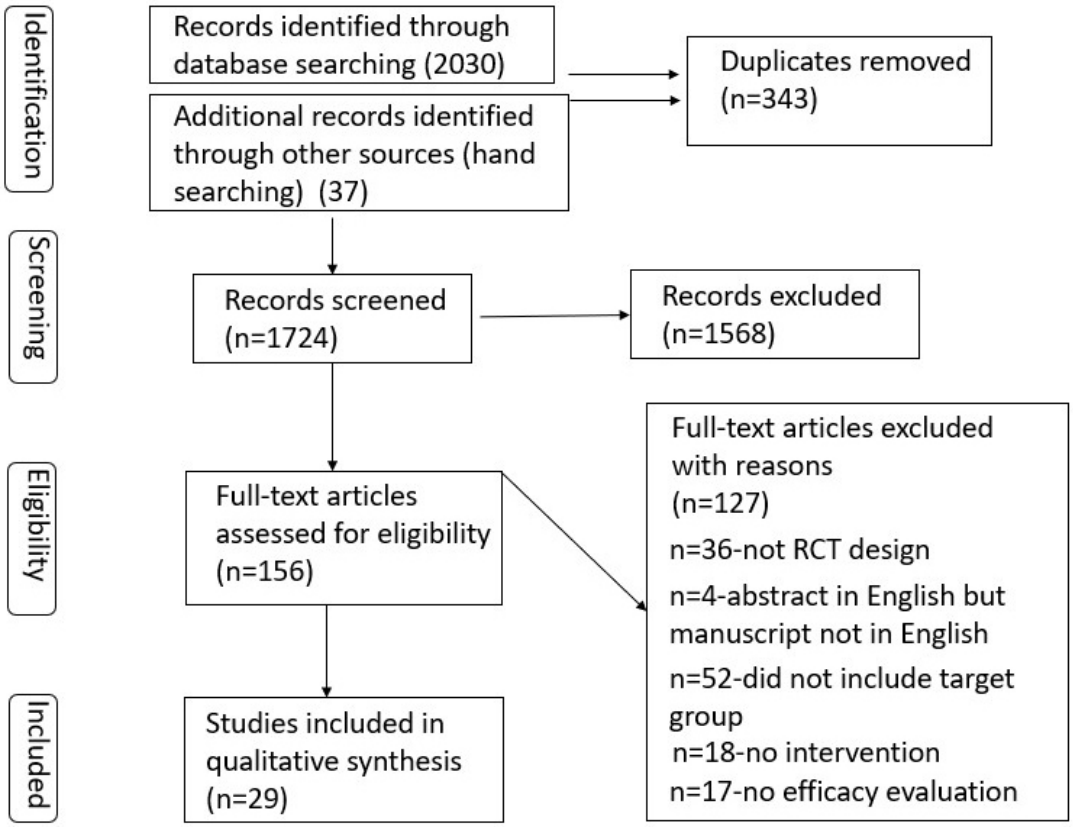

Fig. 1. Prisma flow diagram.

Table 2. Frequency of methodological quality of included studies.

PEDro scale criteria	Frequency n (%)
1. Specification of eligibility criteria (standard, this item is excluded in the final score)	29 (100)
2. Random allocation	29 (100)
3. Concealed allocation	13 (45)
4. Assessor blinding	13 (45)
5. Prognostic similarity at baseline	29 (100)
6. Loss to follow-up information provided	29 (100)
7. Over 85% follow-up of at least one key outcome	16 (55)
8. Between-group statistical comparison of at least one key outcome	29 (100)
9. Point estimates and measures of variability of at least one key outcome	29 (100)
10. Intention to treat analysis	18 (62)
11. Intervention fidelity protocol available	29 (100)

included studies were trials examining psychosocial interventions, subject and therapist blinding were unattainable. Moreover, because of the nature of the population studied, 'concealed allocation' and 'assessor blinding' were poorly met. The scores of 'intention to treat analysis' and of 'over 85% follow-up of at least one key outcome' were relatively poor. However, all included studies appeared to have good methodological rigor including specification of eligibility criteria, loss to follow-up information provided, point estimates and measures of variability of at least one key outcome and use of a treatment fidelity protocol.

4.2 Study characteristics

The intervention components, intervention delivery and duration, as well as sample characteristics varied in a total of 22 different types of interventions described in 29 studies (see Tables 3,4, Ref. [42–70]). Most studies were performed in the USA (14 studies), and others were performed in the UK (5 studies), China (2 studies), Japan (1 study), India (1 study), Germany (1 study), Netherlands (3 studies), Norway (1 study), Denmark, Poland and Spain (1 study).

Table 3. Theory basis and caregiver needs assessment for interventions.

Author, year, country	Sample	Theory basis	Needs assessment	People delivering intervention	Duration
Kajiyama, Bruno, *et al*. 2013 USA [42]	Caregivers of relatives with early and later stages of dementia	Not reported	No	No	3 months
Charlesworth, Georgina, *et al*. 2008 UK [43]	Caregivers of relatives with early and later stages of dementia	Not reported	No	Befriending volunteers	6-, 15-, 24-month follow-up
Gonyea, Judith G. *et al*. 2006 USA [44]	Caregivers of relatives with early or moderate dementia	Cognitive behavioral group intervention	No	Therapists	5 weeks
Gonyea, Judith G. *et al*. 2016 USA [45]	Caregivers of relatives with early or moderate dementia	Cognitive behavioral group intervention	No	Therapists	5 weeks and 3-, 6-, 9-, 12-week follow-up
Huang, Huei Ling, *et al*. 2003 China [46]	Caregivers of relatives with early and later stages of dementia	Progressively Lowered Stress Threshold	No	Gerontological nurses	3 weeks and 3-month follow-up
Núñez-Naveira, Laura, *et al*. 2016 Denmark, Poland, Spain [47]	Caregivers of relatives with early and later stages of dementia	Not reported	No	No	3 months
Gitlin, Laura N., *et al*. 2010 USA [48]	Care dyads (relatives with diagnosis of probable dementia or MMSE <24)	Competence-Environmental Press theory	Interview of caregivers to identify patient routines, interests, caregiver concerns	Occupational therapists and advance practice nurses	4-, 9-month follow-up
Garand, Linda, *et al*. 2014, 2019 USA [49, 50]	Caregivers of relatives with mild cognitive impairment or early dementia	Problem Solving Therapy (PST)	No	Social workers	4 weeks, and 3-, 6-, 12-month follow-up
Dias, Amit, *et al*. 2008 India [51]	Care dyads (relatives with mild or moderate dementia)	Not reported	No	Community team (home care advisors, lay counselors, psychiatrists)	Flexible, at least once a fortnight for six months
Tanner, Jeremy A., *et al*. 2015 USA [52]	Care dyads (older people with memory disorders)	Not reported	Checklist for identification of care recipient and caregiver needs	Intervention team (coordinators, nurses, geriatric psychiatrist)	9-, 18-month follow-up
Mittelman, Mary S, *et al*. 2004, 2007, 2004 USA [53–55]	Caregivers of relatives with early and later stages of dementia	Pearlin's stress process model	Systematic assessment for caregiver needs	Certified counselors	4 months, regular follow-up intervals for as long as the caregiver participated in the study

Table 3. Continued.

Author, year, country	Sample	Theory basis	Needs assessment	People delivering intervention	Duration
Drentea, Patricia, *et al*. 2006 USA [56]	Caregivers of relatives with early and later stages of dementia	Pearlin's stress process model	Systematic assessment for caregiver needs	Certified counselors	4 months, regular follow-up intervals for as long as the caregiver participated in the study
Berwig, Martin, *et al*. 2017 Germany [57]	Caregivers of relatives with early and later stages of dementia	Schulz's stress–health process	Risk assessment of 5 caregiver domains	Certified interventionists	6-, 9-month follow-up
Jansen, Aaltje PD, *et al*. 2011 Netherlands [58]	Care dyads (older adults with early dementia)	Not reported	Caregiver Capacity and burden questionnaires	District nurses	6-, 12-month follow-up
Livingston G, *et al*. 2013,2014 UK [59–61]	Caregivers of relatives with early and later stages of dementia	Based on Coping with Caregiving program	A self-completed measure of coping strategies	Supervised psychology graduates	4-, 8-, 24-month follow-up
Whitlatch CJ, *et al*. 2019 USA [62]	Care dyads (persons with early-stage dementia)	Not reported	No	Counselors	6 sessions
Bruvik FK, *et al*. 2013 Norway [63]	Care dyads (persons with early and later stages of dementia)	Not reported	No	Registered nurses, occupational therapists	12 months
Seike A, *et al*. 2021 Japan [64]	Caregivers of relatives with early and later stages of dementia	Adult learning theory, Stress, appraisal and coping theory, Cognitive behavior therapy	No	Physicians, geriatric and dementia care nurses, clinical psychologists, and medical social workers	12 weeks
van Wezel N, *et al*. 2021 Netherlands [65]	Caregivers of relatives with early and later stages of dementia	Not reported	No	Trained educators	1–2 weeks, 3-month follow-up
Brown KW, *et al*. 2016 USA [66]	Caregivers of relatives with early-stage dementia	Not reported	No	Trained facilitators	8 weeks, 3-month follow-up
Kor PP, *et al*. 2020 China [67]	Caregivers of relatives with early and later stages of dementia	Mindful coping model	No	Qualified interventionist	10 weeks, 6-month follow-up
Judge KS, *et al*. 2013 USA [68]	Care dyads (persons with early and later stages of dementia)	Stress Process Model	A strength-based inventory assessing care dyad's strengths across domains	Intervention specialists	6 sessions, around 18.5 weeks
Wenborn J, *et al*. 2021 UK [69]	Care dyads (persons with early and later stages of dementia)	Not reported	No	Occupational therapists	12 weeks, and 26-week follow-up
Boots LM, *et al*. 2018 Netherlands [70]	Caregivers of relatives with early and later stages of dementia	Not reported	No	Personal coach	8 weeks

Table 4. Components and effectiveness of interventions.

Author, year, country	Intervention components	Main outcomes of care-recipients	Main outcomes of informal caregivers	Main findings	Study limitations
Kajiyama, Bruno, *et al*. 2013 USA [42]	Training in stress management	No	Depressive symptoms, perceived stress, level of bother due to disruptive behaviors, quality of life	Greater improvement in perceived stress	Sample primarily on Caucasian women with some college education, low rate of participation, high dropout rate
Charlesworth, Georgina, *et al*. 2008 UK [43]	Befriending support	No	Caregiver wellbeing, perceived social support, positive affectivity, health related quality of life	No significant differences between groups	Narrow difference between intervention and control conditions, low rate of participation
Gonyea, Judith G. *et al*. 2006 USA [44]	Training in behavior management, pleasant events and relaxation	Neuropsychiatric symptom severity	Distress about the neuropsychiatric symptoms of care-recipients, caregiver burden	Less distress about the neuropsychiatric symptoms of care-recipients	Low rate of participation, small sample and no follow-up
Gonyea, Judith G. *et al*. 2016 USA [45]	Training in behavior management, pleasant events and relaxation	Neuropsychiatric symptom severity	Neuropsychiatric symptom-related distress, depressive symptoms, caregiver self-efficacy, caregiver anxiety	Lower neuropsychiatric symptoms severity of care-recipients, less distress about neuropsychiatric symptoms, a greater sense of self-efficacy in providing care, less depressive symptoms	Few male participants, lack of statistical power and no-treatment control group
Huang, Huei Ling, *et al*. 2003 China [46]	Training in helping identify behavior problems and plan environmental modifications + Telephone consultation	Behavioral problems	Caregiver self-efficacy	Decreased care-recipients' behavior problems and increased caregiver self-efficacy	Small sample size and the relatively short follow-up
Núñez-Naveira, Laura, *et al*. 2016 Denmark, Poland, Spain [47]	UnderstAID Application covering education on dementia, skills training + Social network forum	No	Caregiving competence and satisfaction, depressive symptoms	Significantly decreased depressive symptoms	Sample bias based on the caregivers access to the internet, previous experience with smart devices, no follow-up
Gitlin, Laura N., *et al*. 2010 USA [48]	Education in dementia management skills + Training in home safety modifications, simplifying tasks, and stress reduction	Functional dependence, activity engagement,	caregiver well-being, confidence, perceptions of patient quality of life, appraisal of study benefits	At 4 months, improved patient functioning, especially IADLs, patient engagement, caregiver well-being and confidence using activities; at 9 months, no statistically significant differences between two groups	Only 15% male and a higher proportion of male caregivers than female caregivers dropped out
Garand, Linda, *et al*. 2014, 2019 USA [49, 50]	Education (5 topics) + Training (systematic application of PST)	No	Depressive symptoms, symptoms of anxiety, problem solving orientation, objective caregiver burden, subjective caregiver burden	Lower depressive symptom levels and mean anxiety levels, improvements in negative problem-solving orientation (NPO) scores; positive impact on subjective caregiving burden	Small sample size, focus on caregivers residing with care-recipient, no information on length of caregiving, reliance on Registry for recruitment

Table 4. Continued.

Author, year, country	Intervention components	Main outcomes of care-recipients	Main outcomes of informal caregivers	Main findings	Study limitations
Dias, Amit, *et al*. 2008 India [51]	Education on dementia and caregiving skills + Referral resources + Family networking	Behavioral problems and activities of daily living in patients	Caregiver mental health, caregiver burden, distress due to behavioral disturbances of care-recipients	Improvements in caregiver mental health and perceived burden, non-significant reductions in care recipients' behavior disturbances and functional ability	Small sample size, short follow up period
Tanner, Jeremy A., *et al*. 2015 USA [52]	Dementia education + Referral resources + Skills training	No	Objective caregiver burden, subjective caregiver burden, quality of life, depression	No statistically significant group differences in caregiver outcomes	Urban sample, lack of no-treatment control group
Mittelman, Mary S., *et al*. 2004, 2007, 2004 USA [53–55]	Counseling (individual and family) + Support group + Ad hoc counseling	No	Depressive symptoms, self-rated health, number of illnesses, caregiver appraisals of behavior problems in patients	Fewer depressive symptoms sustained for 3.1 years after baseline; better self-rated health sustained for 2 years, fewer illness reported; significantly reduced caregivers' reaction ratings	Usual care group also received support and counseling, measure of number of illnesses was not weighted by severity of illness
Drentea, Patricia, *et al*. 2006 USA [56]	Counseling (individual and family) + Support group + Ad hoc counseling	No	Support satisfaction, size of network, frequency of visit and phone contact, emotional, informational and instrumental support	Higher levels of satisfaction with their social support network over the first 5 years, higher levels of emotional support, more visits, and having more network members	Usual care group also received support and counseling
Berwig, Martin, *et al*. 2017 Germany [57]	Dementia education + Training (problem solving, stress management) + Support group	Frequency of challenging behavior of patients	Caregiver perceived burden and social support, mental health, health-related quality of life, reaction to challenging behaviors of patients	Stabilizing effects on caregiver burden, improvements in health-related quality of life and reactions to challenging behavior of patients, reduced frequency of challenging behavior of patients. Decreased follow-up period effects	Intervention change process was evaluated only basically
Jansen, Aaltje PD, *et al*. 2011 Netherlands [58]	Referral resources + Family meetings + Telephone consultation	Quality of life	Quality of life, depressive symptoms, competence, burden	No significant differences between two groups	Insufficient sample size power to detect a small effect
Livingston G, *et al*. 2013,2014 UK [59–61]	Education + Training (communication, relaxation, behavioral management etc.) + Information support + Plans of maintain skills learnt	Quality of life	Potentially abusive behavior by caregivers towards the recipient, anxiety, depression, mental health, care burden, quality of life	Significantly reduced caregiver anxiety and depression scores, improved mental health, effects persisted at 24-month follow-up	Sample bias based on caregivers with more problems, not enough time and budget to translate the whole manual for non-English speaking participants
Whitlatch CJ, *et al*. 2019. USA [62]	Education + support + referral resources	Completion of a care plan, use of services, dyadic relationship functioning, participant well-being, program satisfaction	Completion of a care plan, use of services, dyadic relationship functioning, participant well-being, and program satisfaction	Able to construct a balanced care plan, increased use of services, dyadic functioning improved for one dimension (decreased emotional disruptions), higher program satisfaction	Lack of long-term effects evaluation, control group is not as usual care, sample is not large and diverse

Table 4. Continued.

Author, year, country	Intervention components	Main outcomes of care-recipients	Main outcomes of informal caregivers	Main findings	Study limitations
Bruvik FK, *et al*. 2013 Norway [63]	Education + counseling + group meeting	Depression	Depression	No statistical significance	Geriatric Depression Scale might not fit well for carers
Seike A, *et al*. 2021 Japan [64]	Dementia education + skill training + social support	Cognitive function, ADL and BPSD	Depression, caregiving time, subjective burden, caregiving appraisal, care coping skills	Improved depression, caregiving appraisals and coping skills, sustained benefits over 24-, 48-week follow-up	Small sample size, not assess which program components were most effective
van Wezel N, *et al*. 2021 Netherlands [65]	Dementia education + support options	No	Knowledge about dementia, perceived ability to talk about dementia, support received and self-perceived pressure	Improvement in knowledge about dementia, a significant increase over time in the support received from home-care staff	Lack of long-term effects evaluation
Brown KW, *et al*. 2016 USA [66]	Class discussion of caregiving + mindfulness exercises	No	Perceived stress, experiential avoidance, mental and physical functioning, caregiver burden, mood, diurnal salivary cortisol, caregiver-recipient relationship quality	Lowe levels of perceived stress, tension, anger and caregiver burden, no statistical significance in 3-month follow-up	Small ample size
Kor PP, *et al*. 2020 China [67]	Psychoeducation on stress + mindfulness activities + peer sharing	Behavioral and psychological symptoms of dementia (BPSD)	Perceived stress, caregivers' burden, depressive symptoms, anxiety, resilience, quality of life, and mindfulness	Improvement in perceived stress, depression, anxiety, BPSD-related caregivers' distress, and mental health-related quality of life	Self-reported questionnaires might have resulted in a social desirability bias, small sample size
Judge KS, *et al*. 2013 USA [68]	Education + training communication skills, cognitive rehabilitation	No	Caregiver mastery, emotional health strain, physical health strain, self-efficacy, role captivity, dyadic relationship strain, quality of life, self-esteem, depression, anxiety	Less emotional health strain, dyadic relationship strain, role captivity, and improved caregiving mastery, fewer symptoms of anxiety and depression	Lack long-term effect evaluation, low adherence to the intervention
Wenborn J, *et al*. 2021. UK [69]	Training problem-solving skills and coping strategies + goal setting and achievement +plan future	Cognition, quality of life, assistance needed with ADL, mood, number of social contacts and leisure activities	Mood, sense of competence, number of social contacts and leisure activities	No significant differences in the validated outcome measures	Sample is not diverse, only English-speaking participants, and no consideration of sample ethnicity
Boots LM, *et al*. 2018 Netherlands [70]	Education + social support+ training coping stress, positive thoughts, communication etc.	No	Self-efficacy, mastery, depression, anxiety, and perceived stress, quality of life	Improvement in self-efficacy, mastery and quality of life	Only computer-literate caregivers included, low adherence to the intervention, lack of long-term effect evaluation

In addition, the years of these published studies varied from 2003 to 2021. In most studies, informal caregivers of relatives with early and later stages of dementia are the sample participants, except for 5 studies [49, 50, 58, 62, 66] where the participants are solely informal caregivers of older people with early dementia. Four studies evaluated a single-element intervention (i.e., education, training) [42–45], and the remaining 25 studies evaluated a multi-component intervention (i.e., support group + training) [46–70]. The interventions are delivered by a wide array of individuals (e.g., nurse, counselor, etc.), and two internet-based interventions are carried out by participants themselves [42, 47]. In two studies [51, 52], the intervention was carried out by an interdisciplinary team, including a home care advisor, lay counselor, nurse, psychiatrist and coordinator. Most interventions were delivered by therapists or nurses [44–46, 48, 53–58, 63, 64, 69], and only interventionists of the NYU Caregiver intervention (NYUCI) and Resources for Enhancing Alzheimer's Caregiver Health (REACH) were officially certified [53–57]. Of the 29 studies, only 5 studies specifically targeted informal caregivers of people with early dementia [49, 50, 58, 62, 66]. The remaining 25 studies evaluated the interventions for informal caregivers of people with early and later stages of dementia.

