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The Qualidem project in Belgium. A two-center study on care needs and provision in dementia care: inclusion criteria and description of the population

by

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Abstract

Aims: *This paper discusses the methodology and results of a three stage diagnostic procedure aimed to select demented subjects and non-demented controls for a prospective field study on the need for care and the primary care provisions for demented persons.*

Methods: *In the first stage, simple assessment of Activities of Daily Living (ADL), Instrumental Activities of Daily Living (IADL) and behaviour were used to detect cognitive loss with great sensitivity. In the second and the third stage more specific diagnostic testing was performed among which the Mini Mental State Examination (MMSE) and finally the Cambridge Examination for Mental Disorders of the Elderly – Revised (CAMDEX-RN) was used to select demented subjects. At each stage a sample of test 'negative' patients were included as a control group.*

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Results: *Primary health care workers initially included 4,431 patients. In the third stage 1,036 persons were eligible for CAMDEX-testing of which 409 (39.5%) were diagnosed as demented, 41 (4.0%) as mild cognitive impaired (MCI) and 127 (12.3%) as depressed.*

Conclusions: *The final study population is a well documented and relevant population to study assessment instruments for the need for care and the quality of life of demented persons and their informal care-givers.*

Keywords: *Dementia, Primary Health Care, Methods, Quality of Health Care.*

Introduction

In 1999, Belgian federal health authorities and health care providers shared the opinion that health care regulations should be updated to meet the specific needs of demented persons. Almost ten years after the implementation of the Belgian ADL Evaluation Scale for reimbursement of elderly care, the limitations of this instrument urged on a specific procedure for funding and quality assurance of dementia care.

After a public tender, an association of two university teams was mandated in September 1999 to join their efforts in a preparatory study for future dementia care. From that moment the Department of General Practice of the Katholieke Universiteit Leuven, for the Flemish part of the country, and the 'Unité de Psychologie Clinique du Vieillissement' of the Université de Liège, for the Walloon region, collaborated in the Qualidem project.

The main objective of the study was to identify high standards of support and care for demented persons and their relatives, and, in addition, to elaborate adequate health insurance reimbursement procedures for these standards.

More specific objectives of the study were:

1. To test and select an affordable and reliable procedure for early recognition and diagnosis of dementia. The diagnostic procedure had to be manageable in general practice, repeatable and data collection had to be spread in time.
2. To identify stages in the development of the disease which are decisive for the type and the need for care, and additionally, to determine the baseline type and amount of care which was administered to demented patients.

3. To test and select instruments which can be used by primary health care providers in an objective way in order to identify the need for support and care of the patients and their relatives.

4. To describe the facilitating opportunities of an adapted architectural and material environment.

5. To define quality of life as a main topic in the support process and a major indicator of quality of care.

6. To develop and test funding and pay-back mechanisms adapted to specific services and provisions for the demented.

7. To enable experts of the health insurance companies to control the procedures and instruments used for the objectives three and six.

This paper discusses the methodological choices made to meet the objectives that required practical investigations in a field study.

Methods

Study population

Because the federal health policy has to be equal in the two major linguistic regions of the country, one of the basic requirements was that the field study should test comparable methods and instruments in the Walloon region and in Flanders. Therefore we selected a study area with about 40,000 inhabitants older than 65 in each region. In Flanders the region of Lier and the surrounding municipalities was selected, in the Walloon region Verviers and its neighborhood were chosen. The global level of urbanization of both study areas was not different from the average degree of urbanization in Belgium (1).

Sample size calculation revealed that a final study population of 300 demented study subjects would require to start with a sample of 5,000 subjects eligible to the diagnostic procedure.

In order to reach the prefixed sample size, a broad announcement was launched including repeated postal newsletters, phone calls and personal visits by the investigators. GPs and independent home care nurses were informed by way of their local professional associations. All home care organizations and residential care facilities were visited by the investigators.

