Access to Timely Formal care

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The proposed project ACTIFCare (ACcess to TImely Formal Care) aims to increase our understanding of why PwD and their caregivers use, or fail to use formal care services. In our study, formal care includes home nursing care, day care services and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Dementia and amnestic conditions
Study type	Observational non invasive

Summary

ID

NL-OMON47170

Source
ToetsingOnline

Brief title
Actifcare

Condition

- Dementia and amnestic conditions

Synonym
Dementia, memory disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMw (i.h.k.v. Joint Programming Neurodegenerative Diseases)

Intervention

Keyword: Access, Best-practice, Dementia, Middle-stage

Outcome measures

Primary outcome

Service use (measured by means of the RUD, Resource Utilization in Dementia)

Needs (measured with the CANE, Camberwell Assessment of Needs in the Elderly)

Secondary outcome

Measures

Measures that the person with dementia and the carer will complete together

with the interviewer:

* A service use checklist to capture services that are being used, those not

used and reasons for non-use will be developed specifically for this project.

* A brief questionnaire to collect socio- demographic information will be

developed specifically for this project.

Measures that the person with dementia will complete with the interviewer:

* Quality of life will be measured with the 13-item Quality of Life-

Alzheimer*s disease Scale (QOL-AD). This measure has reported good validity and

reliability and it has been recommended in a European consensus paper.

* Health related quality of life of the PwD will be assessed with the EQ-5D-5L.

This measure has been validated in a number of European countries and has

recognised potential as a health utility measure.

* The ICECAP-O is a recently developed outcome measure that is not yet

available on the EU level, and which is being validated as part of this project.

* Health-related quality of life will be measured with the DEMQOL-U a brief

measure that will be used to inform economic evaluation.

* Quality of the relationship with the primary carer will be measured by the 5 item Positive Affect Index (PAI).

* The participant*s cognitive functioning will be assessed with the Mini Mental State Examination (MMSE).

Measures that the carer will complete about themselves:

* The carer*s anxiety and depression will be assessed with the 14 item Hospital Anxiety and Depression Scale (HADS).

* *Perseverance time* * a single item simple estimate of how long the carer considers they could continue if the situation remains unchanged

* Stress specific to care-giving will be assessed with the 15 item Relative*s Stress Scale (RSS).

* The Locus of Control of Behaviour Scale, a 17 item self-report scale which provides a measure of both internal and external locus of control.

* The carer*s sense of coherence will be assessed with the 13-item SOC-13 scale.

* Social isolation will be measured by the Lubben Social Network scale (LSNS-6).

* Quality of relationship will be evaluated from the carer*s perspective using the PAI.

* The CarerQol is a recently developed measure that is being validated as part of the project.

* EQ-5D-5L will be completed by the carer regarding his/her own situation.

* ICECAP-O will be completed by the carer regarding his/her own situation.

Measures that the carer will complete about the person with dementia:

* Functional ability in activities of daily living will be assessed by the Lawton Instrumental Activities of Daily Living Scale (IADL) with the Physical Self-Maintenance Scale (PSMS) used for more basic skills.

* Behavioural problems will be assessed with the Neuropsychiatric Inventory questionnaire (NPI- Q).

* DEMQOL- U Proxy will be completed by the carer in relation to the quality of life of the PwD.

* QOL-AD will be completed by the carer in relation to the quality of life of the PwD.

* EQ-5D-5L will be completed by the carer in relation to the quality of life of the PwD.

* ICECAP-O will be completed by the carer in relation to the quality of life of the PwD.

Measures that the researcher will complete:

* Met and unmet needs will be assessed with the Camberwell Assessment of Need for the Elderly (CANE) based on discussion with both the PwD and carer.

* Comorbidity will be assessed with the Charlson Comorbidity Index.

* The participant*s severity of dementia will be summarised with the Clinical Dementia Rating Scale (CDR).