4.3 Theory basis and caregiver needs assessment for interventions

Table 3 shows the theory basis of interventions and caregiver needs assessment matched with the interventions. Not all studies reported the theory basis of the interventions, except for the following studies: (1) A home-based caregiver training program was based on the Progressively Lowered Stress Threshold Model (PLST), which is tailored to individual needs of caregivers to improve their self-efficacy [46]. (2) A behavioral home-based Care of Persons with Dementia in their Environments (COPE) intervention was based on the Competence-Environmental Press theory, which targeted modifiable environmental stressors to maximize physical function in people with dementia and build dementia management skills in caregivers [48]. (3) A PST intervention was based on the Problem-Solving Therapy (PST) which focuses on training caregivers in adaptive problem-solving attitudes and skills [49, 50]. (4) An evidence-based multi-component intervention (NYUCI) and the Acquiring New Skills While Enhancing Remaining Strengths (ANSWERS) intervention are conceptually grounded in the Stress Process Model, which aims to build and improve the resources of caregivers in adapting to and managing care demands [53–56, 68]. and (5) A multi-component individualized intervention (REACH) was based on the Schulz's Stress–health Process Model, which aims at reducing risks in five caregiver domains (see below caregiver needs assessment) [57]. (6) A 5-week behavioral intervention reported in 2 studies [44, 45] and an individual therapy program (START, STrAtegies for RelaTives) reported in 3 studies [59–61] were based on the Coping with Caregiving (CWC), which was based on principles of cognitive behavioral therapy to reduce caregiver distress related to neuropsychiatric symptoms of people with dementia and general caregiver burden. (7) A group-based multicomponent psychoeducation intervention was grounded in the Adult learning theory, Stress, appraisal and coping theory and Cognitive behavior therapy, which aims to reduce caregiver depression, and improve caregiving appraisals and coping skills, and improve the conditions of people with dementia [64]. In addition, the mechanism of a modified mindfulness-based cognitive therapy is the mindful coping model [67].

Of all the 29 studies, only 12 studies mentioned the use of a caregivers' needs assessment, including: (1) An individualized, comprehensive assessment battery for caregivers in the NYUCI systematically assessed the caregiving role, physical health and emotional health of caregivers, social support, caregiver understanding and response to the illness and social support [53–56]. (2) An initial interview consisted of a core battery of caregiver assessment used by all REACH sites [48]. (3) The COPE used the Johns Hopkins Dementia Care Needs Assessment (JHDCNA) consisting of 4 major caregiver domains (i.e., caregiver education, resource referral, mental healthcare, medical healthcare) [52]. (4) Individual treatment strategies in the REACH intervention were selected based on an individualized risk assessment of five caregiver domains (i.e., knowledge of dementia, ability to care, perceived social support, emotional and physical well-being and challenging behavior) [57]. (5) The caregiver's situation was explored by a nurse with a capacity and burden questionnaire to formulate a care plan [58]. (6) The START intervention used a brief COPE, a validated self-completed measure of coping strategies by the caregiver, with subscales measuring problem focused, emotion focused, and dysfunctional coping [59–61]. (7) The ANSWERS intervention applied a strength-based inventory assessing care dyad's strengths across different domains, including cognitive, physical health, social activities, personality, life roles, leisure activities, and history and culture [68].

4.4 Components and effectiveness of interventions

All interventions were categorized into a single-element or a multi-component group based on the intervention components and most interventions reported effective outcomes on informal caregivers. These studies reported a variety of health outcomes in informal caregivers, including depression, stress, anxiety, caregiver self-efficacy, caregiver burden and quality of life. Some studies also collected other outcomes including social support, role captivity, positive affectivity, self-rated health, wellbeing, appraisal of study benefits, completion of a care plan, use of services, dyadic relationship functioning, potentially abusive behavior by caregivers towards the care recipients and

caregiver's appraisals of behavior problems in care recipients [43, 48, 53–57, 59–62, 68]. In 14 studies, outcomes about the care recipients were also evaluated, such as quality of life, functional dependence, depression, completion of a care plan, use of services, dyadic relationship functioning, wellbeing, program satisfaction, activity engagement, assistance needed with ADL, mood, number of social contacts and leisure activities, behavioral problems, frequency of challenging behavior, and neuropsychiatric symptom severity [44–46, 48, 51, 57–60, 62–64, 67, 69]. Detailed information of the interventions is shown on Table 4.

4.4.1 Single-element interventions

Four studies that evaluated a single-element intervention were identified [42–45]. Three of them had good methodological quality [42, 44, 45]. One of the four studies (25%), whose intervention is to provide informal caregivers with befriending support, did not report significant effects [43]. Three studies whose single intervention element is training reported statistically significant effects, including lower levels of neuropsychiatric symptoms severity in care recipients, reduced caregiver stress, a greater sense of self-efficacy in providing care, less depressive symptoms and less distress about the neuropsychiatric symptoms [42, 44, 45]. Among the three training programs, one's [42] intervention emphasis is to provide stress management training for informal caregivers, and it was carried out via internet by a video tape. The other two interventions [44, 45] mainly focused on the training on behavior management of care recipients, planning of pleasant events and relaxation techniques, and these interventions were delivered by therapists.

4.4.2 Multi-component interventions

The other 25 studies evaluated multi-component interventions. 17 studies were categorized as of good methodological quality [46–52, 58, 62–70], and 8 studies even had excellent methodological quality [53–57, 59–61]. 4 of the 25 studies (16%) did not show statistically significant benefits [52, 58, 63, 69]. 11 of 12 studies which had a common intervention component (i.e., social support) reported benefits for caregivers, such as improvements in mental health, emotional support, caregiving appraisals and coping skills, mastery, increased use of services [46, 47, 51, 53–57, 62, 64, 70], except for 1 study [58]. 10 of 12 studies which shared a common intervention component (i.e., training) all reported significant effectiveness for caregivers, such as improved quality of life and caregiver self-efficacy, reduced caregiver burden, less emotional health strain, less dyadic relationship strain, less role captivity, less distress and depressive symptoms [46, 48–50, 57, 59, 60, 64, 68, 70], except for 2 studies [52, 69]. 14 out of 16 studies which had a common intervention component (i.e., education) reported benefits for caregivers, such as increased caregiver self-efficacy, mastery, coping skills, improved wellbeing and quality of life, reduced caregiver burden and depressive symptoms, less role captivity [47–51, 57, 59, 60, 62, 64, 65, 67, 68, 70], except for 2 studies [52, 63].

Six interventions that had common intervention components (i.e., education and social support) demonstrated beneficial effects on caregiver's depressive symptoms, caregiver's mental health and perceived burden, caregiving appraisals, coping skills, and quality of life [47, 51, 57, 62, 64, 70]. 9 of 10 studies which shared common intervention component (i.e., education, training) reported such benefits for caregivers as improved quality of life, reduced caregiver burden, improved caregiving mastery [48–50, 57, 59, 60, 64, 68, 70], except for one study [52]. Among them, the COPE intervention consisting of education and training components improved patient functioning and activity engagement as well as caregiver wellbeing at 4 months, yet no significant effect was found in outcomes during the 9 months follow-up period [48]. Similarly, one study reported that the REACH intervention composed of education, training and support group based on individualized assessment of caregivers' needs, had a reduced stabilization effect on the burden caused by care in the follow-up period [57]. Of all the effective interventions, only the NYUCI and the START intervention presented sustained benefits after years of follow-up due to its unique intervention elements, not found in other interventions (i.e., on-going support group participation, ad hoc counseling, plans of maintaining skills learnt) [53–56, 59, 60]. Sustained effective outcomes include fewer depressive symptoms for 3.1 years, better self-rated health for 2 years, higher levels of satisfaction with social support network in caregivers for 5 years [53–56], improved mental health and reduced anxiety and depression for 2 years [59, 60].

5. Discussion

This systematic review identified 29 studies describing 22 different types of interventions for informal caregivers of older people with early dementia. Most studies reported effective outcomes on informal caregivers, and 19 of the 22 different types of interventions comprised two or more components (i.e., education, training, support group). Only 10 different types of interventions mentioned the theoretical underpinnings. This paper represents the very first to systematically assess randomized controlled trials (RCTs) for informal caregivers of older people with early dementia.

Well-established evidence emphasized the great benefits of timely support for informal caregivers of older people with early dementia [71]. One recent systematic review also reported that informal caregivers of people with dementia felt it was the right time to receive information and support directly after or at the time of diagnosis [72].

However, 15 different types of interventions identified in our systematic review are effective for informal caregivers of older people with early and later stages of dementia [42, 44–48, 51–57, 59–61, 63–65, 67, 68, 70]. Furthermore, 3 different types of effective interventions solely focused on informal caregivers of older people with early dementia [49, 50, 62, 66]. To provide timely target support for this type of caregivers, future research should consider more clinical trials to develop and implement effective interventions for them.

Psychosocial interventions for informal caregivers need to be person-centered through structured needs assessment, as interventions for the persons with dementia [73, 74]. A needs-matched intervention for informal caregivers of people with cognitive decline should be developed further [75]. Yet our review showed that only five studies applied a structured needs assessment for informal caregivers prior to or when delivering the intervention [53–57]. Namely, only 2 different types of psychosocial interventions (i.e., NYUCI, REACH) were person-centered and tailored to informal caregivers' comprehensive needs. Moreover, just one study developed and validated a screener based on interRAI assessments to assess informal caregivers' wellbeing [76]. A validation study of a systematic assessment for informal caregivers is still lacking.

In addition, one systematic review summarizing systematic reviews of psychosocial interventions for caregivers of people with dementia showed that the most effective interventions should include both the education and therapeutic component [77]. Compared to previous systematic reviews, this systematic review firstly identified which interventions could better support informal caregivers of older people with early dementia on one hand, determining which elements are essential for this caregiver group and why on the other hand. Our systematic review revealed that intervention components, including caregiving skills training, dementia education, counseling and social support have beneficial effects on different caregiver outcomes. In addition, ongoing intervention support (e.g., ad-hoc counseling, plans of maintaining skills learnt) is of great significance for the sustainable effects of the interventions [53–56, 59, 60]. This can also be supported in another two studies identified in our review, which reported the intervention effects decreased or disappeared during the follow-up period [48, 57]. We also pointed out the theoretical underpinnings of effective interventions directly, including Progressively Lowered Stress Threshold, Competence-Environmental Press Theory, Stress process model and Schulz's stress-health process, and Adult learning theory, Stress, appraisal and coping theory, Cognitive behavior therapy. These findings could improve our understanding of the effects of interventions and facilitate future successful translation studies in this area. Furthermore, it will be possible to provide timely targeted interventions specifically for informal caregivers of people with early dementia. Beyond the implications for dementia care, the essentials of effective interventions identified in this review will inform the future development, adaptation and implementation of evidence-based interventions in similar caregiving practices (e.g., chronic diseases). Finally, future research could also consider the cost effectiveness potential in different combinations of intervention essentials, given that the dementia care is considerably expensive.

Strengths and limitations

A strength of this systematic review is the fact that we used the PEDro scale to assess the methodological quality of the studies. This rigorous scale made it possible to evaluate the studies and find which ones were more robust and met the quality criteria. A limitation is the fact that we only included peer-reviewed journal articles written in English in our systematic review. Maybe we have missed some interventions reported in 'grey literature' or written in another language than English, which might have had a significant effect on caregiver outcomes. Another limitation is that we only included RCT studies, as this was a choice we have made to make sure studies had some standardization in the measurements, as well as a control group to evaluate the effectiveness of the interventions.

6. Conclusions

Through rigorous searching and screening, we finally identified 29 RCT-studies and a total of 22 different types of interventions. The methodological quality of studies and the intervention essentials combined with corresponding effectiveness of these interventions were critically assessed. The findings of this systematic review can provide knowledge on which and why psychosocial interventions are effective for informal caregivers of older people with early dementia.

The review findings revealed that there is a paucity of effective interventions on supporting informal caregivers of older people with early dementia. Future research should consider more evaluation trials to develop and implement compact interventions for them, given that timely support for this caregiver group has considerable benefits to the health care systems. The development or adaptation of this compact interventions should consider carefully the following essentials: a validated theoretical underpinning (e.g., stress process model, health-stress theory, PLST), tailored support matched with a systematic assessment of caregiver needs, ongoing support provision (e.g., ad-hoc counseling, plans of maintaining skills learnt) and the inclusion of multi-components in an intervention (e.g., education, social support, training). Furthermore, we highlight there is a lack of systematic caregiver needs assessment prior to or when delivering an intervention and further studies needed. The findings from our systematic review could serve as a comprehensive summary of the current state of effective

psychosocial interventions for informal caregivers of older people with early dementia. This is informative for policymakers and researchers from several disciplines to further develop and implement effective interventions for caregivers in similar caregiving contexts.

7. Author contributions

Study concept and design: SW, JM, AD; Drafting of the manuscript: SW; Critical revision of the manuscript for important intellectual content: SW, JM, AD; all authors agreed with the final manuscript.

8. Ethics approval and consent to participate

Not applicable.

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11. Conflict of interest

The authors declare no conflict of interest.

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Appendix

Review question

Assessing psychosocial interventions for informal caregivers of people with early dementia: A systematic review of randomized controlled evidence.

We aim to answer the following questions:

(1) What components of psychosocial interventions are effective for informal caregivers of older people with early dementia?

(2) What theories underpin these interventions?

(3) What caregivers' needs are assessed in these interventions?

Searches

PubMed, CINAHL, Embase, Cochrane and Web of Science.

Types of study design to be included

Randomized controlled trials (RCTs).

Condition or domain studies to be included

Early dementia or early cognitive decline or memory loss.

Participants

Informal caregivers of older people with early dementia.

Interventions

Psychosocial interventions, including counselling, education, training, support, problem solving, coping strategy, cognitive behavior therapy, art, music, singing and museums.

Context

Home setting.

Outcomes

All outcomes related to health and life quality in informal caregivers (and care recipients).

Study selection

Two reviewers will select studies for inclusion and exclusion against the criteria through screening the titles and abstracts. Uncertainties will be resolved through discussion with a third reviewer.

Study quality assessment

Two reviewers will assess the quality of each study using a modified 11-item version of the PEDro scale. Differences in scoring will be discussed and resolved collaboratively with a third reviewer.

Data extraction

Two reviewers will read the full text of each study included in the review and extract key content of the studies. According to our research aim and questions, the following characteristics will be extracted with a standardized electronic form: (1) author, year and country, (2) theoretical underpinning, (3) caregiver needs assessment, (4) sample, (5) people delivering the intervention, (6) intervention duration, (7) intervention elements, (8) main outcomes of care recipients, (9) main outcomes of caregivers, (10) main findings, (11) study limitations.

Keywords: Review; Informal caregivers; Aged; Psychosocial interventions; Early dementia; Cognitive decline

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Chapter 4

Factors associated with informal caregiver's ability to continue care: a subgroup analysis

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RESEARCH PAPER

Factors associated with informal caregiver's ability to continue care: a subgroup analysis

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Abstract

Background/objective: maintaining informal caregiver's ability to continue care can prevent early institutionalisation and decrease health care costs, contributing to sustainable health care. This study aims to identify factors associated with informal caregiver's ability to continue care across several degrees of cognitive decline and risk of burden.
Methods: this is a cross-sectional study that collected nationwide data on frail older people and their informal caregivers living in the community. Instruments used were InterRAI Home Care, Zarit Burden Interview and questionnaire for the informal caregiver. Multivariate logistic regression analyses and a stratification of the population were performed.
Results: a total of 8,309 people had at least one primary caregiver, and a majority of them were able to continue care (68.2%). Cognitive impairment was a risk factor for being able to continue care, even the borderline (odds ratios (ORs): 0.72; 95% CI: 0.61–0.85) or mild condition (OR: 0.52; 95% CI: 0.43–0.61). Protective factors like social participation of older people, strong family support and availability of a secondary caregiver showed the highest association in subgroups with mild cognitive impairment (ORs: 2.20, 2.08, 1.64) and in subgroups at low risk of burden (ORs: 1.91, 2.77, 1.64).
Conclusion: factors associated with informal caregiver's ability to continue care vary across several degrees of cognitive decline and risk of burden. Interventions related to family and social support resources are recommended, and informal caregivers at a lower level of risk may benefit most. Supportive counselling should be proactively provided to informal caregivers, considering the changes of associated factors with the ongoing caregiving situation.

Keywords: determinants, family support, continuity of informal care, risk of burden, mild cognitive problems, older people

Key Points

- Primary informal caregivers of people with borderline or mild cognitive impairment also perceived burden and were at risk of not being able to continue care.
- Behavioural problems and provision of activities of daily living help were risk factors associated with informal caregiver's ability to continue care in subgroup at low risk of caregiver's burden (CaRE).
- The CaRE algorithm was applied to stratify the study population across the risk of burden and can be considered as an innovative tool to quickly assess informal caregivers' risk of burden.
- Protective factors related to family and social support resources make a greater contribution to informal caregiver's ability to continue care in subgroups at a lower level of risk.
- The development of timely interventions for maintaining informal caregiver's ability to continue care is needed and should consider the identified protective and risk factors.

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Introduction

Given the projected trends in population ageing, the number of people with dementia will increase to 152.8 million cases in 2050 [1]. This will cause an increasing demand for health care resources and a threat to sustainable health care [2]. Informal caregivers can bring a valuable contribution to sustainable health care by providing care at home longer, considerably relieving burden on formal care and reducing public care expenditure [3–7]. Nevertheless, such contribution may be affected by informal caregivers' premature discontinuation of care, especially when caring for people with cognitive problems. Multiple demands and cumulative burden borne by an essential caregiver may cause a gradual decrease in care activities, eventually leading to institutional placement of care recipients [8–12]. Furthermore, some informal caregivers may abruptly decrease their caring activities due to lack of experience and support in caregiving, while they start as being a caregiver and perceive relatively lower burden than other caregivers [13, 14].