The selected patients had to be relevant to the objectives of the study. Usually the investigator's major concern is that the included patients meet the inclusion criteria. However, another important concern is that the study subjects should form a random sample of all subjects

meeting the criteria (2). This was a major concern in our study, and therefore efforts were made to avoid active selection of eligible patients for other reasons. One method that was frequently used was randomizing part of the study subjects into control groups for comparison and into reserve groups when the workload of administering assessment instruments and diagnostic tests exceeded the available efforts.

Diagnostic process

A three-stage diagnostic procedure was used to identify demented study subjects and non-demented controls (first objective). Although a three stage diagnostic procedure is a common method in population-based prevalence surveys, there is a substantial variation in the instruments used for screening and diagnosis and in the performance of these instruments in different studies (3). The rationale of the choices we made in instruments and cut-off points was that at an early stage, the objective was to detect cognitive loss with great sensitivity, while towards the end of the diagnostic process, more specific diagnostic instruments were used. Our previous research on the diagnosis of dementia by general practitioners seemed to support this idea (4).

Diagnostic instruments in the selection procedure

In the first stage, inclusion of eligible subjects was carried out using four basic assessment instruments: the official Belgian ADL evaluation scale (5), an assessment scale for disruptive behavior, Instrumental Activities of Daily Living (IADL) (6) and the Frail and Autonomy Instrument Leuven (FRAIL) (4).

During the second stage the Mini Mental State Examination (MMSE) (7) was administered as a screening instrument for dementia.

In the third stage the Cambridge Examination for Mental Disorders of the Elderly – Revised (CAMDEX-RN) (8) was used as the final diagnostic reference.

The Belgian ADL-Evaluation Scale is a cultural adaptation of the 'Index of ADL' (9). The adapted assessment tool evaluates the six original domains of the 'Index of ADL': bathing, dressing, transfer, toileting, continence, and eating. In contrast with the original scale, each function has four instead of three possible scores. In nursing homes two additional items are scored from 1 to 5: orientation in time and orientation in living space. The global scale score can easily be deduced with the

aid of a boolean logic algorithm into one of four hierarchical levels of dependency, which are coded with the capitals O (lowest dependency), A, B, and C (highest dependency) for nursing home care or into three levels of dependency, which are coded A (lowest dependency), B, and C (highest dependency) for home care nursing. The global scale score A for any of the two algorithms was chosen as the minimum score for inclusion (Table 1). A sum score of three for the orientation items was chosen as the minimum score for inclusion.

TABLE 1
Eligibility criteria and inclusion criteria

Patient characteristics for eligibility	
65 years of age and one of the following: – Residential facility resident – Home care during at least one month – Suspect for dementia	
Assessment instruments for inclusion	**Criterion**
ADL evaluation scale: 2 algorithms for determination of fixed payment system levels: – Residential care facilities Boolean logic algorithm: global scores: O, A, B,C – Home care nursing Boolean logic algorithm: global scores: no fixed payment, A, B, C	 Global score A Global score A
Orientation assessment: 2 items, scores 1-5	Sum >= 3
Behaviour assessment: 6 items, scores 1-5	Sum >= 8
Lawton's IADL: 8 items, scores 1-4	Sum >= 10
FRAIL: 12 items, scores 1-4	Sum >= 19

The assessment scale for disruptive behaviour used to be part of the obligatory resident file in residential care facilities. The instrument evaluates six behavioral aspects of dysfunction or disturbing behaviour: verbal expression, verbal disturbing behaviour, maladjusted behaviour, restless behaviour, destructive behaviour and disturbing behaviour at night. The instrument was well known by nurses in institutions. A sum score of eight was chosen as the minimum score for inclusion.

The Instrumental Activities of Daily Living Scale evaluates eight functions: ability to use telephone, shopping, food preparation, housekeeping, laundry, mode of transportation, responsibility of own medications, ability to handle finances. A sum score of ten was chosen as the minimum score for inclusion.