Study description

Background summary

Neurodegenerative diseases such as Alzheimer*s Disease and related disorders constitute the most significant health, social and economic challenge of the 21st century. It is estimated that 9.9 million people in Europe have dementia [1] accounting for over 28% of the total number of people with dementia worldwide. The total cost of medical and social care for Alzheimer*s disease in Europe is an estimated USD 135.04 billion [1]. Two thirds of people with dementia (PwD) are living in the community, either alone or with a family member. In the early stages, people can often continue to perform many tasks independently. As the condition progresses, PwD will need increasing amounts of care and support from sources such as family and social care services, as they start to lose the ability to perform everyday tasks. Significant care and support is provided by unpaid family carers; over 70% of PwD in Europe are currently receiving unpaid care [2]. These informal carers are often partners of advanced age who face health and social care challenges themselves. Informal carers can experience high levels of stress, depression, social isolation and physical health problems [3].

In recent decades, the European Parliament, together with national and international organisations such as Alzheimer*s Disease International (ADI), have adopted strategies to promote timely recognition of dementia [4]. An early diagnosis is regarded as a prerequisite for improving dementia care, creating an opportunity for all involved to proactively collaborate to make key life-changing decisions regarding post-diagnostic care. Furthermore, early diagnosis enables appropriate support services to be identified, and allows health care professionals to plan and utilise resources, and avoid crises (for example, as described in reports from ADI, NHS, Alzheimer Associations etc).

Timely access to these dementia care services is seen as crucial to reduce health care costs by postponing nursing home placement, increasing quality of life for patients, and reducing carer burden. Timely services are preferred to early services in this context, with the emphasis on support being personally tailored and so reducing the risk of overtreatment, under treatment and maltreatment. Improved home care support will help to maintain independence and dignity, enabling the PwD to stay at home longer with their families if the right support is put in place that focuses on their needs. Most countries acknowledge this is important and have policies to develop better home-based and community services and aim to reduce institutionalisation [5].

Unfortunately, research has revealed that PwD and their carers are not receiving the correct type of services or quality needed, and that they experience much difficulty accessing and working with community care services, even when having a diagnosis of dementia [6, 7]. This can put increasing pressure on PwD and their carers which might lead to admission to a residential home simply because the appropriate support is not in place [8]. Thus, despite the favourable outcomes of timely access to formal care and the need for these services to support informal carers, low rates of service use can still be observed. Additionally, there is great diversity and inequity among different health care and social care systems related to dementia between and within individual European countries.

The right to health care is an essential element of the Universal Declaration of Human Rights [9] and of the UN Convention on the Rights of Persons with Disabilities [10]. It is widely acknowledged that social and economic inequalities in access to health care should be eliminated to meet the needs of older persons [11]. Therefore, there is a need for research based studies to chart, analyse and evaluate the strengths and weaknesses of individual pathways to care. The impact of dementia on the population of Europe is of such a magnitude that this problem must be addressed collaboratively across European countries.

The Andersen Behavioural Model of Use of Health Service [12-14] is a theoretical framework which can be used to better understand access to and use of services. The main assumption in this model is that certain factors predispose a patient and their carer to service use (predisposing variables), while other factors enable such use (enabling variables), and others determine the need for care (need variables), which precedes service use. Predisposing variables are intrapersonal factors such as demographics and attitudes. Enabling variables are resources (such as access systems, waiting lists, health insurance coverage and rurality) that support or impede service use. Need variables are impairments of patients and caregivers that require services. There is a complex relationship between needs and the demand for care and service use in dementia due to needs changing constantly because of the progressive nature of dementia and due to the fact that individuals are able to adapt to their situation [15]. The Anderson model will be used to assess the potential equality of access to and utilisation of services in Europe, by identifying associations between service use and a broad spectrum of predisposing and enabling variables, while controlling for need. To date it is not clear to what extent the equality of service access and delivery influences the quality of life of patients and their carers, and whether this differs between countries. This type of information is very important for our understanding of existing social and health care systems and will provide the basis for subsequent initiatives.