Timely supporting informal caregivers may contribute to maintaining their ability to continue in caring activities, reducing the probability of institutional placement [15, 16]. Timely interventions focusing on informal caregivers at risk of adverse outcomes could enhance caregiver's resilience to stress and increase their capacity to provide care [17–20]. Such interventions should therefore be developed, evaluated and implemented in scale [21]. A recent systematic review found that early interventions can improve caregiver's well-being and ability to care for people with mild cognitive impairment or early dementia [22]. These early interventions, however, are scarce. Further research on the development and evaluation of interventions for informal caregivers of mild cognitive impairment or early dementia is needed [23, 24].

The stress process theory [8] shows how a mix of context (e.g. characteristics, family network), stressors (e.g. cognitive status, role strains) and resources (e.g. coping, social support) can variably impact caregiver's outcomes (e.g. depression, physical health) over the caregiving process. Pearlin *et al.* also proposed that this mix of context, stressors, resources and outcomes is dynamic with the ongoing caregiving situation. Emotional health problems (e.g. depression) are likely to surface first, then physical health deterioration. They also assumed that a reduction or yielding of caregiving is more likely to occur when caregivers experience both mental and physical health problems [8]. Bastawrous discussed the caregiver burden in the context of role theory, facilitating a deeper understanding of role strains. Informal caregiver's social role, especially female or adult child, will particularly impact caregiver burden due to the occurrence of role overload and role conflict. The author recommended a combination of role theory and stress process theory to understand the process of burden thoroughly [25].

Based on the combination of the stress process theory and role theory, we aim to investigate multiple factors associated informal caregiver's ability to continue to care for frail older people at home, considering the different levels of risk of caregiver's burden and levels of care recipient's cognitive impairment. Literature shows that compared to other caregivers, those who care for people with cognitive problems are more likely to move care recipients into nursing homes due to dementia-related behaviours, the need for more assistance and skilled care, greater emotional stress and lack of timely support [9–11]. Focusing on subgroups stratified by levels of cognitive impairment and levels of risk of burden, we can identify most relevant factors associated with informal caregiver's ability to continue care depending on the level of risk, provide timely intervention and monitor as well as prevent some risk factors as the disease or caregiving situation is going worse.

Methods

This is a cross-sectional study nested in a larger nationwide project called Protocol 3 [26]. Trained professional caregivers filled out the interRAI Home Care (HC) for eligible frail older people. Identified informal caregivers filled out the Zarit Burden Interview (ZBI-12) and informal caregiver questionnaire. The population was stratified by the degree of cognitive decline (CPS) [27] and risk of burden (CaRE algorithm) [28]. All statistical analyses were conducted using SAS 9.4 software.

Details of methods, including study context, participants, measures, data collection and statistical analysis, are explained in the appendix (References [27–37, 39–44] were mentioned in this appendix).

Results

Profile of the population

As shown in Table 1, from a total of 8,309 people who had at least one primary caregiver, about half of them had a secondary caregiver as well (n = 4,198, 50.5%). The mean age of primary caregiver was 61 years (SD = 13.2), and the mean age of frail older people was 80 years (SD = 8.8). Almost two thirds (67.5%) of frail older people were female. Adult children made up 55.5% of the sample, spouses, other relatives and others made up 30.6%, 6.6% and 7.3%, respectively. Approximately half of primary caregivers were retired (45.5%), and the proportion of employed caregivers decreased with the level of risk of burden (from low to moderate, high, very high risk: 34.6%, 22.3%, 18.9%, 10.2%). A majority of primary caregivers (n = 5,636, 68.2%) were able to continue care, and this percentage decreased with the level of risk of burden, respectively from low to moderate, high, very high risk: 75.5%, 69.7%, 60.4%, 50.1%. Strong family support for primary caregivers followed the same pattern, namely from low to moderate, high, very high risk: 83.0%, 79.1%, 71.2%, 62.1%. The mean ZBI-12 score was 12.2 (SD = 8.4), which means that the average score represents burden in the population, as the cut off of the Zarit-12 is

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Table 1. Profile of the whole population and subgroups stratified by level of risk of burden (CaRE)

Primary caregiver	Total, n = 8,309	Low (CaRE = 1), n = 3,721	Moderate (CaRE = 2), n = 1,421	High (CaRE = 3), n = 2,438	Very high (CaRE = 4), n = 729
Mean age (SD)	61 (13.2)	56 (9.8)	66 (14.3)	64 (13.8)	68 (12.7)
Co-residence	3,314 (39.9)	0	1,118 (78.7)	1,467 (60.2)	729 (100.0)
Mean ZBI score(SD)	12.2 (8.4)	9.6 (7.2)	10.6 (7.3)	14.8 (8.6)	19.2 (9.2)
Able to continue care	5,636 (68.2)	2,809 (75.5)	990 (69.7)	1,472 (60.4)	365 (50.1)
Provision of ADL help	4,002 (48.4)	883 (23.7)	903 (63.5)	1,631 (66.9)	585 (80.2)
Provision of IADL help	7,189 (86.8)	3,054 (82.1)	1,279 (90.0)	2,175 (87.6)	681 (93.4)
Mean hours spent in last 3 days (SD)	13.3 (20.3)	2.9 (3.8)	20.5 (23.0)	20.0 (23.2)	29.4 (27.0)
Strong family support	6,400 (85.1)	3,088 (83.0)	1,124 (79.1)	1735 (71.2)	453 (62.1)
Relationship to older people					
Spouse	2,542 (30.6)	59 (1.6)	817 (57.5)	1,102 (45.2)	564 (77.4)
Adult child	4,609 (55.5)	2,803 (75.3)	532 (37.4)	1,132 (46.4)	142 (19.5)
Other relative	549 (6.6)	445 (12.0)	28 (2.0)	67 (2.7)	9 (1.2)
Others	609 (7.3)	414 (11.1)	44 (3.1)	137 (5.6)	14 (1.9)
Secondary caregiver available	4,198 (50.5)	2040 (54.8)	702 (49.4)	1,134 (46.5)	322 (44.2)
Job status					
Retired	3,613 (45.5)	1,045 (28.1)	840 (59.1)	1,258 (51.6)	470 (64.5)
Employed	2039 (25.7)	1,286 (34.6)	317 (22.3)	462 (18.9)	74 (10.2)
Unemployed	302 (3.8)	93 (2.5)	57 (4.1)	116 (4.8)	36 (4.9)
Others (e.g. housewife)	1984 (25.0)	1,124 (30.2)	253 (17.8)	486 (19.9)	121 (16.6)
Frail older people	**Total, n = 8,311**	**Low (CaRE = 1), n = 3,723**	**Moderate (CaRE = 2), n = 1,421**	**High (CaRE = 3), n = 2,438**	**Very high (CaRE = 4), n = 729**
Mean age (SD)	80 (8.8)	82 (7.7)	80 (9.3)	80 (9.3)	77 (9.4)
Gender (female)	5,583 (67.5)	2,833 (76.1)	842 (59.3)	1,574 (64.6)	334 (45.8)
ADL dependence	6,002 (73.3)	2,491 (66.9)	1,137 (80.0)	1815 (74.4)	559 (76.7)
IADL dependence	6,955 (94.2)	3,129 (84.0)	1,207 (84.9)	2004 (82.2)	615 (84.4)
Behavioural problems	1,093 (13.3)	230 (6.2)	91 (6.4)	481 (19.7)	291 (39.9)
Communication problems	2,878 (34.7)	767 (20.6)	472 (33.2)	1,059 (43.4)	580 (79.6)
Daily pain	1847 (26.1)	932 (25.0)	231 (16.3)	554 (22.7)	130 (17.8)
Risk of falls	2,898 (37.0)	1,424 (38.2)	446 (31.4)	782 (32.1)	246 (33.7)
Social participation	4,860 (58.7)	2,390 (64.2)	848 (59.7)	1,294 (53.1)	328 (45.0)
Visit by family or friends	7,930 (95.8)	3,605 (96.8)	1,356 (95.4)	2,313 (94.9)	656 (90.0)
Cognitive impairment					
Mild (CPS = 1–2)	2,448 (46.8)	1,146 (30.8)	382 (26.9)	803 (32.9)	117 (16.0)
Moderate (CPS = 3–4)	1882 (36.0)	590 (15.8)	297 (20.9)	650 (26.7)	345 (47.3)
Severe (CPS = 5–6)	903 (17.3)	94 (2.5)	164 (11.5)	378 (15.5)	267 (36.6)

Notes: Primary caregiver (n = 8,309) < frail older people (n = 8,311) due to two missing data.

a score of 10. The Zarit-12 score increased with the level of risk of burden (from low to moderate, high, very high risk: 9.6, 10.6, 14.8, 19.2). Regarding activities of daily living (ADL) and instrumental ADL (IADL) dependence, present in 73.3% and 94.2% of the study population, the proportion of primary caregivers providing ADL help and IADL help were 48.4% and 86.8%. Compared to subgroup with low risk of burden, the mean hours spent in care in the last 3 days of the subgroup with moderate risk of burden was about seven times higher (20.5 versus 2.9).

As shown in Table 2, out of a total 8,309 primary caregivers, 5,232 cared for frail older people who had cognitive problems (CPS = 1–6). Out of these 5,232 primary caregivers, a large proportion were able to continue care (62.6%). This proportion decreased with the level of cognitive impairment of the person they were caring for (from mild to moderate, severe: 63.5%, 62.3%, 58.5%). Almost one out of four (24.9%) primary caregivers experienced feelings of distress, anger or depression, and this percentage increased with the level of cognitive impairment (from mild to moderate, severe: 18.1%, 28.3%, 36.1%). The provision of ADL help increased with the level of cognitive impairment (from mild to moderate, severe: 47.6%, 60.3%, 80.8%), as well as the average hours spent in care in the last 3 days by the primary caregiver (10.7, 18.0, 31.6). Additionally, primary caregivers who cared for people with borderline or mild cognitive impairment also perceived burden (ZBI = 12.1, SD = 8.2). Out of 8,311 frail older people, 5,233 had cognitive impairment (CPS = 1–6). Frail older people who had borderline to mild cognitive impairment (n = 2,448) also presented high percentages of risk of falls, depression, daily pain and reduced social interactions (35.8%, 32.4%, 21.4%, 40.1%).

Multivariate logistic regression analysis

Tables 3 and 4 show the odds ratios (ORs) of significant factors associated with primary caregiver's ability to

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Table 2. Profile of the whole population and subgroups stratified by care recipient's level of cognitive impairment (Intact cognition CPS = 0 excluded, i.e. total 5,232 primary caregivers)

Primary caregiver	Total, n = 5,232	Borderline to mild (CPS = 1–2), n = 2,447	Moderate (CPS = 3–4), n = 1,882	Severe (CPS = 5–6), n = 903
Mean age (SD)	62.3 (13.5)	60.5 (13.2)	63.0 (13.6)	65.7 (13.0)
Co-residence	2,474 (47.3)	863 (35.3)	931 (49.5)	680 (75.3)
Mean ZBI score (SD)	13.7 (8.6)	12.1 (8.2)	15.2 (8.6)	15.2 (9.1)
Able to continue care	3,253 (62.6)	1,553 (63.5)	1,172 (62.3)	528 (58.5)
Provision of ADL help	3,029 (59.1)	1,164 (47.6)	1,135 (60.3)	730 (80.8)
Provision of IADL help	4,565 (87.6)	2078 (84.9)	1,649 (87.6)	838 (92.8)
Mean hours spent giving care in the last 3 days (SD)	16.2 (22.1)	10.7 (17.1)	18.0 (22.6)	31.6 (27.6)
Feelings of distress, anger, depression	1,302 (24.9)	443 (18.1)	533 (28.3)	326 (36.1)
Strong family support	3,757 (81.2)	1784 (72.9)	1,335 (70.9)	638 (70.7)
Frail older people	**Total, n = 5,233**	**Borderline to mild, n = 2,448**	**Moderate, n = 1,882**	**Severe, n = 903**
Mean age (SD)	80.5 (8.9)	81.0 (8.3)	80.0 (9.4)	80.3 (9.8)
Gender (female)	3,328 (64.0)	1,645 (67.2)	1,166 (62.0)	517 (57.3)
ADL dependence	3,879 (75.4)	1,684 (68.8)	1,386 (73.6)	809 (89.6)
IADL dependence	4,405 (96.5)	2048 (83.7)	1,580 (84.0)	777 (86.0)
Impaired decision-making	4,492 (85.8)	1820 (74.3)	1769 (94.0)	903 (100.0)
Risk of falls	1799 (37.0)	877 (35.8)	653 (34.7)	269 (29.8)
Depression	1886 (37.0)	792 (32.4)	710 (37.7)	384 (42.5)
Daily pain	943 (18.0)	523 (21.4)	289 (15.4)	131 (14.5)
Behavioural problems	392 (7.5)	95 (3.9)	185 (9.8)	112 (12.4)
Reduced social interactions	2,388 (46.1)	981 (40.1)	930 (49.4)	477 (52.8)

Notes: Primary caregiver caring for frail older people with cognitive problems (n = 5,232) < frail older people with cognitive problems (CPS = 1–6, n = 5,233) due to one missing data.

continue care among the whole population and across different subgroups.

As shown in Table 3, primary caregivers with strong family support were most likely (OR: 1.80; 95% CI: 1.55–2.09) to be able to continue care at home, compared to caregivers without strong family support. Another protective factor was the availability of a secondary caregiver (OR: 1.54; 95% CI: 1.38–1.72), whose ORs decreased with the level of risk of burden (from low to moderate, high: 1.64, 1.50, 1.47). The ORs of social participation of frail older people followed the same pattern (from low to moderate, high: 1.91, 1.75, 1.69). In contrast, the ORs of visit by family or friends (OR: 1.55; 95% CI: 1.18–2.05) had an opposite pattern (from low to moderate, very high: 1.84, 2.06, 2.50), showing that visits by family or friends had the highest impact when people were in the subgroup at very high risk of burden.

Furthermore, risk factors (OR < 1) associated with caregiver's ability to continue care were: frail older people with cognitive impairment, daily pain, depression; provision of ADL help by primary caregiver, feelings of distress, anger or depression. Among the six levels of cognitive impairment (CPS = 1–6), even primary caregivers who cared for frail older people with borderline (CPS = 1, OR: 0.72; 95% CI: 0.61–0.85) and mild (CPS = 2, OR: 0.52; 95% CI: 0.43–0.61) cognitive impairment were significantly at risk of not being able to continue care, compared to caregivers of frail older people with intact cognition (CPS = 0).

In caregiver subgroup at low risk of burden (CaRE = 1), protective factors were visits by family and friends (OR: 1.84; 95% CI: 1.13–3.01), social participation of frail older people (OR: 1.91; 95% CI: 1.60–2.28), strong family support (OR: 2.77; 95% CI: 2.19–3.51) and a secondary caregiver available (OR: 1.64; 95% CI: 1.38–1.96). Risk factors for being able to continue care were when care recipients presented behavioural problems (OR: 0.69; 95% CI: 0.49–0.97) or age > =65 (OR: 0.55; 95% CI: 0.33–0.92) or needed ADL help (OR: 0.43; 95% CI: 0.35–0.52).

As shown in Table 4, protective factors (OR > 1) included visits by family or friends, social participation of frail older people, strong family support and a secondary caregiver available. Risk factors (OR < 1) included frail older people with daily pain, behavioural problems, at risk of burden and provision of ADL help. Moreover, the ORs of risk of burden decreased with the level of CaRE (from moderate to high, very high: 0.76, 0.59, 0.47), indicating that primary caregivers at very high risk of burden (CaRE = 4) had the greatest likelihood (OR = 0.47) of not being able to continue care at home compared to caregivers at low risk of burden (CaRE = 1).

Across the subgroups with mild, moderate and severe cognitive impairment, the ORs of social participation of frail older people (OR: 2.20; 95% CI: 1.80–2.67), strong family support (OR: 2.08; 95% CI: 1.61–2.69) and secondary caregiver available (OR: 1.64; 95% CI: 1.34–2.00) were

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Table 3. Logistic regressions for factors associated with primary caregiver's ability to continue care among the whole population and across subgroups stratified by level of risk of burden (CaRE)

	Whole population (n = 6,788)	Low CaRE = 1 (n = 3,259)	Moderate CaRE = 2 (n = 1,152)	High CaRE = 3 (n = 1923)	Very high CaRE = 4 (n = 544)
Frail older people					
Cognitive impairment					
CPS = 1 (Ref = 0)	0.72 [0.61, 0.85]				
CPS = 2 (Ref = 0)	0.000***				
CPS = 3 (Ref = 0)	0.52 [0.43, 0.61]				
CPS = 4 (Ref = 0)	0.000***				
CPS = 5 (Ref = 0)	0.68 [0.57, 0.81]				
CPS = 6 (Ref = 0)	0.000***				
	0.67 [0.53, 0.84]				
	0.000***				
	0.81 [0.65, 1.02]				
	0.069				
	0.58 [0.38, 0.88]				
	0.011*				
Age ≥ 65	_	0.55 [0.33, 0.92]	_	_	_
		0.023*			
Behavioural problems	*0.86 [0.72, 1.03]*	0.69 [0.49, 0.97]	_	*0.82 [0.65, 1.04]*	*0.79 [0.56, 1.12]*
	0.091	0.031*		*0.099*	*0.182*
Daily pain	0.86 [0.76, 0.98]	_	_	*0.85 [0.69, 1.04]*	0.56 [0.37, 0.85]
	0.022*			*0.115*	0.006**
Depression	0.82 [0.73, 0.93]				
	0.002**				
Visit by family or friends	1.55 [1.18, 2.05]	1.84 [1.13, 3.01]	2.06 [1.01, 4.21]	_	2.50 [1.26, 4.96]
	0.002**	0.014*	0.047*		0.009**
Social participation	1.71 [1.52, 1.91]	1.91 [1.60, 2.28]	1.75 [1.34, 2.28]	1.69 [1.40, 2.04]	_
	0.000***	0.000***	0.000***	0.000***	
Primary informal caregiver					
Age ≥ 65	_	_	_	*0.86 [0.71, 1.04]*	*0.73 [0.51, 1.03]*
				0.117	*0.073*
Provision of ADL help	0.68 [0.60, 0.76]	0.43 [0.35, 0.52]	0.73 [0.55, 0.95]	_	_
	0.000***	0.000***	0.021*		
Strong family support	1.80 [1.55, 2.09]	2.77 [2.19, 3.51]	*1.36 [0.87, 2.10]*	1.61 [1.27, 2.04]	*1.35 [0.91, 1.99]*
	0.000***	0.000***	*0.176*	0.000***	*0.138*
Secondary caregiver available	1.54 [1.38, 1.72]	1.64 [1.38, 1.96]	1.50 [1.15, 1.96]	1.47 [1.21, 1.78]	_
	0.000***	0.000***	0.003**	0.000***	
Feelings of distress, anger, depression	0.55 [0.48, 0.63]				
	0.000***				

Notes: Significance: $^{***}P < 0.001$, $^{**}P < 0.01$, $^{*}P < 0.05$. Out of a total of 8,309 caregivers (The number was 8,309 due to CPS = 0–6 included, and reference was CPS = 0), data of 6,788 could be included in the logistic regression due to at least one necessary item missing. 'Blank' in the table represents the collinearity among CaRE and the scales of depression and cognition and the item 'feelings of distress, anger or depression'. A 'short line' in the table represents no significance. Numbers in italic font style also represent no significance, but were kept here due to the stopping criterion used in the backward logistic regression analysis.

the highest, and feelings of distress, anger and depression (OR: 0.54; 95% CI: 0.42–0.70) were the lowest in subgroup with mild cognitive impairment. This indicates that these protective factors and this risk factor had the greatest impact on the subgroup with mild condition. In subgroup with mild cognitive impairment (n = 2,118), primary caregivers who provided ADL help (OR: 0.65; 95% CI: 0.53–0.80) were also significantly at risk of not being able to continue care compared to caregivers who did not.