The FRAIL evaluates ten functions and two social support mechanisms: ADL, IADL in the house, IADL outside the house, sensory functions, responsibility of own medications, ability to handle finances, memory, normal adapted behaviour, orientation, planning and problem solving, the family network, the social network. A cut-off score Ş 19 was chosen as the minimum score for inclusion.

The MMSE is probably the most widely used measure of cognitive function (10). In the MMSE different domains are assessed: orientation to time and place, registration of three words, attention and calculation, recall of three words, language, and visual construction. The maximum score is 30 points, indicating excellent cognitive function. A cut-off score Ş 23 was used to select study subjects (11).

The CAMDEX was designed to provide a formal diagnosis according to operational diagnostic criteria in one of 11 categories. Four types of dementia, Alzheimer's disease, multi-infarct dementia, mixed Alzheimer's and multi-infarct dementia, and dementia due to other causes, delirium, depression, anxiety or phobic disorders, paranoid or paraphrenic illness, and other psychiatric disorders (10). In our study the CAMDEX-RN provided support for five diagnostic categories: dementia, delirium, depression, mild cognitive impairment (MCI) or none of these. The Cambridge Cognitive Examination (CAMCOG), a subscale of the CAMDEX-RN, is a concise neuropsychological test for the assessment of cognitive impairment in elderly people. CAMCOG assesses a broad range of cognitive functions including memory, language, attention, perception, praxis and executive functioning. The CAMCOG also samples important domains within an area of cognitive functioning; for example, memory items include assessment of remote and recent memory, semantic and episodic memory, intentional and incidental learning, and recall and recognition measures of retrieval.

In this study Mild Cognitive Impairment (MCI) was diagnosed according to the operational criteria of Petersen et al. (12): abnormal memory performance, corroborated by an informant who knows the subject well, while normal general cognitive performance and no significant functional deficit.

Other diagnostic and assessment instruments

AGGIR (13;14)

The AGGIR-system evaluates six basic ADL functions and two psychological functions: coherent behaviour and orientation. The global scale score is calculated by a computer program into one of six levels

of autonomy, named GIR1 (lowest autonomy) to GIR6 (highest autonomy) (Groupe Iso-Ressources).

Alzheimer Disease Related Quality of Life scale (15)

The Alzheimer Disease Related Quality of Life scale (ADRQL) was administered by a trained examiner to a knowledgeable informant. The scale covers five dimensions of the patient's life: the ability to relate to other people, the awareness of self, the feelings and mood, the relationship to the surroundings and the enjoyment of activities.

CERAD Behavioral Rating Scale (16)

The CERAD Behavioral Rating Scale is a 46 item rating scale of psychopathology in patients with probable Alzheimer's disease. The items were administered by a trained examiner to a knowledgeable informant. Six subscales of psychopathology were revealed: Depressive Symptoms Subscale Score, Inertia Subscale Score, Vegetative Symptoms Subscale Score, Irritability/Aggression Subscale Score, Behavioral Dysregulation Subscale Score, Psychotic Symptoms Subscale Score.

Clinical Dementia Rating Scale (17;18)

The Clinical Dementia Rating Scale (CDR) is a global rating of dementia. Six domains are assessed: memory, orientation, judgement and problem solving, community affairs, home and hobbies, personal care. CDR ratings are 0 for healthy people, 0.5 for questionable dementia and 1, 2 and 3 for mild, moderate and severe dementia as defined in the scale. The total CDR rating is made from the sum of the boxes which represents an aggregate socre of each individual's areas.

Clock Drawing Test (19)

The Clock Drawing Test (CDT) is a screening measure of severity in dementia. The patient is asked to draw a clock face marking the hours and then draw the hands to indicate a particular time. Three standardized methods of interpretation by the clinician have been described by Brodaty and Moore (20). Interrater reliability of the CDT was studied and reported separately (21).