Study objective

The proposed project ACTIFCare (ACcess to TImely Formal Care) aims to increase our understanding of why PwD and their caregivers use, or fail to use formal care services. In our study, formal care includes home nursing care, day care services and community or long-term medical, nursing, and social care structures and processes, and excludes domestic home help, housekeepers, volunteers, support groups, transport services, and meal programmes. A European cohort study will assess the access to formal care in relation to met and unmet needs and quality of life in community dwelling PwD and their carers and will gather clinical data of dementia patients and their carers. Cost data are a necessary prerequisite for political and stakeholder decisions, and will be collected alongside the clinical assessments in order to generate an empirical basis for the identification of best practices. The potential equality of access to and delivery of services will be assessed by analysing associations between service use and predisposing and enabling variables, while controlling for need in accordance with the Andersen Behavioural Model of Health Service Use. The results of the project will greatly help to define best-practice strategies for access to formal care in dementia across Europe, enabling PwD and their caregivers to receive the right amount and intensity of formal care when and where needed, and to increase their quality of life.

The current proposal is innovative as it explicitly focuses on the middle stage of dementia, which until now has not received proper attention, in contrast with early stages of dementia or later stages of institutionalisation.

We will build on a FP7 project called Right Time Place Care (RTPC) but with a different focus, going deeper into aspects that were only touched on by the RTPC. In RTPC, establishing a case manager throughout the trajectory was regarded as a sign of best-practice and tailor-made care indicated compliance with the concept of person-centered care. This will be explored in more depth in the qualitative semi- structured interviews in Work Package 3 (described below). The use of combined methodology using both qualitative and quantitative outcomes will yield a far broader insight into the reasons why PwD and their carers use, or do not use, available services, and these outcomes will be essential for a better alignment with patients* needs. A timely arrangement of formal care services i.e. a personalised optimal timing (not too soon, not too late) at which the transition from informal care to formal care takes place may offer significant benefits in the future that relate to the quality of life of PwD and their carers. Timely service utilization might have important implications such as delaying institutionalisation [22]. Knowledge about enabling and predisposing factors regarding access to care services can advance the state of the art in health systems research into pathways to dementia care, in order to benefit PwD and their informal carers.

Additionally this project will provide the opportunity to validate two novel patient and carer related outcome measures on Quality of Life aspects, the ICE-CAP-O and the CarerQoL, which have been designed already, but are not available yet on the EU level.

Overall aims

The aims of the ACTIFCare project are:

1) To better understand access pathways to formal care for PwD living in the community across Europe.
2) To identify factors that determine the appropriateness of timely access to formal community services at macro and individual levels.
3) To analyse costs and consequences of access pathways to formal home care.
4) To evaluate the utility of two recently developed patient and carer outcome measures in support of this (i.e. the ICECAP-O and CarerQol).
5) To develop and promote best-practice strategies.

Study design

Overall methodology

To achieve the above aims, the work plan consists of six work packages (WPs). Work package 1 comprises the overall project management. WP2 involves a review of access pathways to formal home care, based on literature review, expert consultation, and focus groups. In WP3 a European cohort study will be performed to examine the predisposing and enabling factors in relation to access to formal care, needs and quality of life in community dwelling dementia patients and their carers. A cost*consequences analysis, based on the clinical and economic data assessed in the cohort study, will be performed in WP4. WP5 focuses on the identification of good-practice pathways to access formal care and the development of best-practice strategies, in terms of costs and consequences. WP6 concerns the public awareness of the project, dissemination of the results to relevant stakeholders, including national political decision makers, and providing implementation support, dissemination of best-practice strategies, and initialisation of a platform for research and advocacy regarding economic evaluations of dementia care across Europe.

The following protocol aims to provide a detailed description of the qualitative and quantitative work involved for package 2 (access to timely formal care in Europe), package 3 (the European cohort study) and package 4 (economic aspects).