Discussion

This study explored factors associated with informal caregiver's ability to continue care at home among the whole population, and across several degrees of cognitive decline (CPS) and risk of caregiver's burden (CaRE). To our knowledge, this is the first study to use the CaRE algorithm and CPS to stratify a population from a nationwide study.

Most studies have focused on the negative effects that caregiving has on informal caregivers, particularly burden associated with caregiving. These prior studies indicated that daily pain [29], depression [30,31] and behavioural problems [32–35] in care recipients, caregiver's distress [36] and depression [37,38], as well as being the sole caregiver [38] explained higher burden, with high resilience and social support identified as protective factors [39–42]. Regarding the evidence of factors associated with informal caregiver's ability to continue care, a few studies reported the following factors: mental impairment of care recipients, resilience, physical and mental health of caregivers, caregiving-related expenses, use of respite services and family support [43–48].

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Table 4. Logistic regressions for factors associated with primary caregiver's ability to continue care among the whole population and subgroups stratified by level of frail older people's cognitive impairment (CPS)

	Whole population (n = 6,878)	Intact CPS = 0 (n = 2,710)	Mild CPS = 1–2 (n = 1955)	Moderate CPS = 3–4 (n = 1,442)	Severe CPS = 5–6 (n = 681)
Frail older people					
Daily pain	0.87 [0.77, 0.99] 0.030*	_	*0.82 [0.66, 1.03] 0.089*	_	*0.74 [0.50, 1.10] 0.141*
Depression	_	0.65 [0.50, 0.84] 0.000***	_	*0.80 [0.64, 1.01] 0.057*	_
Behavioural problems	0.77 [0.66, 0.91] 0.002**	0.38 [0.20, 0.72] 0.003**	_	_	_
Visit by family or friends	1.58 [1.21, 2.07] 0.000***	2.40 [1.39, 4.13] 0.002**	*1.52 [0.91, 2.54] 0.107*	_	*1.81 [0.93, 3.54] 0.080*
Social participation	1.74 [1.55, 1.94] 0.000***	1.59 [1.30, 1.96] 0.000***	2.20 [1.80, 2.67] 0.000***	1.54 [1.24, 1.92] 0.000***	*1.39 [1.00, 1.93] 0.052*
Primary informal caregiver					
Age ≥ 65	*0.89 [0.79, 1.01] 0.075*	*1.17 [0.94, 1.46] 0.173*	*0.84 [0.67, 1.05] 0.126*	_	_
Risk of burden					
CaRE = 2 (Ref = 1)	0.76 [0.64, 0.90]				
CaRE = 3 (Ref = 1)	0.001**				
CaRE = 4 (Ref = 1)	0.59 [0.51, 0.68] 0.000***				
	0.47 [0.38, 0.59] 0.000***				
Provision of ADL help	0.72 [0.64, 0.81] 0.000***	0.51 [0.41, 0.63] 0.000***	0.65 [0.53, 0.80] 0.000***	_	_
Strong family support	1.93 [1.67, 2.24] 0.000***	1.71 [1.28, 2.28] 0.000***	2.08 [1.61, 2.69] 0.000***	1.62 [1.22, 2.15] 0.000***	*1.43 [0.94, 2.18] 0.099*
Secondary caregiver available	1.53 [1.37, 1.70] 0.000***	1.60 [1.31, 1.95] 0.000***	1.64 [1.34, 2.00] 0.000***	1.43 [1.15, 1.79] 0.002**	_
Feelings of distress, anger, depression	_	0.38 [0.28, 0.52] 0.000***	0.54 [0.42, 0.70] 0.000***	0.57 [0.45, 0.73] 0.000***	0.69 [0.50, 0.96] 0.029*

Note: Significance: *** $P < 0.001$, ** $P < 0.01$, * $P < 0.05$. 'Blank' in the table represents the collinearity among CaRE and the scales of depression and cognition and the item 'feelings of distress, anger or depression'. A 'short line' in the table represents no significance. Numbers in italic font style also represent no significance, but were kept here due to the stopping criterion used in these backward logistic regression analyses.

Further, caregivers' resilience was associated with their emotional (e.g. anxiety, depression) and physical status, appraisal and coping, and personality features [49], family resources and social support [50,51].

The current study identified multiple protective and risk factors among the whole population through adjusted logistic regression models. The results were consistent with what was previously found, but they were further refined across different subgroups. Aged 65+ years and behavioural problems of frail older people were significant determinants for subgroups at low risk of burden. Daily pain of frail older people was significant for subgroups at very high risk of burden. Provision of activities of daily living (ADL) by caregivers was significant for subgroups at low or moderate risk of burden, and for subgroups with intact cognition or mild cognitive impairment. No trends were found for behavioural problems of frail older people and provision of ADL by caregivers. These were significant for subgroups with lower levels of risk, which might be linked to a greater acceptance and more competence of caregivers towards the caregiving process [51]. Depression, behavioural problems, visits by family members and friends of frail older people were significant for subgroups with intact cognition. The only common determinant for all cognitive impairment subgroups was the feelings of distress, anger and depression of caregivers. Factors associated with informal caregiver's ability to continue care varied depending on the level of risk of burden and level of cognitive impairment. The caregiver's social role (i.e. spouse or adult child), as shown in the role theory, is included in the algorithm of CaRE, as an associated factor with the risk of burden. The factors included in the CaRE algorithm are aligned with the combination of the role theory and stress process theory, as it is recommended in literature [25]. The combination of both theories increases conceptual clarity of burden, and they were both considered in the construction of the CaRE algorithm to identify caregivers with a risk of burden in a thorough way [28].

Looking at the trends showed in some factors across subgroups at different levels of risk, social participation of frail older people, strong family support for primary caregivers and availability of a secondary caregiver played a greater role in subgroups with a lower risk of burden and a lower level of cognitive impairment. Moreover, feelings of distress, anger and depression in caregivers had the greatest impact on the subgroup with mild cognitive impairment. These findings confirm the benefits and needs of timely support

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for early primary caregivers to maintain their well-being and continue in caring activities [17–21]. Pearlin's stress process theory also indicates that timely social support, such as expressive support (e.g. perceived availability of a second caregiver), prevents or inhibits development of secondary stressors, helping caregivers earlier find inner growth (e.g. self-competence) as they face bigger challenges of caregiving. Support for early caregivers can enhance caregiver resilience, such as coping and appraisal [8]. Moreover, previous studies found that timely interventions, including such components as counselling, education, family support group and social support resources available for early primary caregivers, also showed beneficial effects in caregivers' outcomes [22,52–54].

Strengths and limitations

One strength of this study is the large sample size, which makes it possible to stratify the whole population by level of risk of burden (CaRE) and by level of care recipient's cognitive impairment (CPS). This allowed us to identify factors that should play a role in timely supporting informal caregivers at different levels of risk (e.g. subgroup with CaRE = 1, CPS = 1–2). Another strength is the fact that, by using such a comprehensive geriatric assessment as the interRAI HC, multiple factors can be considered, such as context, social, physical and psychological factors.

A limitation of the study is that the data were cross-sectional. Longitudinal data would allow us to explore factors associated with the changes among caregivers from being able to continue care to long-term care admission. Another limitation is that the number of variables related to the primary caregiver was limited, so we could not fully delve into all factors associated with informal caregiver's ability to continue care.

Recommendations for clinical practice

Given the clinical relevance of support for early informal caregivers along the caregiving process, the findings discussed can provide insights for professional caregivers from various disciplines (e.g. nurses, social workers, occupational therapists, etc.) regarding both assessment and interventions.

By using the CaRE algorithm and the CPS, informal caregivers can be stratified by levels of risk of burden and by levels of care recipient's cognitive impairment. The validated CaRE algorithm and the CPS are automatically calculated after completion of an interRAI HC assessment, which is currently used internationally and being mandatorily implemented in Belgium for long-term care. The assessment is filled out by professional caregivers, such as physicians, nurses, occupational therapists, etc. Professional caregivers can utilise the information gained via CaRE and CPS to assess the informal caregiver's level of risk of burden (e.g. low, high risk, etc.) and stages of caring for people with cognitive decline (e.g. early, advanced stages, etc.).

Regarding interventions, professionals can proactively address the most relevant factors associated informal caregiver's ability to continue care depending on the level of risk assessed via CaRE and CPS. We recommend interventions that educate primary caregivers on the importance of family and friends' support that make referrals to available resources (e.g. counselling, psychotherapy, information meetings, social activities for care recipients). It is also recommended to pay more attention to informal caregivers at a lower level of risk who may benefit most from early interventions. Moreover, individualised counselling on request should be provided to informal caregivers as professional caregivers can track these associated factors, foresee and prevent further problems with the ongoing caregiving situation.

Conclusion

Factors associated with informal caregiver's ability to continue care vary across several degrees of cognitive decline and risk of burden. Interventions related to family and social support resources are recommended, and informal caregivers at a lower level of risk may benefit most. Supportive counselling should be proactively provided to informal caregivers, considering the changes of associated factors with the ongoing caregiving situation.

Supplementary Data: Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

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Details of methods

Study context

This is a cross-sectional study nested in a larger nationwide research project called Protocol 3, which aimed at evaluating the effectiveness of innovative community care interventions for frail older people living at home. The study was approved by the Belgian Privacy Commission, as well as the Ethics Committees of the Université Catholique de Louvain and KU Leuven with reference number B40320108337 [26].

Participants

The eligibility criteria for frail older people for the study were: 1) age 65+, 2) being frail, measured by a score of 6+ in the Edmonton Frail Scale [27] or a minimum level of A, B or C on the Belgium version of the Katz Scale [28], or a diagnosis of dementia stated by a geriatrician, neurologist or neuro-psychiatrist.

The primary informal caregiver was defined as the person who was most involved in caring activities, such as Activities of daily living (ADL) tasks, supervision and emotional support. The primary caregiver could be a spouse, adult child or other relative, friend or neighbor, but not a paid care provider or volunteer.

Measures

The following instruments were used: the interRAI Home Care (HC) instrument, the Zarit Burden Interview (ZBI-12), and a questionnaire for the informal caregiver developed specifically for the study.

The interRAI HC instrument is an internationally validated, comprehensive assessment that can map the care context and needs of the care recipients [29-30]. This assessment has been used in many countries [31-34] and a 7-year evaluation project in the Belgian home care setting showed evidence that the interRAI HC is a valid instrument to be used in the community setting. Currently, this assessment is being mandated for Belgium routine care in nursing homes and in community long term care [35-36]. From this instrument, the following items were included in the analysis: the ability to continue care (yes/no), which is the main outcome in this study; characteristics of frail older people and their caregivers, hours spent in care in the last 3 days, strong family support (yes/no), co-residence (yes/no), secondary caregiver available (yes/no), visit by family or friends and social participation of frail older people (0=Never; 1=More than 30 days ago; 2=8 to 30 days ago; 3=4 to 7 days ago; 4=In the last 3 days; 8=Unable to determine).

Additionally, the following scales and Client Assessment Protocols (CAPs) from the interRAI HC were included: ADL Hierarchy scale (ADL-H), IADL Performance scale (IADL-P), Cognitive Performance scale (CPS), Pain scale, Depression Rating scale (DRS), Communication scale, Behavioural problems CAP and Falls CAP. The interRAI scales are internationally validated and are automatically generated when the interRAI HC instrument is completed [37-42]. The CAPs

are algorithms that are also generated from the interRAI instruments and are tools for care decision support. The scales and CAPs were dichotomized for use in the multivariate logistic regression analysis, using validated cut-off values.

The Activities of daily living hierarchy scale (ADL-H, range 0-6) measures physical functioning. A cut-off point of two or higher indicates at least mild functional impairment [37].

The Instrumental activities of daily living (IADL) performance scale assesses items such as independence in housework, managing finance and medication. A cut-off point of 14 or higher indicates at least moderate impairment in performing those tasks (range from 0 to 48) [37].

The Cognitive performance scale (CPS, range 0-6) measures a person's cognitive status. The CPS takes account of the following items: short-term memory, cognitive skills for daily decision making, comatose, being understood by others, and activities of daily living (ADL) self-performance in eating. A cut-off point of two or higher indicates at least mild impairment [38].

The Pain scale (range 0-4) measures the frequency and intensity of pain. A cut point of two or more indicates daily pain [39].

The Depression rating scale (DRS, range 0-14) can accurately predict a clinical diagnosis of depression with a cut-off point of 3, indicating depressive symptoms if the score is 3 or higher [40].

The Communication scale (range 0-8) measures a person's communication abilities. Higher score indicates less functional ability to communicate [41].

The Behavioural problems CAP has three scores: 0, 1 or 2. A score of one or more indicates the presence of behavioural problems [42].

The Falls CAP has three scores: 0, 1 or 2. A score of one or more indicates that the person is at risk for falls [42].

The ZBI-12 consists of 12 questions in the style of a Likert scale and each question is scored from zero to four. The scale ranges from 0 to 48 and a score of 10 or above indicates that the informal caregiver perceives burden [43].

The informal caregiver's questionnaire includes socio-economic questions about the informal caregiver, such as demographical and work-related questions (i.e. job status and left job to give care), total hours spent on care during one week, use of formal care and services [44]. This questionnaire is filled out by the informal caregiver.

The Caregiver Risk Evaluation (CaRE) algorithm is a recently developed screening tool to assess the level of risk of burden in the homecare context. This tool has been validated using a Canada sample study, in which higher CaRE scores had a great association with long-term care admission. The CaRE algorithm has a range from 0 to 4 indicating low, moderate, high, and very high level of risk of burden in the informal caregiver. The screening tool is calculated using the following items and scales from the interRAI HC instrument: primary caregiver expresses feelings of distress; primary caregiver expresses anger or depression; primary caregiver lives with the client; primary caregiver's relationship with the client; hours of

informal care in the last 3 days; cognitive performance scale (CPS); depression rating scale (DRS) [45].

Data collection

The interRAI HC instrument was filled out by trained professional caregivers (e.g., nurses, social workers, occupational therapists, etc.). They could also consult other healthcare professionals involved in the care or consult other family members, if needed. Informal caregivers filled out the ZBI-12 scale and the informal caregiver questionnaire.

Statistical analysis

All statistical analyses were conducted using SAS 9.4 software. Descriptive analyses were performed to demonstrate the characteristics of frail older people and their informal caregivers. Multivariate logistic regression models were built to explore the factors associated with informal caregiver's ability to continue care. The population was stratified by the level of risk of caregiver burden (CaRE algorithm) [45], and by the level of care recipient's cognitive impairment (CPS) [38]. The CaRE algorithm and the CPS were automatically calculated from the data collected with the interRAI HC. The reason why we focused on cognitive impairment measured by the CPS is the fact that other functional impairments are usually linked or even caused by cognitive decline. By using a variable 'providing ADL help', we covered the ADL condition of older people in the analysis. The ADL provision is important to consider when the goal is to identify caregivers at risk of burden. When ADL care provision is necessary, it is caregivers can perceive burden and extra formal help at home for ADL may be needed.

Chapter 5

Feasibility, acceptability, and potential helpfulness of the PROACTIVE intervention in Flanders, Belgium: A survey study

This chapter is under review in journal PLOS ONE:

Shanshan Wang, Johanna de Almeida Mello, Mary S. Mittelman, Anja Declercq. Feasibility, acceptability, and potential helpfulness of the PROACTIVE intervention in Flanders, Belgium: A survey study, PLOS ONE (Under review after revision)

Feasibility, acceptability, and potential helpfulness of the PROACTIVE intervention in Flanders, Belgium: A survey study

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Abstract

Background/objectives: A feasibility study is necessary to reduce waste for intervention adaptation and cost-effectiveness evaluation. This study aimed to explore the feasibility of a Flemish adaptation of the NYU Caregiver Intervention (NYUCI) modifying the recruitment and intervention content for informal caregivers of people with early cognitive decline, and across different subgroups.

Methods: Researchers constructed, tested, and sent out a survey consisting of 43 questions on the following topics: awareness of symptoms of early cognitive decline, present symptoms of cognitive impairment, acceptability, and potential helpfulness of the intervention, and sociodemographic characteristics. Quantitative data were analyzed using descriptive statistics and logistic regression with SAS 9.4©. Qualitative data was analyzed using an inductive content analysis.

Results: A total of 463 informal caregivers completed the survey (mean age 58.8 ± 11.8, 83.6% female). Among them, 124 respondents who cared for people with early cognitive decline

indicated they would probably or certainly participate in the intervention, which is over the required experimental sample (i.e., 64) for sufficient power for our planned research. Identified factors influencing recruitment were cognition, co-habitation, education, and employment status. Over half of the target caregivers indicated almost all services from the intervention could satisfy their needs. A majority perceived the PROACTIVE intervention would be helpful (69.4%), especially the CPS2=3 (76.1%) and CPS2=4 (74.1%) subgroups.

Conclusion: The recruitment of enough target participants for a subsequent RCT evaluation study is feasible, and identified associated factors should be considered during the recruitment process. The PROACTIVE intervention and core components except 'peer-group participation' were perceived as potentially helpful by most caregivers. The CPS2=3-4 subgroups was most acceptable for the intervention and may benefit more.

Key words: cognitive decline, older people, informal caregiver, feasibility, acceptability, intervention

Introduction

According to the 2019 World Population Prospects, 16% of the world population will be over age 65 and 426 million people will be over age 80 by 2050 [1]. Given the projected trends in population ageing, the number of people with dementia will increase to 152.8 million cases in 2050 [2]. This will cause an increasing demand for healthcare resources and a threat to sustainable healthcare [3]. Providing early support for informal caregivers can improve their wellbeing and ability to care, keeping older people with cognitive decline at home longer and diminishing public healthcare costs [4-8]. However, scientific literature has shown that very few psychosocial interventions target informal caregivers at the early stage of caregiving [8-9]. In Belgium, a nationwide research project showed that informal caregivers of older people with early cognitive decline perceived burden and were at risk of discontinuing care at home [10].