The comorbidity index (22)

Charlson's weighted comorbidity index is a method of classifying comorbid conditions which might alter the risk of mortality in longitudinal studies. It takes into account the number and seriousness of comorbid disease.

MDS/RAI (23)

The United States Minimum Dataset/Resident Assessment Instrument (MDS/RAI) is a standardized comprehensive assessment system implemented nationwide in the USA for improving care planning and quality of care.

Pathos (24)

The Pathos system uses a classification of 50 disorders and 12 care delivery profiles to calculate the required care time for eight professional disciplines in elderly care: geriatrician, psychiatrist, nursing, rehabilitation, psychotherapy, medical scientist (laboratory tests), medical imaging, pharmacology.

Supervision Rating Scale (25)

The Supervision Rating Scale (SRS) rates the level of supervision that a patient receives from caregivers on a 13-point ordinal scale that can optionally be grouped into five ranked categories: Independent, Overnight Supervision, Part-Time Supervision, Full-Time Indirect Supervision, and Full-Time Direct Supervision.

Time diary for informal and professional care (26).

The time diary is a micro-economic research instrument designed to obtain a detailed picture of the care for a demented patient and the costs of care at the level of the patient and his/her family. The time diary for professionals was left at the home of the patient during a period of four weeks. The professional carers were asked to fill in the diary whenever they visited the patient, registering what caring activities they undertook and how much time they spent on these activities. The informal carers were asked to fill in the diary on the informal care spent, distinguishing type of activities and identity of the carer.

Self report measures for informal caregivers

Burden Interview (27)

The Zarit Burden Interview is an interview about the feelings of burden of caregivers in caring for an older person with dementia. In this study the 12-item short version was used.

Ways of Coping Checklist (28;29)

The Ways of Coping Checklist is a designed to assess the coping strategies in carers of patients with Alzheimer's disease. In this study the 41-item short version was used.

Zung Self-Rating Depression Scale (30)

The 20-item Zung Self-Rating Depression Scale has been used for the assessment of mood in older people and depression in carers of patients with dementia. Each item is graded on a 4-point scale (1-4), so that a global score out of a maximum of 80 gives a measure of the severity of depression. Converted to a percentage, >50% is suggested to indicate possible depression.

Procedures

In the first stage primary health care providers included eligible patients. GPs, nurses and nursing assistants in home care or nursing homes scored the inclusion document. Patients older then 65 were eligible for inclusion if they resided in a residential care facility or received home care nursing or homemaker services for more than one month, or if they were suspect for dementia for different reasons: multiple (psychiatric) admissions, complaints about cognitive performance, …(Table 1).

Independently living subjects were included by their general practitioner or home care nurse. Institutionalised subjects were included by nurses working in the institution.

A subject's inclusion score was positive, indicating some degree of dysfunction, if the subject had a positive score for one of six prefixed criterions on the inclusion scales (Table 1). When the inclusion score was negative, indicating that the patient had no difficulties performing IADL, ADL or behavioural disturbances, the patient was to be included in a control group (controls 1) (Figure 1).

In the second stage all subjects with complete inclusion data, or their proxies, were asked written informed consent by the GP or nurse who had included the subject, using a protocol approved by the ethical committee of the Leuven University Medical School. According to Belgian privacy legislation, all study subjects remained anonymous for the investigators until informed consent was given. After informed consent had been obtained, the GP or nurse administered the MMSE and the CDT. All GPs and nurses received a detailed manual and a training video about administering the MMSE. Comorbid diseases were registered by the subject's GP according to the taxonomy developed by Charlson (22).

