PROJECT
ValueCare

Project acronym: VALUECARE
Grant Agreement Number: 875215
Project full title: Value-based methodology for integrated care
supported by ICT
Call identifier: H2020-SC1-DTH-11-2019

D5.1 – Agreed-upon pilot sites evaluation framework

Version:	0.1
Status:	First draft
Dissemination Level:	Public
Due date of deliverable:	30.09.2020
Actual submission date:	30.09.2020
Work Package:	WP5 - Formative and summative evaluation of the VALUECARE pilot
Lead partner for this deliverable:	EMC
Partner(s) contributing:	FBK, VI, VIDAVO, UVEG, AGE, IFIC and KVC

Main author(s):

Esmée Bally	EMC
Amy van Grieken	EMC
Hein Raat	EMC

Other author(s):

Nhu Tram	AGE
Tamara Alhambra Borrás	UVEG
Vanja Vasiljev	MEDRI

Statement of originality

Abstract

This deliverable describes the evaluation of the ValueCare approach. The aim is to evaluate the ValueCare approach in a pre-post controlled design in terms of effects for the target groups (older people, their families, and health and social care providers). The second objective is to evaluate different dimensions of the 'process'. In this deliverable a description of the evaluation framework is provided.

TABLE OF CONTENTS

LIST OF TABLES

EXECUTIVE SUMMARY

The value-based methodology for integrated care supported by ICT (ValueCare) approach aims to deliver efficient outcome-based integrated health and social care to older people with chronic health conditions, frailty or (mild) cognitive impairment. ValueCare, in comparison with 'usual care', is expected to achieve more favourable outcomes, including health-related quality of life (HR-QoL), of older adults and their informal caregiver, such as family members. It will also take into account the job satisfaction and the wellbeing of the health and social service providers. The project's vision of integrated value-based care will be supported by a robust, secure and scalable digital solution that will be tested and evaluated in 7 large-scale pilots in Europe.

The evaluation of the ValueCare approach has a specific pre-post controlled design (Miller et al., 1989). Data will be collected during the baseline-measurement at inclusion (T0), and follow-up measurements will take place after 12 months (T1) and after 18 months (T2). The sample, in each pilot site, will be composed by 120 patients (120 in control and 120 in intervention group), 50-70 informal caregivers (e.g. family members, friends), 30-40 health and social professionals and 5-10 IT experts. The effects of the intervention are measured in multiple domains, including health-related quality of life (HR-QoL), overall health, fall risk, appropriate medication use, loneliness, happiness, frailty, autonomy and control, participation and decision making, time spent in the hospital, carer burden and direct health costs.

A multilevel modeling approach is used for the analyses. In addition, a preliminary cost-effectiveness analysis will be performed. A process evaluation is used to provide insight into the reach of the target population, the extent to which elements of the ValueCare approach are executed as planned and the satisfaction of the participants.

The ValueCare project will provide new insight into the feasibility and effectiveness of a value-based methodology for integrated care supported by a digital solution for older adults, their families, and health and social care providers in different European settings.

1   Purpose, objectives and scope

The population of older people in the European Union – defined as those aged 65 and over – is projected to rise 47% between 2018 and 2050 (Eurostat, 2019). Age is associated with the presence of chronic conditions, including cancer, cardiovascular diseases and neurodegeneration (Niccoli & Partridge, 2012). Across the EU in 2017, about half (56.9%) of the people aged 65-74 years reported the presence of one or more chronic conditions. A chronic condition is a condition or health problem that lasts for at least six months (Eurostat, 2019). The prevalence increases with age: approximately two thirds (66.9 %) of people aged 75-84 years and almost three quarters (72.5 %) of people aged 85 years or more report a long-standing chronic condition or health problem (Eurostat, 2019).