The NYU Caregiver Intervention (NYUCI) aims to improve informal caregivers' wellbeing and thereby enable them to keep caring for the person with dementia at home longer. The NYUCI is a multicomponent intervention that includes a comprehensive assessment of the caregiver, followed by an individual counseling session, four family counseling sessions, and then a second individual session within four months of enrollment. Participation in a support group is recommended. Additional counseling, called "ad hoc" counseling, is available to caregivers and participating families as needed. The intervention was implemented in a variety of community settings and has proven sustained and multiple benefits, including improved social support and self-rated health, reduced depression and reactions to problem behaviors, postponement of residential care placement and major healthcare cost savings [11-17] in many replications and translations over the past 30 years. The improvement of key outcomes (e.g., caregiver burden, symptoms of depression) was also achieved among adult child caregivers, although the NYUCI was originally designed for spousal caregivers [18-19].

The PROACTIVE intervention will be the first Flemish adaptation of the NYUCI focusing specifically on informal caregivers of people with early cognitive decline, compared to the NYUCI which includes caregivers of people at all stages of dementia [20]. In Flanders, we will

focus on caregivers of people at the early stage of cognitive decline, as these caregivers often receive no help or support at the beginning of their caregiving activities and are often left out of formal help services. Evidence also shows that the target population of our intervention are often hard to reach, because these informal caregivers struggle with self-identification as caregivers, identifying and acknowledging needs and with accepting help [21-22]. Moreover, effects of an intervention are highly dependent on the context. To reduce research waste and successfully replicate effects of the NYUCI, a careful and systematic adaptation process improves the likelihood of achieving a good intervention-context fit [23]. A brief description of the planned PROACTIVE intervention was mentioned in our protocol [20]. Potential barriers to success include low acceptability of the intervention, difficulties with recruitment capability and retention, as well as difficulties with convincing participants to complete questionnaires necessary to evaluate the intervention. A feasibility study can provide information about how to overcome these barriers, especially for these vulnerable hard-to-reach participants [24-25].

The UK Medical Research Council (MRC) provides a framework for developing and evaluating complex interventions, including the identification or development of an intervention, and the feasibility, evaluation, and implementation phases. Each phase should consider the following core elements: context, program theory, stakeholders, key uncertainties, intervention refinement, and cost-effectiveness [26]. Using the MRC framework, this study has the objective of exploring the feasibility of the PROACTIVE intervention, including the feasibility of recruiting participants and the adequacy and helpfulness of the intervention content. Specifically, we wish to answer the following questions: 1) Can we recruit enough participants for the evaluation of the PROACTIVE intervention, and what barriers should we address when conducting this recruitment? 2) Can the intervention content meet the needs of the target participants and are there different needs among subgroups stratified by the level of cognitive performance (acceptability of the intervention content)? 3) Are the intervention and its core components perceived as helpful by the target participants and across subgroups stratified by the level of cognitive performance (potential helpfulness of the intervention)?

Methods

The study was approved by the Ethics Committee of the KU Leuven under the number G-2020-1771-R2(MAR). The collection and processing of personal data meets the requirements of the General Data Protection Regulation (GDPR) confirmed by KU Leuven's Data Protection Officer ('DPO'). At the beginning of our anonymous online survey, we clearly state the respondent's right to confidentiality, possible risks, and benefits from participating in our study. Informed consent was also obtained from all participants. The reporting of this survey follows the Checklist for Reporting of Survey Studies (CROSS) [27].

Study design and recruitment

The survey was programmed in Qualtrics©. An anonymous link was provided to respondents and no personally identifiable information was collected in the survey. The survey was conducted in February 2022 and closed in June 2022. Eligible participants were informal caregivers who were aged 18 years or older, and who provided support to a community-dwelling person who had cognitive problems. In this study, informal caregivers were defined

as family members, siblings, other relatives, friends, or neighbors. They could be primary caregivers or secondary caregivers.

Participants were recruited through newsletters of organizations (e.g., memory clinics; Belgian Alzheimer centers, etc.), via social media posts (e.g., posts in Facebook groups), or by recommendation from physicians. We also recruited participants from organizations working with older people with cognitive decline (day care centers, home care organizations). We encouraged all the respondents to share the link to the survey within their networks (e.g., family, friends). Most informal caregivers (93%) filled out the survey online, while some informal caregivers (7%) filled out the survey on paper. No remuneration was offered for participation in this study.

Outcome measures

The survey was constructed by the research team based on the intended benefits of the NYUCI components, evaluation forms and questionnaires from the NYUCI, and knowledge about the symptoms of early cognitive decline. Eligible informal caregivers whose relatives had cognitive problems filled out the survey which included their rating of their relative's level of cognitive impairment through the items from the interRAI Cognitive Performance Scale (CPS2) [28]. We pretested the survey three times with 21 potential participants, once with 7 participants and again with another 7, and again with a third set of, and three revisions of the survey were built, until a final version was approved by the research team. In the first version, we changed some professional and technical/clinical wording into familiar language more appropriate for participants' age, education, and experiences. Last, we corrected some spelling mistakes after some additional adaptations, such as language formulation to improve content comprehensibility, the final version of the survey was built in the Qualtrics software application. The 43 questions included in the survey covered the following domains: awareness of symptoms of their relatives' cognitive decline, international validated Cognitive Performance Scale (CPS2) to assess their relatives' level of cognitive impairment, acceptability and potential helpfulness of the PROACTIVE intervention, willingness to participate in the PROACTIVE study, and sociodemographic characteristics.

The first module of the survey contained six questions with a 5-point Likert scale (1=never, 2=occasionally, 3=sometimes, 4=often, 5=always) on the respondents' awareness of their relatives' symptoms of early cognitive decline. Questions about symptoms of cognitive decline include 'repeating or asking the same thing over and over', 'hard to follow conversations', 'confused about time and place'. We also included the question 'Do you agree your relative's symptoms are a natural part of ageing?' in a 5-point Likert scale (1=strongly agree, 2=agree, 3=neutral, 4=disagree, 5=strongly disagree).

The second module of the survey consisted of the Cognitive Performance Scale (CPS2) which assesses the caregiver's perception of six domains of cognition: short-term memory (Yes/No), making self-understood (5 scoring levels), cognitive skills for daily decision-making (6 scoring levels), managing finances (7 scoring levels), managing medications (7 scoring levels), and walking (8 scoring levels). Compared to the original CPS (range 0 to 6), a study demonstrated that the CPS2 scale (range 0 to 8), when used in repeated assessments, is sensitive to detect changes particularly in early levels of cognitive decline [28]. Mini-Mental State Examination

(MMSE) has been mandatorily used in Belgium, and a study found the MMSE and CPS have almost similar performance for cognitive impairment test in nursing home residents [29]. Another study explored the score conversion between Montreal Cognitive Assessment and CPS and CPS2 using a large cohort of older people with mild physical and cognitive impairment. It showed that the highest scores observed were 3 for CPS and 5 for CPS2 in this mild impairment sample [30]. According to Morris JN, et al (2015), the scores of the CPS2 scale have the following descriptions: 0=intact1, 1=intact2, 2=borderline1, 3=borderline2, 4=moderately impaired1, 5=moderately impaired2, 6=severe1, 7=severe2 and 8=very severe impairment. In this study, we defined 'early cognitive decline' as equivalent to a CPS2 score of 1-4 and we selected our target population based on this CPS2 selection criteria throughout this research.

Acceptability refers to the extent to which the intervention components can meet the needs of the target population and how well the intervention can be delivered to the target population (e.g., acceptability of intervention delivery methods and tools) [31]. In the third module, we included 14 questions on the services the PROACTIVE intervention would provide, to be rated on a 5-point scale (1=not applicable, 2=satisfied, 3=low need, 4=need, 5=high need). The 14 questions were designed to explore if the intervention content could satisfy or meet the needs of our target population, namely the acceptability of the intervention content. These services covered five domains: coping with changes (in relationship, in behavior or changes to be expected in the future) (4 items), informational support for informal caregivers or care recipients (2 items), talking to a professional counselor (2 items), peer support group participation (1 item), support from family members and family meetings (5 items). In the next preparation phase of the intervention adaptation, we will further explore the acceptability of the intervention delivery (e.g., delivery format).

In the fourth module, the potential helpfulness of the entire PROACTIVE intervention (1 item) and the components of the intervention (4 items) were explored using a 5-point scale (1=not at all helpful, 2=a little helpful, 3= helpful, 4=very helpful, 5=extremely helpful). These five questions allowed us to explore to what extent the participants think the intervention, and each of the intervention components would be helpful. The last question of the module was the following: 'Would you want to participate in the PROACTIVE study?' (1=not at all, 2=possibly, 3=probably, 4=certainly). This question allowed us to investigate whether we could expect sufficient recruitment for the RCT evaluation study and to identify factors associated with their willingness to participate in the PROACTIVE intervention.

The last section contained ten questions about sociodemographic characteristics. The PROACTIVE intervention will be developed by adapting the NYUCI to the context of Flanders, one of the three Belgian regions. The survey was in Dutch, so respondents were mostly from the Germanic ethnic group native to Flanders, Belgium. The adaptation phase of the intervention will include people from other ethnicities, who will also be involved in the stakeholders' group. In this section, we asked questions about age, gender, highest level of education attained, relationship status, employment status, caring for children or others, co-habitation with the person with cognitive decline (defined as living together for at least 6 months), frequency of contact with the person with cognitive decline, relationship with the

person with cognitive decline. The survey ends with an open-field question to welcome any feedback or thoughts from the respondents.

Statistical analysis

First, a descriptive analysis was performed on the total sample and on subgroups stratified by the extent of willingness to participate in the PROACTIVE study. We included all levels of cognitive performance (CPS2=1-8) in the descriptive analysis and ordinal regression analysis, in order to get a whole picture of our sample around their willingness to participate in the PROACTIVE study and associated factors (e.g., level of cognitive performance). Ordinal regression analysis was then performed to identify factors associated with the willingness to participate in the intervention through modeling the possible determinants. We chose ordinal regression analysis to be able to predict the likelihood of our dependent outcome considering several predictors. We started with a full model and conducted a backward stepwise variable selection method until the significant determinants were retained. Our backward ordinal logistic model was built with the following variables: age=60+, under 65, gender, relation to person cared for, marital status, having children, help for caring for own children or other dependents, employment status, professional education/college and higher education, co-habitation, level of cognitive impairment. The 95% confidence interval (CI) was used to estimate the precision of the odds ratio (OR). OR>1 means higher odds of outcome, and OR < 1 lower means lower odds.

In addition, a descriptive analysis was also performed to identify the potential helpfulness and acceptability of the PROACTIVE intervention among the informal caregivers of older people with early cognitive decline (CPS2=1-4). A one-way ANOVA analysis was then performed to explore if there were significant differences in helpfulness and acceptability of the PROACTIVE intervention across subgroups stratified by the level of cognitive performance (CPS2=1,2,3 and 4). We did not perform Bonferroni correction, considering that our study is exploratory involving post-hoc testing [32]. Potential helpfulness of the PROACTIVE intervention was defined as the combination of responses ‘helpful, very helpful, extremely helpful’. Acceptability of the PROACTIVE intervention was defined as the combination of responses ‘low need’, ‘need’, ‘high need’ of the five domains of services which the PROACTIVE intervention provides. The 5-point scale (1=not at all helpful, 2=a little helpful, 3= helpful, 4=very helpful, 5=extremely helpful; 1=not applicable, 2=satisfied, 3=low need, 4=need, 5=high need) was dichotomized to help us better explore the differences in the acceptability and helpfulness of the intervention across subgroups, stratified by the level of cognitive performance. We summed 3 of them (3,4,5) and interpreted it as a positive response to explore more possibilities and obtain a broader view of the acceptable and helpful intervention content. Quantitative data analyses were conducted in SAS software version 9.4.

Qualitative data was analyzed by means of an inductive content analysis. Factors, including translator, back-translation, culture, and language, influence the quality of translation during cross-language qualitative data analysis [33]. During data preparation, the collected data in the source language (i.e., Dutch) was translated to the target language (i.e., English) with a focus on maintaining the integrity of the original content. One researcher analyzed the data in the target language (i.e., English). Another bilingual researcher proficient in both languages

analyzed the data in the source language (i.e., Dutch). In accordance with the research questions, words of the given text responses were independently classified into much smaller content categories (i.e., open coding, creating categories and abstraction) by two researchers while keeping in mind the context for meaning of the responses [34]. The written words of the given text response were read through several times. The two researchers came to a decision as to which things to put in the same category. Each researcher independently worked on the data analysis, and any discrepancies or differences were discussed and resolved through collaboration.

The qualitative data was collected and analyzed simultaneously with the quantitative data, as the open-field question was embedded in the end of the survey (i.e., embedded design) [35]. Integration focused on the concordance between qualitative and quantitative results. The qualitative results were to validate the quantitative results while also looking for inconsistencies [36]. This integration was to enhance the interpretation and understanding of the quantitative results, providing a more comprehensive picture of the research findings.

Results

A total of 463 people completed the survey. We can assume that people who are interested in an intervention will be more inclined to fill out the survey. Most of them (355, 76.7%) became aware of the survey through social media (online groups about informal care, dementia, etc.), others through the newsletter of an organization (26, 5.6%), or via professionals or care organizations (e.g., home care services) (82, 17.7%). In the whole sample, the most frequently perceived cognitive problems were 'Forgetting recent events or objects' (347, 74.9%), and 'Asking the same thing over and over' (343, 74.1%). Half of the whole sample agreed with the statement that memory problems are a normal part of ageing (204, 44.1%). A total of 230 respondents (49.7%) reported that they would probably or certainly participate in the PROACTIVE study, and 182 respondents (39.3%) reported that they would possibly participate in the study.

As shown in table 1, the mean age of the respondents was 58.8 (SD=11.8, range 21-97), with 83.6% being female. Most of the respondents were married (74.7%) and had at least one child (77.5% - mean number of children: 1.7 SD=1.2). About 84.4% of the respondents had almost daily contact with their relatives with cognitive problems. Almost half of respondents were in the <=60 age group (57.2%) and had to care for their own children or others (47.5%) and about 40.2% lived with their relatives with cognitive problems. Adult children made up 29.4% of the total sample, while spouses/partners, parent/guardian, and others (e.g., friend) made up 32.0%, 27.0% and 11.6% respectively. Regarding the representativeness of our sample, a comparison was made with a larger nationwide study on informal caregivers of frail older people (N=11,363). In that nationwide sample, the median age of primary caregiver was 59 and about 38.5% lived with frail older people, which is like our sample (58.8, 40.2%). But in the nationwide sample, most primary caregivers of frail older people were adult children (55.5%), spouse and others made up respectively 30.6% and 13.9% [10].

Table 1 Profile of the whole population and subgroups stratified by the extent of willingness to participate the PROACTIVE study

Respondents	Total= 463 n (%)	To what extent would you like to participate the PROACTIVE study			
		Not at all= 51 n (%)	Possibly= 182 n (%)	Probably= 146 n (%)	Certainly= 84 n (%)
Age group					
<=60 (*Min*=21)	265 (57.2)	23 (45.1)	102 (56.0)	82 (56.2)	58 (69.0)
>60 (*Max*=97)	198 (42.8)	28 (54.9)	80 (44.0)	64 (43.8)	26 (31.0)
Age mean (*SD*)	58.8(11.8)	62.2(9.4)	59.5 (11.6)	58.6 (12.8)	55.6(10.9)
Gender (Female)	387 (83.6)	42 (82.4)	147 (80.8)	126 (86.3)	72 (85.7)
Married/Partner	346 (74.7)	39 (76.5)	138 (75.8)	106 (72.6)	63 (75.0)
Number of children mean (*SD*)	1.7 (1.2)	1.9 (1.0)	1.8 (1.2)	1.7 (1.2)	1.6 (1.2)
Number of children >=1	359 (77.5)	45 (88.2)	144 (79.1)	118 (80.8)	63 (75.0)
Have almost daily contact with the person with cognitive decline (Yes)	391 (84.4)	44 (86.3)	155 (85.2)	117 (80.1)	75 (89.3)
Live with the person with cognitive decline (Yes)	186 (40.2)	23 (45.1)	64 (35.2)	60 (41.1)	39 (46.4)
Help with childcare or have other dependents (Yes)	220 (47.5)	27 (52.9)	81 (44.5)	59 (40.4)	53 (63.1)
Relationship to the person with cognitive decline					
Child/Child-in-law	136 (29.4)	13 (25.5)	51 (28.0)	46 (31.5)	26 (31.0)
Spouse/Partner	148 (32.0)	18 (35.3)	52 (28.6)	51 (34.9)	27 (32.1)
Parent/Guardian	125 (27.0)	13 (25.5)	60 (33.0)	31 (21.2)	21 (25.0)
Others (e.g.e.g., sibling, friend, neighbor)	54 (11.6)	7 (13.7)	19 (10.4)	18 (12.3)	10 (11.9)
Education					
Middle school and others	125 (27.0)	24 (47.0)	50 (27.5)	35 (24.0)	16 (19.0)
Professional education	84 (18.1)	11 (21.6)	37 (20.3)	21 (14.4)	15 (17.9)
University or Higher education	254 (54.9)	16 (31.4)	95 (52.2)	90 (61.6)	53 (63.1)
Employment status					
Employed full time/Self-employed	126 (27.2)	7 (13.7)	41 (22.5)	41 (28.1)	37 (44.0)
Employed part time	115 (24.8)	13(25.5)	50 (27.5)	29 (19.9)	23 (27.4)
Retiree/Volunteer/Housewife	222 (47.9)	31 (60.8)	91 (50.0)	76 (52.0)	24 (28.6)
Levels of the relatives' cognitive performance (CPS2=1-8)					
Intact2 to Borderline1 (CPS2=1-2)	82 (17.7)	16 (31.4)	36 (19.8)	18 (12.3)	12 (14.3)
Borderline2 (CPS2=3)	138 (29.8)	10 (19.6)	63 (34.6)	39 (26.7)	26 (31.0)
Moderately impaired1 (CPS2=4)	58 (12.5)	6 (11.8)	23 (12.6)	18 (12.3)	11 (13.1)
Moderately impaired2 (CPS2=5)	61 (13.2)	3 (5.9)	22 (12.1)	28 (19.2)	8 (9.5)
Severe1 to severe2 (CPS2=6-7)	80 (17.1)	9 (17.6)	25(13.7)	30 (20.5)	16 (19.0)
Very severe (CPS2=8)	44 (9.6)	7 (13.7)	13 (7.1)	13 (8.9)	11 (13.1)

Across the four subgroups stratified by the extent of willingness to participate in the PROACTIVE study, from 'Not at all' to 'Possibly' to 'Probably' to 'Certainly', the mean age was 62.2, 59.5, 58.6, 55.6 respectively, and the mean number of children was 1.9, 1.8, 1.7, 1.6 respectively. The proportion of full time employed/self-employed respondents increased across the four subgroups along with the extent of willingness to participate the PROACTIVE study (from 'Not at all' to 'Possibly' to 'Probably' to 'Certainly': 13.7%, 22.5%, 28.1%, 44.0% respectively). This trend was also observed in respondents' education with university or higher

education (31.4%, 52.2%, 61.6%, 63.1%). The percentage of respondents who had a relative with intact2 to borderline1 cognitive performance (CPS2=1-2) followed the opposite pattern of willingness to participate (from 'Not at all' to 'Possibly' to 'Probably' to 'Certainly': 31.4%, 19.8%, 19.2%, 14.3%). Respondents who had a relative with borderline2 cognitive performance (CPS2=3) were most willing to participate in the PROACTIVE study (31.0%).