Study subjects with a MMSE sum score lower then 24 were selected to enter stage three. From the group of subjects with a score higher then

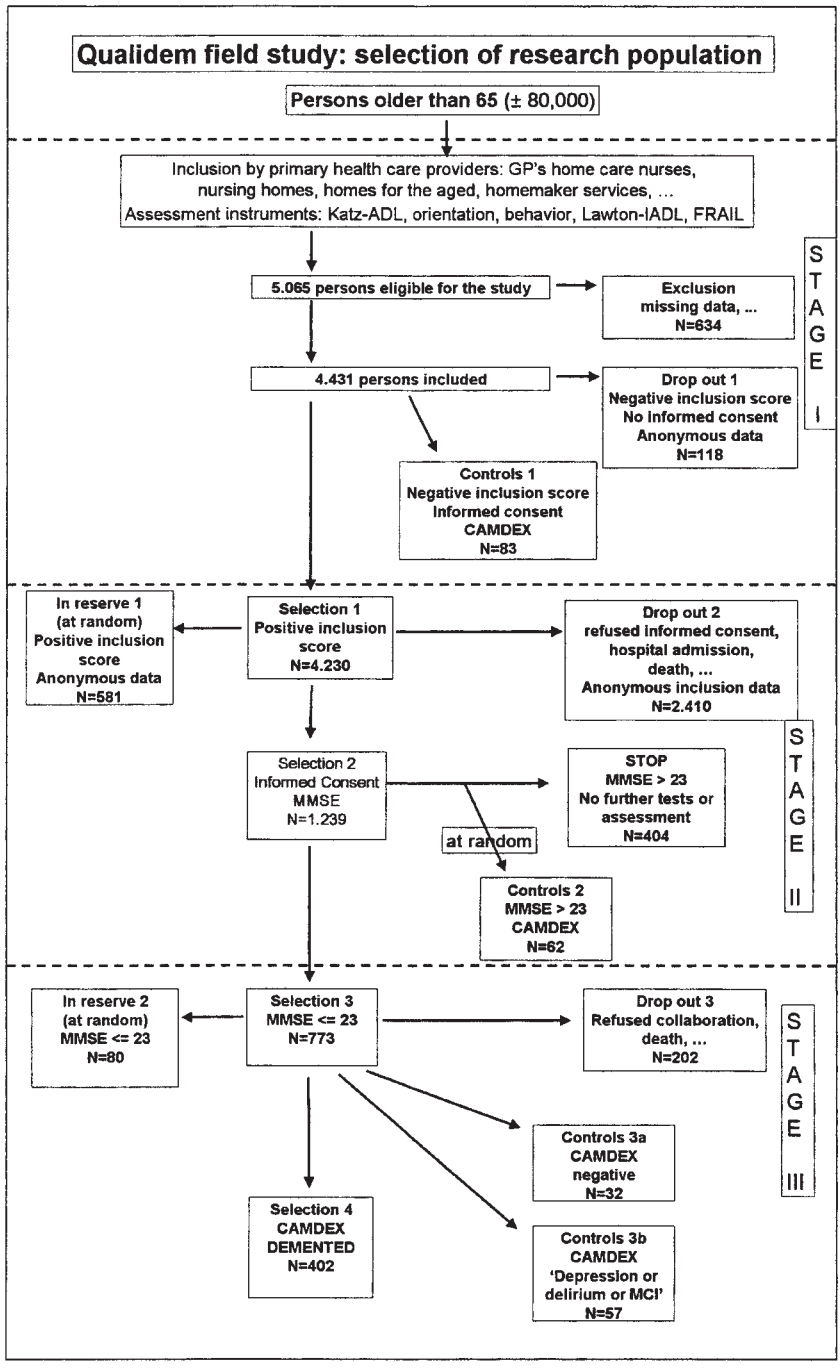

Fig. 1: The three stage selection procedure of demented study subjects

23 a random sample was drawn to form a second control group (controls 2).

In the third stage all selected subjects as well as the subjects of both control groups, and a second informant (e.g. caregiver) for each included patient, were interviewed by the investigators using the CAMDEX-RN. Also an additional battery of clinical assessment scales were administered by the investigators to randomised groups of the subjects and their relatives.