Work Package 3: Development, implementation and analysis of a cohort study on factors associated with the (non) utilisation of formal care services in Europe.Research Objectives

1) Exploring the predisposing and enabling factors that are associated with the use of formal care services.
2) Exploring the association between the use of formal care, needs and quality of life in PwD and their informal carers.
3) Comparing these across participating EU countries.

Method

All 8 partner countries (Germany, Ireland, the Netherlands, Norway, Sweden, United Kingdom, Italy and Portugal) will be included in the cohort study to maximise variety and contrast e.g. between northern and southern European countries. The cohort study will be a one-year, international, prospective, observational study.

Work Package 4: Economic aspects

Research objectives

1. Understanding the costs and consequences of formal care services utilisation in people with unmet needs in Europe.
2. Determining the major costs and quality of life drivers and the relation with formal care services across European countries.
3. Validation of the ICECAP-O instrument and the CarerQol instrument for the assessment of quality of life in relation to the timing of formal care in Europe.

Research methods
Costs and effects will be examined based on the principle of cost-consequence analysis. This type of analysis lists all relevant costs and consequences in order to capture as much information as is feasible, in order to allow decision makers to choose the outcome of interest for inclusion in economic analyses [3]. Data on several HTA measures will be gathered in the cohort study of Work Package 3 in all participants (N=50 in all 8 countries). A detailed description of the sample, recruitment, design and measures is described in the work package 3 chapters of this protocol.

Study burden and risks

Since no intervention is applied in this study, the risk for patients and their carers is expected to be nil. Patients and informal caregivers participating in the cohort study may however experience some burden due to the time investment of the applied questionnaires and clinical tests. In addition, the questionnaires and tests may be confronting resulting in emotional strain. The direct benefit for patients and carers participating in the cohort study is increasing awareness of formal care services in dementia and own care needs. However, the project will mainly benefit society, as the best-practice recommendations will be implemented in national and European guidelines and laws. In addition, there are indirect benefits to society in terms of contribution to significant knowledge on access to formal home care in Europe.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

(1) The patient has a diagnosis of dementia meeting DSM IV TR criteria following an assessment by a clinical professional.
(2) The person with dementia has a Clinical Dementia Rating indicating mild or moderate degree of dementia (i.e. scores 1 or 2) and scores 24 or less on the MMSE. (Note: overall in each country the intention is that the sample should comprise 50% people with CDR of 2).
(3) The patient is not receiving regular assistance from a paid worker with personal care, on account of his/her dementia, such as help with dressing/undressing; washing/ bathing/ showering; toileting; feeding/drinking; taking medication. (Note: *regular* is defined as at least once per week; *paid worker* includes those paid by health and social care services and those paid direct by the person and his/her family).
(4) A professional judges that additional assistance with personal care is likely to be considered / required within one year.
(Note: The concept of need for additional assistance is rather ambiguous, and a subjective risk estimate will be used to assess this need. This estimation will be made by any health care professional who is involved in the care of the patient and is in a position to judge the level of care needed. This will include multiple sources, including psychologists, general practitioners, memory clinic staff members, and other health care or social care professionals.
(5) The person with dementia has a carer who is able and willing to participate also and is in contact at least once per week. The carer does not have to be residing with the carer, they could be a relative, friend or neighbour in regular contact.
(6) The person with dementia and their carer consent to participate.
(7) The person with dementia is competent to participate in the current study

Exclusion criteria

(1) The person with dementia has no identified carer in regular contact.
(2) The person with dementia or their carer is not able to complete the assessments due to communication/ language/ hearing/ understanding/ literacy problems that cannot be compensated for.
(3) The person with dementia or their carer has a terminal condition or comorbidities

(including long-standing severe mental illness) contributing to a significant level of disability.
(4) The person with dementia or their carer has a life-long learning disability or severe physical impairment that would prevent them from being able to complete the assessments.
(5) The person with dementia resides in a care home or nursing home or has been resident in a care home or nursing home (e.g. for respite) during the previous six months.
(6) The person with dementia has a diagnosis of alcohol-related dementia or of Huntington*s disease.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-03-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	23-12-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	05-07-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL49382.068.14