As shown in table 2, results of the regression analysis showed that the most significant factor predicting willingness to participate was cognitive performance (OR:2.21, 95%CI: 1.41 – 3.48). It meant that compared to people who had a relative with intact2 to borderline1 cognitive performance, people who were caring for a person with higher impaired level of cognitive performance also had an increased likelihood of willing to participate in the PROACTIVE study (i.e., from 'not at all' to 'possibly' to 'probably' to 'certainly'). Three other significant factors were 'Full-time employed/self-employed' (OR:2.04, 95%CI: 1.27 – 3.29), 'University or higher education' (OR:2.04, 95%CI: 1.34 – 3.10), and 'Living with the relative with cognitive problems' (OR:1.64, 95%CI: 1.13 – 2.39).

Table 2 Ordinal regression analysis for factors associated with the extent of willingness to participate the PROACTIVE study

Predictors	OR	OR (95%-CI)	*P*
Cognitive performance (Ref=intact2 to borderline1, CPS=1-2)	2.21	1.41 – 3.48	0.000***
Full-time employed/self-employed (Ref=part-time employed)	2.04	1.27 – 3.29	0.003**
University or higher education (Ref= lower education)	2.04	1.34 – 3.10	0.000***
Living with the relative with cognitive problems	1.64	1.13 – 2.39	0.009**
Gender (Ref=Male)	1.60	0.99 – 2.60	*0.056*

Notes: Grey numbers in Italic Font style also represent no significance but were kept here due to the stopping criterion used in the backward logistic regression analysis. Significance: ****p*<.001, ***p*<.01, **p*<.05.

Table 3 Potential helpfulness of the PROACTIVE intervention by respondents' relative with early cognitive decline (CPS2=1-4, N=278)

Potential helpfulness of intervention and its components	Total=278 n (%)	CPS2=1 n (%)	CPS2=2 n (%)	CPS2=3 n (%)	CPS2=4 n (%)	*P*
Entire PROACTIVE intervention	193(69.4)	5(38.5)	40(58.0)	**105(76.1)**	43(74.1)	0.04*
Family meeting with a counselor	**199(71.6)**	4(30.8)	37(53.6)	110(79.7)	48(82.8)	0.000***
Talking to a professional counselor	194(69.8)	4(30.8)	39(56.5)	103(74.6)	48(82.8)	0.008**
Telephone/email consultation on request over the disease course	185(66.5)	3(23.1)	37(53.6)	102(73.9)	43(74.1)	0.01*
Peer-support group participation	133(47.8)	5(38.5)	27(39.1)	68(49.3)	33(56.9)	0.131

Notes: Ratings of these items were made on a 5-point Likert scale (1=Not at all helpful, 2=A little helpful, 3=Helpful, 4=Very helpful, 5=Extremely helpful). 'Helpfulness' is based on summed values of 'helpful, Very helpful, Extremely helpful'. Significance: ****p*<.001, ***p*<.01, **p*<.05.

As shown in table 3, in the total sample of people with early cognitive decline (CPS2=1-4, N=278), a majority thought that all components of the PROACTIVE intervention would be helpful (69.4%). In their opinion, across the four intervention components, the most helpful was 'Family meeting with a counselor' (71.6%) and the least helpful was 'Peer-support group participation' (47.8%).

Across the 4 subgroups of levels of cognitive performance, namely intact2, borderline1, borderline2 and moderately impaired1, the subgroup caring for someone with borderline2 cognitive performance (CPS2=3) mostly thought the entire intervention would be helpful (76.1%). In subgroups with borderline2 and moderately impaired1 (CPS2=3,4), participants thought the most helpful intervention component would be 'Family meeting with a counselor' (79.7%, 82.8% respectively). In the subgroup with borderline1 cognitive performance (CPS2=2), the most helpful intervention component would be "primary caregiver can talk to a professional counselor' (56.5%).

Table 4 Needed services which the PROACTIVE intervention can provide in total, and subgroups stratified by the relatives' level of cognitive performance (CPS2=1-4)

Needed services	Total=278 N (%)	CPS2=1 N (%)	CPS2=2 N (%)	CPS2=3 N (%)	CPS2=4 N (%)	*P*
Knowing what changes to expect and how to adapt	184(66.2)	7(53.8)	38(55.1)	98(71.0)	41(70.7)	0.02*
Proactive planning for future, e.g., financial plan.	167(60.1)	5(38.5)	36(52.2)	85(61.6)	41(70.7)	0.067
Regularly talking to a professional counselor	165(59.4)	5(38.5)	36(52.2)	85(61.6)	39(67.2)	0.085
Accessing information/support for you as a caretaker/caregiver	162(58.3)	6(46.2)	37(53.6)	83(60.1)	36(62.1)	0.511
Other family members understand relative's condition and your needs	151(54.3)	5(38.5)	35(50.7)	77(55.8)	34(58.6)	0.103
Telephone/email consultation on request over entire disease course	147(52.9)	4(30.8)	29(42.0)	78(56.5)	36(62.1)	0.03*
Knowing potential support that other family members can provide	143(51.4)	3(23.1)	34(49.3)	77(55.8)	29(50.0)	0.076
Knowing how to solve time conflicts for family meetings	141(50.7)	2(15.4)	29(42.0)	79(57.2)	31(53.4)	0.000***
Talking to peer groups	142(51.1)	5(38.5)	28(40.6)	73(52.9)	36(62.1)	0.070
Knowing how to communicate with your relative about the changes	142(51.1)	3(23.1)	33(47.8)	73(52.9)	33(56.9)	0.03*
Knowing how to cope with changes in relationship	142(51.1)	7(53.8)	26(37.7)	74(53.6)	35(60.3)	0.007**
Other family members talk to a professional counselor	133(47.8)	3(23.1)	31(44.9)	68(49.3)	31(53.4)	0.497
Knowing reliable information on the relative's condition	131(47.1)	5(38.5)	28(40.6)	65(47.1)	33(56.9)	0.01*
Family meetings to talk about their relatives' condition, future plan	131(47.1)	3(23.1)	31(44.9)	73(52.9)	24(41.4)	0.03*

Notes: Ratings of these items were made on a 5-point Likert scale (1=Not applicable, 2=Satisfied, 3=Low need, 4=Need, 5=High need). Significance: ***p<.001, **p<.01, *p<.05.

As shown in table 4, almost half of the people with early cognitive decline (N=278) said they thought they needed all components of the intervention. Across all the 14 components, the most frequently needed component was related to help to adapt to future changes - 'Knowing what changes to expect and how to adapt to these changes' (66.2%). Three other frequently reported needs were related to proactive planning for the future including 'Proactive planning for future care planning, financial planning etc.' (60.1%),, regular help from a professional counselor (59.4%), and information accessibility and support for you as a caregiver (58.3%), Only three needs were reported by less than 50% of respondents in the sample with early cognitive decline (CPS2=1-4), namely 'Other family members talk to a professional counselor' (47.8%), 'Knowing reliable information on the relative's condition' (47.1%), and 'Family meetings to talk about relative's condition, future plan' (47.1%).

'Telephone/email consultation on request over entire disease course', 'Knowing how to communicate with your relative about the unusual changes', and 'Knowing reliable information on their relatives' condition' showed an increase in proportion to the severity of cognitive performance. The most needed service, felt by more than half of all participants across subgroups, namely 'Knowing what changes to expect and how to adapt (53.8%, 55.1%, 71.0%, 70.7% respectively).

In the intact2 (CPS2=1) subgroup, two other frequently needed services were 'Knowing how to cope with changes in relationship' (53.8%), and 'Accessing information/support for you as a caretaker/caregiver' (46.2%).The least frequently needed services, which also shown a great difference from the borderline1 (CPS2=2) to more severe subgroups, were 'Knowing how to communicate with your relative about the unusual changes' (23.1% vs 47.8%), and 'Knowing how to solve time conflicts for family meetings' (15.4% vs 42.0%).

In the borderline1 (CPS2=2) subgroup, three other frequently needed services were 'Accessing information/support for you as a caretaker/caregiver' (53.6%), 'Proactive planning for future, e.g., financial plan' and 'Regularly talking to a professional counselor' (both were 52.2%). The least needed service was 'Knowing how to cope with changes in relationship', which was even lower than the intact2 (CPS2=1) subgroup (37.7% vs 53.8%).

In the borderline2 (CPS2=3) subgroup, three other frequent needed services were 'Accessing information/support for you as a caretaker/caregiver' (60.1%), 'Regularly talking to a professional counselor' and 'Proactive planning for future, e.g., financial plan' (both were 61.6%). The least frequently needed service was 'Knowing reliable information on their relatives' condition' (47.1%). In addition, the percentages of needed services of 'Knowing how to solve time conflicts for family meetings' were higher than the subgroup with moderately impaired1 cognitive performance (CPS2=4) (57.2% vs 53.4%).

In the moderately impaired1 (CPS2=4) subgroup, two other frequently needed services were 'Proactive planning for future, e.g., financial plan' (70.7%), 'Regularly talking to a professional counselor' (67.2%). 'Telephone/email consultation on request over entire disease course', 'Accessing information/support for you as a caretaker/caregiver' and 'Talking to peer group' shared the same percentage (62.1%). The least frequent needed service was 'Family meetings

to talk about their relatives' condition, future plan', which was even lower than borderline2 (CPS2=3) subgroup (41.4% vs 52.9%).

Regarding the qualitative data analysis, a total of 97 different statements were written in the open field of the survey. Six statements addressed the survey (e.g., a question about whether the disease runs in the family should be added). Twenty statements dealt with caregiving experiences or the care recipients' condition (e.g., 'my father's situation was getting worse', 'I was worried'). Eleven statements explained their relationship to the person who had cognitive problems/dementia (e.g., 'My grandmother has dementia', 'I cared for my ex-partner'). Six statements mentioned that the intervention will be more helpful in their later stage. For example, 'My mother has Lewi Body dementia in its very early stage. Now, we don't need much help. But as the disease progresses, I would make use of possible additional support – such as the intervention described in this survey.' Four statements mentioned that the disease runs in his family (e.g., 'Both father and brother have dementia'). One statement mentioned the stigma against talking about this: 'There is an awareness that something is wrong, but it cannot be talked or helped because of the taboo.' The remaining 49 statements of the total 97 statements were summarized into three main themes.

The first theme concerned negative attitudes and disappointment towards medical or home care services, such as hospitals, medical teams, doctors/neurologists, home care and day care. These are some examples:

'It would help a lot if the patient and caregiver were taken seriously or treated less rudely by doctors/neurologists, especially at the beginning of the treatment process.'

'I was very disappointed that there is no psychosocial support for us when the medical team made the diagnosis of onset dementia. I am very curious about your research and the intervention under development.'

The second theme was about the need for informal caregivers to have timely guidance, training, and support. Respondents reported the need for a coach or a person to guide them through the process. Some examples are:

'There is not much information or support for caregivers who had a relative with onset dementia. There should be! The family caregivers also need care.'

'I have the thought that there should really be a coach who guides me through this. Unfortunately, there is no such thing here.'

'Guidance is a necessity, especially for informal caregivers who work and are not entitled to leave the systems. We don't have time to figure the things out and don't know where we can get timely help.'

The third theme was about some useful ways to help informal caregivers, such as family groups, information meetings, and as the reference person for dementia, which can be helpful. Some examples are:

‘I have already attended several meetings about dementia in the past when my dad was demented. Now my uncle also has dementia. Thanks to the information evenings, I have a lot of knowledge and I am aware of the course of the disease.’

‘I participated in the family group and can contact the dementia reference person in the rest home, which is very important to me. My children are also very involved and supportive.’

Discussion

A feasibility study is necessary to avoid waste of resources for intervention adaptation and evaluation, and to learn from potential users whether an intervention’s content can be acceptable and helpful for the target population. This is the first study to explore the feasibility of a Flemish adaptation of the NYUCI around the recruitment and intervention content for informal caregivers of people with early cognitive decline. Furthermore, differences in acceptability and potential helpfulness of the intervention content were also examined across subgroups stratified by the level of early cognitive decline using the Cognitive Performance Scale (CPS2).

About 49.7% of the total respondents reported that they probably or certainly would participate in the PROACTIVE study. This suggests that we could recruit enough target participants for the next stage of study, which is this intervention testing and evaluation. Considering the representativeness of experimental sample and recruitment bias, we should pay more attention to the identified associated factors, including cognition, co-habitation, education, and employment status, during the recruitment process. For example, a more proactive technique may be conducted to recruit lower education caregiver group to participate in the intervention compared to the university or higher education caregiver group. The associations with poorer cognition [37] and living with the person with cognitive problems were consistent with previous studies [38]. Additionally, misconceptions about early cognitive decline or early onset dementia should also be considered as a possible factor according to our results. About 44.1% of our whole sample agreed with the statement that unusual changes of their relatives, such as memory problems, are a normal part of ageing. Aligned with this finding, a recent study showed that more people with mild cognitive impairment (MCI) were reported in community surveys than those who sought help from healthcare providers [39]. Other studies also reported that the failure to acknowledge unusual changes as disease was a barrier to the acceptance process [21] and to seeking information and support [22].

Regarding the acceptability of the PROACTIVE intervention content (i.e., 14 types of services), our study suggests that all these services, could meet the needs of almost half of the total respondents who cared for a person with early cognitive decline (CPS2=1-4). Our qualitative data analysis results also supported the respondents’ need for guidance, training and information meetings, and perceived helpfulness of participating in a family group meeting. Previous studies also suggest that many caregivers do not take steps to seek help, often because of tensions in the family [40]. They reported the need for interpersonal support, such as help to make other family members understand what the issues of the disease are [41]. The most acceptable and common service across subgroups stratified by the level of early cognitive decline (CPS2=1,2,3, and 4) was ‘Knowing what changes to expect and how to adapt’.

This is in line with two studies that underlined that an early-stage intervention should aim at the facilitation of the adaptation process and future care [42-43]. Through comparisons among the four subgroups, we found that CPS2=3-4 subgroups had a higher acceptance of the intervention services compared to the CPS2=1-2 subgroups. Almost all services were acceptable by over half of respondents from the CPS2=3-4 subgroups, but only two services and five services were acceptable by over half of respondents from the CPS2=1 and CPS2=2 subgroups respectively.

Regarding the potential helpfulness of the entire intervention and intervention core components, only the 'peer-support group participation' component was perceived helpful by less half of the respondents who cared for a person with early cognitive decline (CPS2=1-4). A previous study found that stigma resulted in caregivers' refusal to seek support from families or friends [21-22, 44]. Informal caregivers might want to talk to peer groups, but they may be afraid of the consequences due to stigma, especially in the very early stage of cognitive decline (CPS2=1-2). This stigma was also echoed by the difference between the proportion of CPS2=1-4 group who needed to talk to a peer group (51.1%) and who thought peer-group participation would be helpful (47.8%). Through comparisons among the four subgroups, we found that the intervention was perceived helpful by almost three quarters of the respondents from the CPS2=3-4 subgroups, compared to 38.5% from the CPS2=1 and 58% from the CPS2=2 subgroups. The three core intervention components followed the same pattern. This is also consistent with the higher acceptability of the intervention content in CPS2=3-4 subgroups. It means that the CPS2=3-4 subgroups would be more likely to accept the intervention and thought they could benefit more, and this information should be considered in the further intervention adaptation process. Considering cost-effectiveness issues, a more needed service package might be designed and provided to the CPS2=1-2 subgroups based on the results of acceptability of the intervention services.

Strengths and limitations

The PROACTIVE intervention was adapted from an internationally evidence-based intervention (i.e., NYUCI), which has been put into practice in some states of the US and was adapted in many countries. Our study showed that informal caregivers in Flanders had similar needs to those in the original intervention studies and that the intervention could be of value in Flanders, considering the context of the care sectors in the Flemish region. A second strength of the study is the use of the interRAI CPS2, which is sensitive to assessing early cognitive decline. Based on the results of the subgroup analysis by CPS2=1-4, we can identify the subgroups who would most accept the intervention content and benefit more to achieve a greater cost-effectiveness. Moreover, we can further the intervention adaptation process based on our study results through stakeholder meetings etc. in the following phases.

The main limitation of the study is that we used convenience sampling methods to recruit participants. The respondents of the sample were not selected at random from the population. In addition, people answering the survey might be the ones most in need of intervention or most willing to participate. Although we checked the representativeness according to age, gender, and other characteristics, this may not be a representative sample for the whole population of informal caregivers in Flanders. Considering the limitation of the sample

representativeness, we should be cautious when generalizing to the population in Flanders, Belgium. Another limitation is that we could not make an in-depth qualitative analysis because there was only one open question included in our survey. Given the difference between the few respondents in CPS2=1 and other subgroups, we also should be cautious about the related data analysis results.

Conclusion

This study provided the first evidence of the feasibility, acceptability, and potential helpfulness of a Flemish adaptation of the NYUCI in the context of informal caregivers of older people with early cognitive decline. The recruitment of enough target participants for a subsequent RCT evaluation study is feasible. Identified associated factors should be considered during the recruitment process. Almost all services from the intervention could satisfy the needs of over half of the target caregivers. The PROACTIVE intervention and all core components except 'peer-support group participation' were perceived as potentially helpful by most caregivers. We also found that the CPS2=3-4 subgroups were more accepting of the intervention, and it might be more cost-effective to target them for the intervention. Results from this study will inform the further intervention adaptation process and evaluation design in the following phases based on the MRC framework.

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Chapter 6

Conclusion

Dementia leads to increased costs for individuals, societies, and governments, and to productivity losses for economies worldwide. Dementia is one of the major causes of disability and dependency among older people, and it will cause increasing demands of health and social care [1-2]. This poses a threat to the achievement of sustainability of healthcare in long-term care systems. One potential and promising solution is to leverage the power of informal care, which plays a significant role in health and social care by providing supportive care to frail people at home [3].