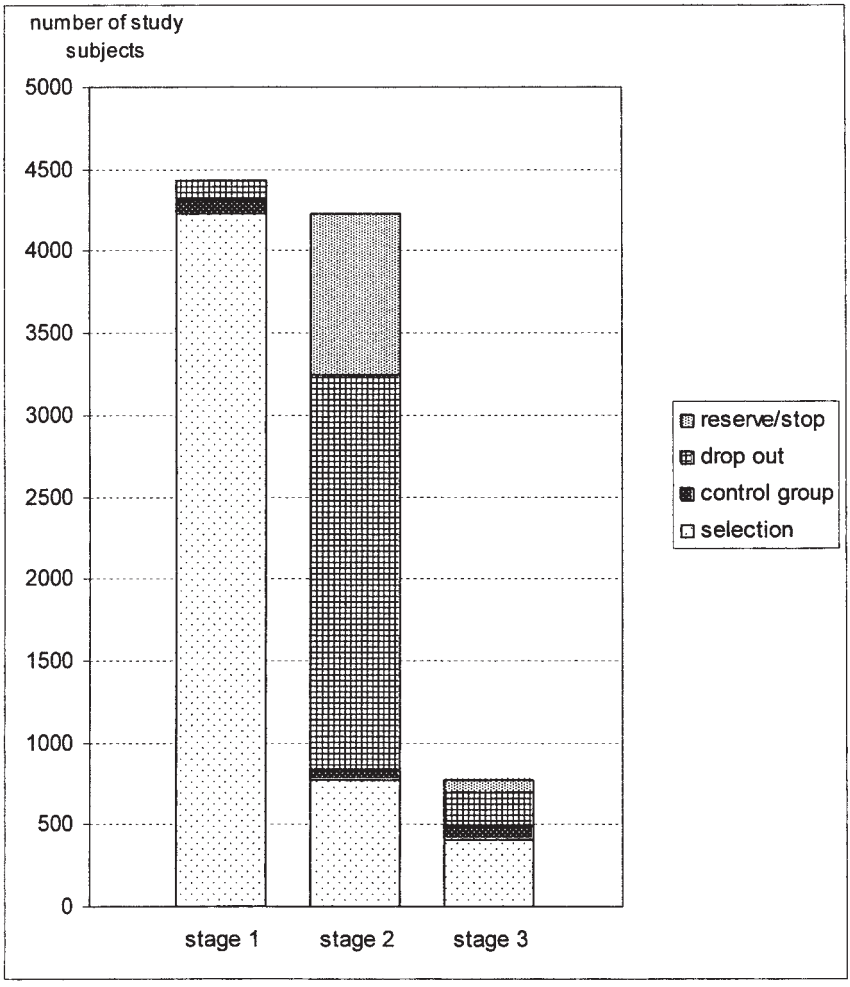

Fig. 2: Results of the selection procedure: number of study participants after selection in a previous stage of the study

Data management and analysis

Data input was performed manually with MS Access. The accuracy of data entry was checked by having two different research assistants enter a random sample of 10 % of all available data during the first study stage. The proportion of different data in both databases was 0.33% (25/7,462).

Data cleaning, data management and analysis was performed using the SAS System version 8.2 and Statistica (Statsoft, 2000).

Results

The results of the selection procedure are summarized in figure 2. The inclusion stage started May 1st 2001 and ended October 31st 2001. Primary health care workers anonymously scored the inclusion forms of 5,065 patients. An inclusion score was computed for 4,431 persons with complete inclusion data and data in accordance with the eligibility criteria. Missing data and age younger then 65 years were the main reasons to exclude 634 persons. The inclusion score was positive for 4,230 persons and negative for 201 (118 + 83) persons. Demographic characteristics of the included study subjects are shown in table 2. Of the included persons, there were 2,661 (60%) nursing home residents and 1,768 (39.9%) community dwelling persons. The age-distribution of study participants at inclusion and in stage 3 is presented in figure 3.

Nurses working in a nursing home included 2,646 residents. This is 59.7% of the subjects in this study, and was almost similar in both areas.

TABLE 2
Demographic characteristics and inclusion scores of study subjects

	Total sample	Home care clients	Nursing home residents
	n = 4431 *	n = 1768	n = 2661
Age (mean ± SD)	82.0 ± 7.5	79.5 ± 7.1	83.1 ± 7.2
Female sex (n; %)	3365 (75.9%)	1231 (69.6%)	2133 (80.2%)
Inclusion score (0-6) (mean ± SD)	3.7 ± 1.9	2.8 ± 1.8	4.3 ± 1.7
Number of physical impairments (0-6) (mean ± SD)	3.5 ± 2.9	2.7 ± 2.4	4.0 ± 2.2
Lawton (8-24) (mean ± SD)	17.5 ± 5.5	14.7 ± 4.8	18.6 ± 5.4
FRAIL (6-48) (mean ± SD)	33.9 ± 14	26.3 ± 12.5	39.0 ± 12.6

* Two observations missing in variable 'Residence'.

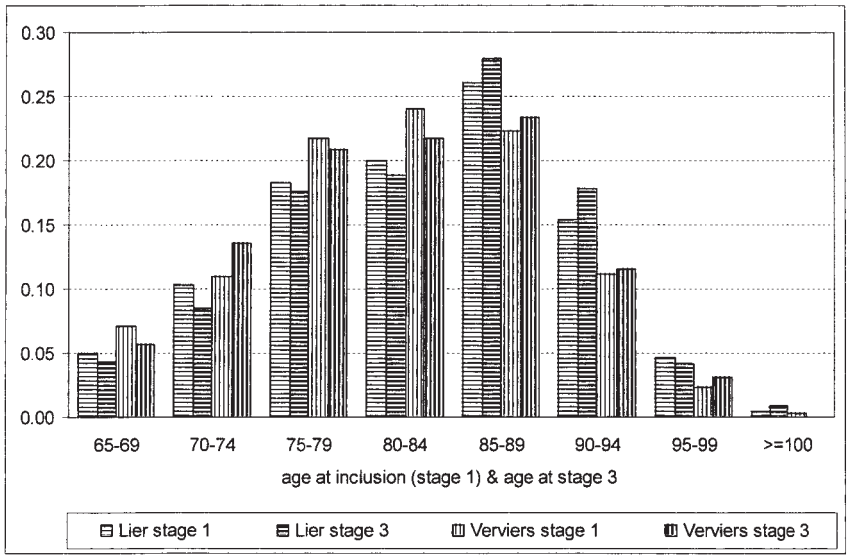

Fig. 3: Histogram of the subjects' age according to study area and stage of the selection procedure (stages 1 and 3)

Inclusion of community dwelling persons was different for the two study areas: in Lier a majority of 879 (186 + 657 + 36) subjects was included by GPs and home care nurses, in Verviers 774 homemaker service's clients were the largest proportion of the study subjects living at home (Table 3). The mean (SD) age of the subjects was 82 (± 7.5) years, 75.9% of the subjects were female.

In the second stage 1,239 persons provided written informed consent. In cases where informed consent could not be obtained, the subject was

TABLE 3
Professional discipline of the health care workers who included the subjects (number of subjects)

Professional discipline	Lier	Verviers	Total
GP	186 (9.1%)	36 (1.5%)	222 (5.0%)
Home care nurse	693 (34.1%)	35 (1.5%)	728 (16.4 %)
Nurse in nursing home	1151 (56.6%)	1495 (62.4%)	2646 (59.7%)
Homemaker service	5 (0.2%)	774 (32.3%)	779 (17.6%)
Other	0 (0.0%)	24 (1.0%)	24 (0.5%)
Missing	0 (0.0%)	32 (1.3%)	32 (0.7%)
Total	2035 (100%)	2396 (100%)	4431 (100%)

not administered the MMSE. For these persons only anonymous inclusion data of the first stage were available for analysis. The testing of the second stage took place between October 1st 2001 and March 31st 2002. The average period between the evaluation in stage one and the testing with MMSE in stage two was approximately five months.