Informal carers who care for a person with early cognitive decline can experience a decline in their health and wellbeing due to the complexity of the disease and care demand. The initial symptoms such as memory loss can be transient and may be accompanied by periods of abnormal behavior, which can bring considerable stress to family members due to uncertainty and confusion. In Flanders, the average time between the start of symptoms and a formal diagnosis can take on average from three to four years, and it takes twice as long in case of young early-onset dementia [4]. In face of the fears and concerns about an occurring deterioration in their relatives, family members experience family conflicts, psychological stress, anxiety, and depression, and they are often left out of formal help. Their health and wellbeing are also impacted by a change in the quality of their relationship with their ill relatives, lack of dementia knowledge, unclear future planning, and weak coping skills for this unpredictable, complex, and progressive disease [5-6].

Timely support for early informal caregivers has been proven beneficial for society and healthcare systems. Interventions directly focusing on early informal caregivers can enhance caregivers' resilience to stress and increase their capacity to provide care [7]. Systematic reviews show that informal caregivers of people with early dementia or mild cognitive impairment can benefit and maintain their wellbeing when psychosocial interventions are provided early on [8]. Using the Medical Research Council (MRC) framework (MRC, 2008), this doctoral thesis aimed at developing and evaluating an evidence-based intervention for informal caregivers of older people with early cognitive decline in Flanders, Belgium. Due to the COVID epidemic, the PhD project had to be adapted. An adaptation to the methodology was also applied to meet the new updated MRC framework (MRC, 2021). This PhD research aimed at developing and evaluating the feasibility of a Flemish adaptation of the New York University Caregiver Intervention (NYUCI), named as the PROACTIVE intervention, in Flanders, Belgium. The following research questions were explored:

- What is the randomized controlled evidence on psychosocial interventions for informal caregivers of older people with early cognitive decline?
- Which factors affect the primary informal caregivers' ability to continue care across several degrees of cognitive decline and risk of burden?
- Is the PROACTIVE intervention feasible, acceptable, and helpful in Flanders, Belgium?

First, a systematic review was performed to identify existing evidence concerning support for informal caregivers of people with early cognitive decline. The searches were performed in the electronic databases PubMed, CINAHL, Embase, Cochrane and Web of Science. For the second question, a large sample data derived from a national project called Protocol 3 was stratified by levels of care recipients' cognitive decline (Cognitive Performance Scale, CPS) and

by the levels of risk of caregivers' burden (Caregiver Risk Evaluation, CaRE). The CPS and CaRE algorithm can be automatically calculated from the interRAI Home Care (HC) instrument used in this study, so that we could explore the factors associated with informal caregivers' ability to continue care across different subgroups. The outcome measures from the various instruments, interRAI HC, Zarit Burden Interview (ZBI-12) and informal caregiver questionnaire, made it possible to explore multiple factors, such as context of care, social, physical, and psychological factors. For the last research question, a survey consisting of four modules was constructed, tested, and sent out to collect data among families who have relatives with cognitive decline. Quantitative data was analyzed, and the population was stratified by the level of cognitive decline of care recipients to investigate the differences in their acceptability and perceived helpfulness of the PROACTIVE intervention across subgroups.

Main findings

Systematic review of randomized controlled evidence on supporting informal caregivers of older people with early cognitive decline

As shown in Chapter 3, through a systematic review of the existing RCT evidence, we identified the robust effective psychosocial interventions after rigorous assessment of the selected studies' methodological quality. The review showed evidence of effective psychosocial interventions timely supporting informal caregivers of older people with early cognitive decline. Among these effective interventions, fifteen different types of effective interventions were targeted at informal caregivers of older people with all stages of dementia, and only three different types of effective interventions were solely focused on informal caregivers of older people with early cognitive decline. The main outcomes included reduced caregiver's burden, depression, anxiety, and stress, improved self-efficacy, quality of life, wellbeing, self-rated health and social support, positive affectivity and appraisals of behavioral problems. The main outcomes of care recipients included quality of life, wellbeing, depression, dyadic relationship, functional dependence, activity engagement and assistance needed with activities of daily living (ADL).

Regarding the elements of effective interventions, three studies categorized as single-element intervention (i.e., only training) showed statistically significant effects, including reduced care recipients' neuropsychiatric symptoms, reduced caregiver stress, distress, and depression, improved self-efficacy in providing care. Twenty-one studies categorized as multi-component intervention showed statistically significant effects. Eleven studies shared an intervention component (i.e., social support), which reported benefits for caregivers, including improved mental health and emotional support, caregiving appraisals and coping skills, mastery, and use of available services. Ten studies shared a common intervention component (i.e., training), which reported improved caregivers' quality of life and self-efficacy, reduced caregivers' burden, improved emotional health, less dyadic relationship strain, less role captivity, reduced distress, and depressive symptoms. Fourteen studies had a common intervention component (i.e., education), which reported benefits for caregivers, including increased caregiver self-efficacy, mastery, coping skills, improved wellbeing and quality of life, reduced caregivers' burden and depressive symptoms, less role captivity. The unique intervention elements (i.e., on-going support group participation, ad hoc counseling, plans of maintaining skills learnt)

presented in the NYUCI and the START intervention produced sustained benefits after years of follow-up, such as fewer depressive symptoms, better self-rated health, higher social support.

The underpinning theories of identified effective interventions were examined to better comprehend the intervention components and their functioning mechanism. The main underpinning theories were: (1) The Progressively Lowered Stress Threshold Model (PLST) and the Problem-Solving Therapy (PST), which were used to improve caregivers' self-efficacy and problem-solving skills. (2) The Competence-Environmental Press theory targeted at modifiable environmental stressors to improve caregivers' dementia management skills and to maximize care recipients' independence. (3) The Stress Process theory focused on building the resources (e.g., social support) for informal caregivers to reduce caregivers' burden and improve caregivers' wellbeing (4) The Schulz's Stress–health Process Model, stress, appraisal and coping theory and Cognitive behavior therapy aimed at reducing risks in five caregiver domains, reducing caregivers' depression, and improving caregivers' appraisals and coping skills.

Caregivers' needs assessment tools were used in twelve studies, such as the Johns Hopkins Dementia Care Needs Assessment (JHDCNA), an individualized risk assessment tool for five caregiver domains, a capacity and burden questionnaire etc. Among these tools, only two were structured needs assessment, which were person-centered and tailored to informal caregivers' comprehensive needs. Moreover, only a validated informal caregiver screener was developed based on the internationally validated interRAI assessments [9]. Structured and individualized needs assessment tools play a key role in the effectiveness and efficiency of psychosocial interventions functioning, which can improve the cost-effectiveness of informal care provision and the wellbeing of informal caregivers [10, 11]. A validation study on systematic assessment for informal caregivers is still lacking and needs-matched psychosocial interventions for informal caregivers of people with cognitive decline should be developed further.

Determinants of informal caregivers' ability to continue care: a subgroup analysis.

As shown in Chapter 4, factors associated with informal caregiver's ability to continue care at home were explored for a whole study population, and across subgroups of several degrees of cognitive decline (CPS) and risk of caregivers' burden (CaRE).

Multiple protective and risk factors associated with informal caregivers' ability to continue care among the whole population were identified. These identified factors were consistent with the results of previous studies, but they were further refined across different subgroups. Aged 65+ years and behavioral problems of frail older people were significant determinants for subgroups at low risk of caregivers' burden. Daily pain of frail older people was significant for subgroups at very high risk of caregivers' burden. Provision of ADL by informal caregivers was significant for subgroups at low or moderate risk of caregivers' burden, and for subgroups with intact cognition or mild cognitive impairment. No trends were found in behavioral problems of frail older people and ADL provision of informal caregivers. The reason why these factors were significant for subgroups with lower levels of risk might be caregivers' greater

acceptance and competence towards the progressive caregiving process [12]. Factors, including depression, behavioral problems, visits from family members and friends, were significant for subgroups with intact cognition. The only common determinant for all cognitive impairment subgroups was caregivers' feelings of distress, anger, and depression. Factors associated with informal caregivers' ability to continue care varied across the levels of risk of caregivers' burden and the levels of care recipients' cognitive impairment.

A few previous studies examined the following determinants: care recipients' mental impairment, caregivers' physical and mental health, caregiving-related expenses, use of respite services, support from other family members, and caregivers' resilience [13–18]. Caregivers' resilience was impacted by their emotional and physical status, appraisal and coping skills, and personality features [19], support from other family members or society [20].

Some associated factors presented trends across informal caregiver subgroups at different levels of risk. Social participation of frail older people, strong family support and availability of a secondary caregiver played a greater role in subgroups with a lower risk of caregivers' burden and a lower level of care recipients' cognitive impairment. Moreover, caregivers' feelings of distress, anger and depression had the greatest impact on the subgroup with mild cognitive impairment. These findings further confirmed the benefits of timely support for early informal caregivers, helping to maintain their well-being and to continue in caring activities. Expressive support (e.g., perceived availability of a second caregiver), as shown in the Pearlin's stress process theory, can prevent development of secondary stressors and help caregivers earlier find their inner growth (e.g., self-competence) with the ongoing caregiving process. Caregivers' resilience could be enhanced by timely support [21]. In addition, the caregiver's social role (i.e., spouse or adult child), as shown in the role theory, was a factor associated with the risk of caregivers' burden. This factor is also included in the CaRE algorithm. Moreover, factors included in the CaRE algorithm are aligned with the combination of the role theory and the stress process theory [22]. The combination of both theories increased conceptual clarity of caregivers' burden, and they were both considered in the construction of the CaRE algorithm to identify caregivers at risk of burden in a thorough way [23].

Feasibility, acceptability, and potential helpfulness of the PROACTIVE intervention

As shown in Chapter 5, a survey study was conducted to firstly explore the feasibility of a Flemish adaptation of the NYUCI (i.e., PROACTIVE) around the recruitment and intervention content for informal caregivers of people with early cognitive decline. Further, differences in informal caregivers' acceptability and potential helpfulness of the intervention content were also examined across subgroups stratified by using the interRAI Cognitive Performance Scale (CPS2).

Results showed that we could recruit enough target participants for the next stage of the study, which is the intervention testing and evaluation. Identified factors associated with the willingness to participate in the intervention, including level of cognition, co-habitation, education, and employment status, should be considered during the recruitment process. Lower cognitive functioning and co-habitation were consistently associated factors as in previous studies [24-25]. Misconceptions about early cognitive decline or early onset

dementia also were a possible factor, because results showed that 44.1% of the whole sample considered that unusual changes (e.g., memory loss) occurred in their relatives are a normal ageing process. A recent study supported our finding. It showed that the number of people who sought help from healthcare providers was less than the number of people who were tested and had mild cognitive impairment (MCI) [26]. The failure to acknowledge unusual changes as disease was reported as a barrier for the individual's acceptance process [27] and to seeking timely information and support [28].

The PROACTIVE intervention content (i.e., 14 types of services), as shown in our results, were acceptable by half of the total respondents who cared for a person with early cognitive decline (CPS2=1-4). Qualitative data analysis results also supported the respondents' need for guidance, training and information meetings, and perceived helpfulness of participation in a family-support group meeting. Tensions in family were reported in previous studies as a barrier for many informal caregivers to proactively seek help from professionals or other people [29]. Informal caregivers needed interpersonal support to help their other family members understand what the disease was and what the current situation was [30]. The most acceptable service shared across subgroups stratified by the level of cognitive decline (CPS2=1,2,3, and 4) was 'Knowing what changes to expect and how to adapt'. This is in line with previous studies which highlighted the importance of facilitation of early caregivers' adaptation process and future care planning [31-32]. Across the four subgroups, CPS2=3-4 subgroups had a higher acceptance of the intervention services compared to the CPS2=1-2 subgroups whose relatives were in very early stage of cognitive decline.

The entire intervention and its core components were perceived helpful by over half of our target population, and the 'peer-support group participation' component was perceived helpful by less than half of the sample. One reason might be the stigma related to dementia, which might cause informal caregivers' refusal to actively seek support from families, neighbors or friends [27-28, 33]. Informal caregivers may be in fear of the consequences of talking to peers due to the stigma, especially in the very early stage of cognitive decline (CPS2=1-2), even though they might want to share their stories. The consequences of the stigma were also echoed by the difference between the proportion of CPS2=1-4 group who needed to talk to peers (51.1%) and who perceived that peer-group participation would be helpful (47.8%). Across the four subgroups, the intervention was perceived helpful by almost three quarters of the respondents from the CPS2=3-4 subgroups, compared to 38.5% from the CPS2=1 subgroup and 58% from the CPS2=2 subgroup. The three core intervention components followed the same pattern. This finding is also consistent with the result of a higher acceptability of the intervention content in CPS2=3-4 subgroups. It means that the intervention would obtain greater cost-effectiveness in the CPS2=3-4 subgroups compared to the CPS2=1-2 subgroups.

Study	Design	Main findings	Implications
Psychosocial interventions for informal caregivers of older people with early cognitive decline	Systematic review	Timely effective interventions for this target group remained scarce. Mainly effective components were training, education, social support, and on-going support. Mainly underpinning theories were Stress Process Theory, PLST, PST, Competence-environmental Press Theory, Stress-health Process Theory, Stress, appraisal, and coping Theory. Systematic caregiver assessments were lacking. Main tools were an individualized risk assessment, JHDCNA, NYUCI caregiver assessment, a capacity and burden questionnaire, and a strength-based inventory.	Systematic caregiver assessments should be further developed and validated. More RCTs for informal caregivers of people with early cognitive decline should be performed. The review first identified the underpinning theories of interventions, effective components, and caregiver assessments. This is informative for researchers and policy-makers who attempt to build effective interventions for caregivers in similar context.
Determinants of informal caregivers' ability to continue care	Cross-sectional	Multiple factors were identified among the national population through combination of Stress process theory and Role theory. Factors were further refined and varied across several subgroups through a stratification of the national population using the CaRE and CPS.	Identified factors can inform future research which aims at developing interventions for caregivers with different levels of risk. Interventions related to family and social support are recommended, especially for subgroups with lower levels of risk. On-going support (e.g., ad-hoc counseling) should be

		Factors related to family and social support make a greater contribution to subgroups with lower levels of risk. Informal caregivers of people with borderline or mild cognitive impairment also perceived burden and were at risk of not being able to continue care.	considered throughout the entire caregiving process. The CaRE algorithm and the interRAI CPS scale can be used to quickly screen the risk levels of informal caregivers. Policy-makers should put emphasis on early caregivers through targeted interventions at the right time.
Feasibility, acceptability, and potential helpfulness of the PROACTIVE intervention	Survey	Recruiting enough participants is feasible and identified associated factors should be considered. The intervention content was acceptable and intervention components were perceived helpful by most respondents. CPS2=3-4 subgroups had higher acceptability and perceived greater helpfulness of the intervention.	Our study about recruitment feasibility and associated factors can inform research to improve recruitment for hard-to-reach populations. Further research on development and evaluation of the intervention is needed for CPS2=1-2 and CPS2=3-4 subgroups.

Strengths and limitations

Strengths

In the systematic review, we used the rigorous and validated PEDro scale to assess the methodological quality of selected randomized controlled studies. In this way, we could find the most robust RCTs which met the quality criteria. This helped us to identify the most promising evidence-based psychosocial interventions which could improve the capacity and wellbeing, as well as health outcomes of informal caregivers of people with early cognitive decline. Guided by the MRC framework, the identified most robust ones also could prepare a ground for our following development phase of our research.

In the study concerning the determinants of informal caregivers' ability to continue care, one strength is the representativeness of the study population as it came from a national project called Protocol 3. This allowed us to stratify the whole population by using the CPS and CaRE

algorithm, and further investigated the determinants across subgroups with different degrees of cognitive performance and risk of caregiver's burden. Moreover, various instruments, including a comprehensive geriatric assessment (i.e., interRAI HC), the ZBI-12 and an informal caregiver questionnaire were used to collect data so that we could consider multiple factors in our regression model building, such as social, physical, psychological, as well as context factors.

In the survey study, we used the interRAI CPS2 to stratify our target population as subgroups with different levels of cognitive performance. The results from the subgroup analyses allowed us to identify which subgroups most accepted the intervention and perceived it helpful to achieve a greater cost-effectiveness. Moreover, based on the results of the subgroup analyses, we will be able to further develop and refine the intervention across different subgroups.

Limitations

We only included peer-reviewed publications written in English in our systematic review, which may have missed effective psychosocial interventions in the 'grey literature' or written in other languages. Also, we only selected studies with an RCTs design, because we attempted to identify the effectiveness of studies with a standardized evaluation of outcomes, including an experimental and control group.

In the study concerning the determinants of informal caregivers' ability to continue care, we used a cross-sectional study sample rather than longitudinal data. This limited our ability to explore factors associated with the changes occurred in informal caregivers' caregiving status, from being able to continue care at home to long-term care admission.

In the survey study, a convenience sampling method with self-selection was used to recruit participants, which is not representative for the whole population in Flanders. The respondents of the sample, however, were recruited through channels that are of interest to informal carers of people with dementia, which implies they may be the ones who need the intervention, and already had basic knowledge about dementia care.

The primary goal of the PhD research is to develop an evidence-based psychosocial intervention and assess its feasibility in Flanders, Belgium using the implementation science framework (i.e., MRC), instead of proposing a conceptual framework for intervention development tailored to the Flanders context. The emphasis is more on the practical development and evaluation of the intervention rather than on theoretical exploration. Regarding the conceptual framing or theory construction of the PhD research, it is limited, although certain theories were applied, like Pearlin's Stress process theory and Role theory.

Given the limited conceptual framing of the current research, a theory-driven approach in future work is considered to develop a theory of change to evaluate the PROACTIVE intervention in Flanders. A theory-based perspective will be included to ground the intervention in a theoretical framework (i.e., theory-based evaluation). The application of Theory of Change (ToC) can strengthen key stages of the MRC framework, developing a theory to improve understanding of how and why the intervention works [34]. This developed theory

will outline the causal pathway of the intervention in Flanders, i.e., under what circumstances, by which means of processes, and what changes are expected.

Practice, research, and policy implications

Practice Implications

Chapter 4 showed that the validated CaRE algorithm and the CPS scale versions CPS or CPS2 can be used as a screening tool to effectively stratify the whole population in subgroups with several levels of risk of caregivers' burden and levels of care recipient's cognitive impairment. The validated CaRE algorithm and the CPS scales can be automatically calculated after professional caregivers' completion of an interRAI HC assessment, which is currently being implemented in Belgium and is used internationally in many countries. Professional caregivers (e.g., physicians, social workers, nurses, occupational therapists, etc.) can utilize the information gained via the CaRE and CPS to identify the informal caregivers are at which levels of risk of burden (e.g., low, high risk, etc.) and at which stage of cognitive decline (e.g., early, advanced stages, etc.). According to the levels of risk at which the informal caregivers are, professionals can proactively address the most relevant factors associated with their ability to continue care to avoid a potential crisis (e.g., long-term care admission) in future. For example, professionals can refer available services concerning family support (e.g., family counseling) to the informal caregiver with low risk of burden, which will make a big difference to this family. In addition, professionals can pay special attention to informal caregivers with a lower level of risk, because these caregivers may benefit more from timely support or help. Moreover, information about individualized counselling on request should be provided to informal caregivers by professional caregivers as these associated factors vary across caregivers at different levels of risk with the ongoing caregiving situation.

Case management is an intervention to improve care quality of frail older people and their informal caregivers through a way of coordination and integration of care, which has been proved effective and implemented in Belgium [35]. A case manager serves as a bridge between older people, healthcare professionals, health care systems and community resources, which can help older people and their informal caregivers navigate the caregiving journey when the support is most needed and best accepted. Under this context, the case managers can help the recruitment of target participants for the PROACTIVE evaluation in the following research phase. Specifically, case managers can help introduce the PROACTIVE program to the family caregivers when they identify older people with early cognitive decline (CPS2=1-4) during the early assessment of older people. Additionally, based on the identified factors associated with the recruitment in Chapter 5, case managers should pay more attention to the following subgroups: family caregivers of people with very-early-stage cognitive decline (CPS2=1-2), family caregivers who are part-time employed, family caregivers with lower education level (e.g., less than high school), family caregivers who live with the older person. These subgroups may need more time or relevant knowledge to understand the PROACTIVE program and then participate in the intervention. A case manager can play a crucial role in proactively finding the early at-risk informal caregiver (e.g., very early or probable dementia caregivers) who are often hidden but vulnerable without any formal help from the healthcare system.

In Belgium, the general practitioner (GP) plays a crucial role in engaging with older people, as a gatekeeper for personal health. When a person presents cognitive problems, the GP usually conducts initial cognitive screening using tools like the Mini Mental State Examination (MMSE) or the Clock Drawing Test. Behavioral problems are often assessed through interviews with the accompanying caregiver. While some GPs do refer patients to specialized services, such as hospitals, memory clinics, geriatricians, neurologists, it is not the norm across the healthcare system yet [36]. Some GPs are unaware of family caregivers' problems or they are unaware of early cognitive decline presented in older people due to perceived lack of time, time-consuming assessment process, and the sense that they have nothing to offer until later in the disease [37]. Efforts to promote training and awareness among GPs regarding BelRAI Screener, BelRAI Home Care instruments. This would facilitate the GPs' access to CPS2 and CaRE assessment results and management, as well as improving collaboration between GPs, professional caregivers and specialized services, could enhance the timely recognition of people with early cognitive decline and early identification of at-risk informal caregivers, and provide them with timely referrals and targeted support during the entire caregiving process. Moreover, GPs can help the recruitment process to the PROACTIVE program when they identify the people with early cognitive decline through accessing the CPS2 and CaRE algorithm results. They are key partners in the use of this strategy, as they are the ones who establish a trusted relationship with the patient, informal caregiver, and other family members. They can especially help for recruiting hard-to-reach groups.

The feasibility study showed that the CPS2=3-4 subgroups had a higher acceptability and greater perceived positive effect of the intervention compared to the CPS2=1-2 subgroups. Considering the cost-effectiveness of a multi-component intervention and the capacity of counselors to deliver the intervention, the CPS2=1-2 subgroups could be referred to available local initiatives (e.g., 't moNUment inloophuis dementia etc.) by professional caregivers based on their needs reported in this survey study. In addition, the stigma of dementia, family tensions and acknowledgement of cognitive decline are still big problems at the beginning. Professional caregivers should keep an eye on these potential problems that occurred in dementia families and give some guidance and information to them when it is necessary.

Research implications

The findings of our systematic literature review revealed that effective psychosocial interventions on supporting informal caregivers of older people with early cognitive decline are still lacking. Most interventions focused on informal caregivers who cared for a person with dementia regardless of the stage of the disease. Future research should consider more RCTs to develop and evaluate psychosocial interventions for early informal caregivers, especially those who care for people with early cognitive decline. Timely effective interventions for this early caregiver group could contribute to the sustainability of healthcare. In addition, in order to deliver needs-matched and cost-efficient interventions for caregivers, the international systematic assessment tool, interRAI Self-report of Carer Needs (SCaN) (https://catalog.interrai.org/SCaN-manual-standard-10.0), should be used and validated in future studies. This is the first literature review to identify the underpinning theories of effective interventions and intervention core components for informal caregivers of people with early cognitive decline. These findings can help researchers to better understand why

these interventions could produce the expected effective outcomes, as well as which intervention components are more promising and which intervention components have a unique functioning compared to other interventions. For example, provision of ongoing support (e.g., ad-hoc counseling, plans of maintaining learnt skills) showed a unique functioning of the intervention to produce the sustained benefits for years. This is informative for researchers from several disciplines who are seeking to build effective interventions for caregivers in similar caregiving contexts. Moreover, multi-component interventions (e.g., education, social support, training etc.) showed to be more effective than single-element interventions.

To our knowledge, this is the first study to stratify a large sample of vulnerable people from a national project called Protocol 3, as informal caregiver subgroups with several levels of risk of burden and levels of cognitive impairment using the CaRE algorithm and the CPS. Two theories - Pearlin's Stress process theory and the Role theory, were applied in this study to explore multiple factors associated with informal caregivers' ability to continue to provide care at home across subgroups with different levels of risk. The results showed that the associated factors vary across several degrees of cognitive decline and risk of caregivers' burden. These associated factors (e.g., availability of a secondary caregiver etc.) can contribute to future research that attempts to develop or adapt psychosocial interventions for informal caregivers with different levels of risk. The stratification of the study population can also be a valuable strategy to provide targeted intervention for caregiver groups with different levels of risk, which could produce more cost-efficient outcomes using available resources. Moreover, the study suggested that informal caregivers with a lower level of risk may benefit more from interventions with family and social support resources included compared to subgroups with higher levels of risk. This finding further confirms the benefits of timely interventions on supporting early informal caregivers and highlights the significance of research to timely support for early informal caregivers in future. Timely support for early informal caregivers to maintain their wellbeing and ability to continue care should be put emphasis on in future research. Identified factors in this study can help researchers design their research on interventions for informal caregivers in similar context (e.g., chronic condition, cancer etc.).

This study provides first evidence for the feasibility, acceptability, and potential helpfulness of a Flemish adaptation of the NYUCI (i.e., PROACTIVE) on supporting informal caregivers of older people with early cognitive decline. This feasibility study can avoid research waste and prepare a ground for future evaluation research. Results of this study showed that we could recruit enough participants to conduct the intervention testing and evaluation in the next research phase. Factors associated with the willingness to participate in the intervention were also examined. The findings could give insight on the recruitment of hard-to-reach, vulnerable populations for intervention implementation studies in the field of implementation science. Further, a stratification of the respondents was performed using the interRAI CPS2. Compared to the subgroups with very early stage of cognitive decline (CPS2=1-2), the CPS2=3-4 subgroups showed higher acceptability and greater perceived helpfulness of the intervention. This helps to reconsider the original target population of the intervention and the delivery of the intervention according to the levels of cognitive decline (CPS2). It also helps researchers to pay more attention to the specifics of target population when they develop and evaluate a multi-component intervention for informal caregivers, especially where exist budget and cost

issues. Cost-effectiveness should be considered and targeted interventions for the right population at the right time could save cost as well as achieve effectiveness.

Pearlin's Stress process theory is a product of considerable exploratory research among spouses and adult children who care for relatives with Alzheimer's disease, which provides a general understanding of the stress process [38]. The New York University Caregiver Intervention (NYUCI) underpinned by Pearlin's Stress process theory targets family caregivers of relatives with all stages of dementia as well [39]. Building on this existing theory, the empirical findings of Chapter 4 and Chapter 5 provide some insights about caregivers' needs and ability to continue care at the early-stage caregiving process (i.e., early cognitive decline) across several degrees of cognitive decline and risk of burden. Early-stage caregivers' needs and associated factors with caregivers' ability to continue care were further explored and refined across several subgroups, which extends the existing Stress process theory by adding several early-stage caregiving processes. For example, social participation of frail older people is a protective factor associated with caregivers' ability to continue care across several degrees of cognitive decline and risk of burden. People with early cognitive decline mostly still can participate in social activities. Whether this factor can be added to the 'Mediators' domain of the Pearlin's Stress process model, which may need further research on early-stage caregiving process in future. Caregivers' feelings of distress, anger, depression is an outcome in the Pearlin's Stress process model, however, it is a risk factor when the outcome is caregivers' ability to continue care in our study findings. Moreover, we found some interesting trends in factors associated with caregivers' ability to continue care, i.e., factors related to family and social support play a greater role in subgroups at lower levels of risk. This may inform future theoretical study on caregiving processes in different caregiver subgroups at different stages building on our findings and existing stress process model. In Chapter 5, we found that early-stage caregivers of people with early cognitive decline most need help with early adaptation, future planning, problems with changes in relationships. This finding can inform future theoretical exploration on if these factors can be added to the 'Coping and Social support' domain of the Pearlin's Stress process model.

Policy implications

The healthcare system faces increasing pressure from the ageing population and a greater proportion of people with dementia. Informal care is well recognized and increasingly emphasized by policy-makers, as people 'Ageing well in place' who are cared for by informal caregivers could reduce public healthcare expenditure. It is crucial for policy-makers to support informal caregivers more efficiently, because informal care is actually costly due to opportunity cost, such as caregivers' worsening health, productivity loss etc.

The findings of this study suggest that policy-makers should put emphasis on supporting early at-risk informal caregivers through targeted interventions at the right time. Informal caregivers of older people with early cognitive decline were also at risk of not being able to continue care for their relatives at home. Informal caregivers at a lower level of risk can benefit more from family and social support resources, which is informative for policy-makers' decision on supporting early informal caregivers who are often left out of formal help. The needs of these early informal caregivers should be recognized by policy-makers as well as the

hidden cost can be saved by enhanced health and wellbeing of informal caregivers through policy support. If these informal caregivers' needs are not addressed at the right time, older people with early cognitive decline and their family caregivers may inadvertently undermine their health and wellbeing, thus leading to long-term care admission of care recipients and healthcare cost of informal caregivers due to their worsening health condition.

The stratification strategy using the CaRE algorithm and the CPS would enable policy-makers to quickly assess informal caregivers' levels of risk of burden and stages of care recipients' cognitive decline. The assessed data can be monitored and accessible by healthcare professionals through the integrated platform (i.e., BelRAI), as the CaRE algorithm and the CPS can be automatically calculated from the interRAI HC. The general practitioners (GPs), as the first contact with clients, often have a close and trusted relationship with the clients and the families. Policy-makers and continuing education programs of university medical faculties can foster the provision of brief training courses concerning the CaRE algorithm and the CPS for the GPs, so that they can make timely referrals for informal caregivers with different levels of risk. In Flanders, a formal diagnosis of dementia usually comes 3–4 years after the first symptoms of cognitive problems and it takes twice as long in the case of a young early-onset dementia. Policy-makers can also tap into the BelRAI Screener to quickly screen people with early cognitive decline (i.e., CPS2=1-4), as this instrument has been a tool for eligibility of home care services.

Regarding the possibility of the uses of the 226.000 results of the BelRAI Screener in Flanders, these data can be used in machine learning models to identify predictors of people with different levels of cognitive decline. By examining the characteristics and factors associated with different levels of cognitive decline indicated in the CPS2, which can be automatically calculated in the BelRAI Screener, predictors for specific levels of cognitive decline can be recognized. Based on the fast predicted level of cognitive decline and findings of chapter 4 and 5, GPs and professional caregivers could efficiently provide targeted referral services and timely support interventions, helping reduce relevant risks in identified families. Another possibility is to analyze trends and patterns of cognitive decline at Flemish population-level using the real-time large data from the BelRAI Screener. Policy-makers can gain insights into the prevalence of people with different levels of cognitive decline, identify vulnerable groups who most need support, and efficiently provide targeted services. This can help avoid potential caregiving crisis during the 3–4-year period without any awareness of the risk and formal help.

Future research

The latest Informal Care Plan in Belgium emphasizes that healthcare professionals should be aware of the role of informal caregivers and provide more and better professional support for them. Early informal caregivers, however, are often left out of formal help. Especially, there is a diagnosis time gap (i.e., 3-4 years) from when people show early signs of cognitive decline to when people get a formal diagnosis of dementia. Our results showed that informal caregivers with lower levels of risks of perceived burden could benefit more from targeted interventions at the right time. Professional caregivers (i.e., assessors) could use the CaRE and CPS to quickly screen these early informal caregivers with several levels of risks in routine care,

by using the BelRAI system with a digital platform in Belgium. To close the diagnosis time gap and to provide timely support for these early caregivers, prospective studies should consider how physicians (e.g., GPs, neurologist, geriatricians, etc.) and the assessors (nurses, physiotherapists, social workers, etc.) could cooperate and communicate the information (i.e., diagnosis results, the CaRE and CPS levels) more smoothly and efficiently to help early informal caregiver navigate their caregiving journeys since the beginning. The GPs who have a trust relationship with families can assess the risk level of informal caregivers (i.e., the CaRE), the cognitive performance level of care recipients (i.e., the CPS), the formal diagnosis. This allows GPs to make timely referrals for these at-risk families. It is also important to ensure the GPs and other caregivers to be aware of local available resources for informal caregivers, a brief training package may be needed to develop. This cooperation between physicians and the whole care and support system, including assessors can proactively provide timely support to at-risk hidden caregivers, thus efficiently avoiding potential family crisis for 3-4 years period without any formal help. A study also reported the success of recommendation of support services from the GPs to informal caregivers [40].

Regarding the opportunity for future research projects due to the reform of home care in Flanders and the implementation of the BelRAI HC and the BelRAI LTCF, the further application of CaRE algorithm and innovative approaches to care for informal caregivers and patients can be explored due to the BelRAI integrated platform and large real-time datasets. For instance, we can explore the development of personalized care models or AI algorithmic care models for at-risk caregivers based on the large real-time datasets and explore the personalized support package based on the research findings. Further, we could investigate the effectiveness, feasibility, and acceptance of these new approaches in improving outcomes and experiences for at-risk caregivers.

Further research on development and evaluation of the PROACTIVE intervention in CPS2=1-2 and CPS2=3-4 subgroups is needed through the combination of the Theory of Change (ToC) and MRC frameworks. This combination can strengthen the development and evaluation stages in the MRC framework by providing a visual tool which covers detailed and dynamic specific factors in all stages of the causal pathway through which the factors impact a sequence of outcomes. The visual tool is developed through enhanced stakeholder engagement and embedded in the local context, which establishes the commitment of the required local resources and can make the intervention have an impact in real world through implementation. Context analysis (e.g., national plans, policy, local initiatives etc.) and stakeholder meetings (e.g., representatives of target population, experts, local communities etc.) will be performed to refine the intervention content for CPS2=1-2 and CPS2=3-4 subgroups within the contextual conditions to smoothly implement the intervention in real world. Moreover, informal caregivers of young people with early cognitive decline will be included in the target population in future research.

To refine the core components of the PROACTIVE intervention, it is important to explore additional resources (e.g., secondary caregivers) to supplement and extend the single-family caregiver model in future research. Supplemental caregivers showed beneficial effects for the primary informal caregiver in our study. Future research should consider establishing an

extended family network for the primary informal caregiver, where the professionals treat the whole family as a unit and provide such support as family tension solving. It is promising and has great potential benefits to involve other family members in the primary caregivers' caregiving process in Belgium. In addition, the feasibility (e.g., budget, cost-effectiveness, capacity of counselors etc.) of individualized counseling tailored to the primary caregiver and to other family members should be studied in future considering the success of this core component. The validity and usefulness of the interRAI Self-Reported Carer Needs (SCaN) in Flanders will also be studied in future research, so that the professionals can provide tailored support to families based on the results of this systematic caregiver assessment.

Conclusion

This study provided evidence that informal caregivers of people with early cognitive decline need support for their caregiving activities and that interventions targeting this group of caregivers can have positive effects on their health and wellbeing, as well as give them motivation and support to continue with their care activities. The study also added value about the feasibility, acceptability, and potential helpfulness of a Flemish adaptation of the NYUCI (i.e., PROACTIVE) on supporting informal caregivers of older people with early cognitive decline in Belgium. The recruitment of enough target participants for a subsequent RCT evaluation study is feasible. For most informal caregivers, the intervention content is acceptable. They also perceive the intervention as helpful. The PROACTIVE intervention has great potential to improve the health and wellbeing of informal caregivers who care for a person with early cognitive decline and a subsequent RCT evaluation study should be considered in future research.

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List of Abbreviations

ADL: Activities of Daily Living

IADL: Instrumental Activities of Daily Living

CAPs: Clinical Assessment Protocols

IADL-P: IADL performance

ADL-H: ADL Hierarchy Scale

CPS: Cognitive Performance Scale

CPS2: updated CPS

DRS: Depression Rating Scale

interRAI HC: interRAI Home Care instrument

ZBI 12: Zarit Burden Interview – 12 items

CaRE: Caregiver Risk Evaluation algorithm

MRC: Medial Research Council

NYUCI: New York University Caregiver Intervention

PROACTIVE: suPpoRting infOrmal cAregivers of older people with early CogniTIVe declinE

Curriculum Vitae

Shanshan Wang was born in Handan, a city in the northeast of China, on July 10 1992. In China, she completed her 4 year bachelor degree in management, 3 year master degree in management, then she started her PhD in LUCAS, KU Leuven with a Scholarship from China. Her PhD research focused on supporting informal caregivers of people with early dementia or cognitive decline under the MRC framework, which was supervised by Prof. dr. Anja Declercq and dr. Johanna de Almeida Mello.

List of publications and presentations (Within 5 years)

Wang S, de Almeida Mello J, Declercq A. Factors associated with informal caregiver's ability to continue care: a subgroup analysis. Age and Ageing. 2022 Dec;51(12):afac275.

Wang S, de Almeida Mello J, Declercq A. Assessing psychosocial interventions for informal caregivers of older people with early dementia: a systematic review of randomized controlled evidence. Frontiers in Bioscience-Landmark. 2021;26(9):556-71. Special Issue 'The polyhedral aspects of dementia'.

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Zhang Y, Wang S, Akram T, Hong Y. Knowledge co-creation with multiple stakeholders: the case of SMEs in China. Journal of Business & Industrial Marketing. 2023 Jan 27.

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Wang, S., De Almeida Mello, J., Declercq, A. (2022). Factors associated with informal caregivers' ability to continue care: A subgroup analysis. Presented in Congress of the European Union Geriatric Medicine Society (EuGMS), London, England.

Wang, S., De Almeida Mello, J., Declercq, A. (2020). EaRly dEmentiA Caregiving supporT (REACT) program: study protocol for experiment and evaluation with interRAI instrument through the Medical Research Council framework. Presented in the World InterRAI Conference Leuven, Belgium.

Annex - list of all PhD in Social Sciences/PhD in Social and Cultural Anthropology

Title: "Doctoraten in de Sociale Wetenschappen en in de Sociale en Culturele Antropologie"

Link: http://soc.kuleuven.be/fsw/doctoralprogramme/ourdoctors