Stage three started February 20th 2002 until July 14th 2002. The average period between stage two and three was approximately four months. Of the 1,036 (selection 3 + controls 1 + dropout 1 + controls 2; 773 + 83 + 118 + 62) persons who were eligible to be tested with the CAMDEX-RN in the third stage, 346 (33,3%) were living in the community and 690 (66.5%) were nursing home residents. 409 (402 + 7) were diagnosed as demented (Table 4). 145 participants (control groups 1 + 2) are available as a control group when examining diagnostic instruments. 89 additional participants (control groups 3a + 3b) are available for comparing care needs of demented and non-demented people.

TABLE 4
Demographic characteristics and MMSE- and CAMDEX-test results of the subjects in the third stage. Group numbers according to figure 1 between brackets.

	Total sample	Home care clients	Nursing home residents	Selection (4)	Controls (1, 2, 3a and 3b)	Dropout
	n = 1,036	n = 346	n = 690	n = 402	n = 234	n = 2,730
Age (mean ± SD)	83.1 ± 7.7	79.3 ± 7.5	84.9 ± 7.1	85,0 ± 7.1	80,3 ± 7.4	81.8 ± 7.6
Female sex (n; %)	815 (78.7%)	243 (70.2%)	572 (82.9%)	337 (83.8%)	172 (73.5%)	2,059 (75.4%)
MMSE score (mean ± SD)	14.0 ± 8.5 (n=863)	17.8 ± 9.4 (n=218)	14.0 ± 7.9 (n=645)	11.8 ± 7.4 (n = 402)	23.1 ± 5.6 (n = 179)*	15.0 ± 8.4 (dropout 3 n = 202)
Dementia (n; %)	409 (58.1%) (n=704)	70 (32.9%) (n=213)	339 (69.0%) (n=491)	402 (100%)	7 (controls 1 & 2 n = 145 4.8%)	0
Depression (n; %)	127 (18,0%) (n=704)	31 (14.6%) (n=213)	96 (19.6%) (n=491)	83 (20.6%)	44 n = 234 18.8%	0
Mild Cognitive Impairment (n; %)	38 (6.9%)	10 (8.1%)	28 (6.5%)	0	41 n = 234 17.5%	0

* MMSE was administered to 28 subjects of controls 1 (n = n(MMSE controls 1) + n(controls 2) + n(controls 3a) + n(controls 3b) = 28 + 62 + 32 + 57 = 179).

Discussion

In this study a group of 402 demented subjects and four smaller groups of controls were selected to calibrate internationally very well known assessment instruments to the Belgian health care sector. The required number of subjects according to the sample size calculation was achieved.

An important objective of the selection process was to avoid systematic selection bias resulting from a pre-selection of the professional study participants. This was important for the acceptability of the study results to all parties in the Belgian health care context. Therefore the efforts were maximised to give all primary health care workers and organizations of the study regions an opportunity to collaborate and to include their patients. Lacking a formal and publicly available registration system for professional health workers, a regional inventory was made of all organizations and collaborating initiatives. Each organization was visited by an investigator of the same professional discipline.

Further selection of the included subjects was based on the assessment or test result in each stage of the study. Randomization of a predefined proportion of subjects was used to select control groups. All these efforts resulted in a study population which was relevant for the Belgian home care patients and nursing home residents. The results of the assessment instruments used in this study may give a detailed documentation of the delivered health care and of the health and health-related conditions of demented patients and their informal caregivers in primary care and nursing homes.

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