Not only the number of people having one chronic condition is increasing, but a growing proportion of patients have two or more chronic conditions at the same time, also referred to as multimorbidity. This may impact a person's quality of life – physically, mentally and socially. It may also impose a burden on public health care expenditures and the health care system as the demand for health care services may increase (Heide, van der, et al. 2015). Most European health care and social care systems are disease-specific and mono-disciplinary oriented (Banerjee 2014; Oelke, 2015). The increasing number of people with one or more chronic conditions has shifted the focus from acute care to long-term care. However, the organisation of care remains tailored towards the provision of acute care, while long-term care (especially for those who suffer from multiple conditions) often requires the coordination of care between multiple providers (Beard et al., 2016; Banerjee 2014). The existing challenge is, therefore, to reform the delivery of health and social care services to people with (multiple) chronic diseases. This will generate increased quality (in terms of effectiveness, efficiency and completeness) and sustainability (in terms of costs and work force) in the near future (Vestjens, 2019; European Commission, 2018).

In response to this challenge, integrated care can reduce discontinuity of care (Vestjens et al., 2019). Integrated care models have in common that they seek to achieve a 'Triple Aim': enhancing the patients' experience of care; improving the health of the general population, and; reducing the health care costs per capita (Berwick, 2008). In this project we aim for a 'Quadruple Aim', that additionally includes that we seek to increase the job satisfaction and wellbeing of the care provider.

Examples of core components of integrated care initiatives include: (i) care coordination and system navigation; (ii) a patient-centred integrated care plan; (iii) a formalised process of interprofessional communication and collaboration; (iv) ongoing assessment of health and social risk factors, and; (v) patient and caregiver support and education about self-management. The use of digital solutions in support of each of these components can foster coordination by facilitating communication between health and social care providers, and providers and patients (Markle-Reid et al., 2019; Slater et al., 2017).

Despite the wide consensus to integrate health and social services, development of integrated care has proven to be a difficult task (Minkman, 2009; Looman, Huijsman & Fabricotti, 2018). Evidence on the effectiveness of integrated health and social care is still limited (Low, Yap & Brodaty, 2011; Baxter, 2018). Previous research on integrated care showed mixed results, depending on the tested outcome measurement (Franse et al, 2018, Deschodt et al, 2020; Everink et al, 2018b; Eklund & Wilhelmson, 2009). Evidence suggests that integrated care can decrease healthcare utilisation and thereby reduce the costs to

society (Looman, et al. 2018; Deschodt et al., 2020; Everink et al. 2018a). However, less is known about the specific effective components of combined health & social integrated care programs (Franse et al., 2018; Eklund & Wilhemson, 2009). In the value-based methodology for integrated care supported by ICT (ValueCare) project, we aim to implement and evaluate outcome-based integrated health and social care for older people. There is a need to evaluate the effectiveness of combined health and social integrated care. In a landscape of diversity in health service delivery and local context, it is valuable to evaluate the effectiveness of approaches in different (international) settings.

1.1   The ValueCare project

The value-based methodology for integrated care supported by ICT (ValueCare) project was established in response to the Horizon 2020 call Digital Transformation in Health and Care. The overall aim of the ValueCare project is to deliver efficient outcome-based integrated health and social care to older people facing cognitive impairment, frailty and chronic health conditions. To this end, ValueCare aims to not only satisfy the 'Triple Aim' of improved care experience, better outcomes for citizens, and greater efficiency in the use of resources, but also taking into account job satisfaction and wellbeing of the care provider ('Quadruple Aim') (Bodenheimer & Sinsky, 2014). Additionally, to support the integration of health and social care, ValueCare will develop a robust, secure and scalable digital solution. In this project, seven large scale pilot sites in Europe (Rijeka, Croatia; Athens, Greece; Cork/Kerry, Ireland; Treviso, Italy; Coimbra, Portugal; Valencia, Spain; and Rotterdam, the Netherlands) will contribute to the implementation of the ValueCare approach in which each pilot site adapts the general framework to their local context.

1.2   Objectives

The first objective of this study is to evaluate the ValueCare approach in a pre-post controlled design in terms of effects for the target groups (older people, their families, and health and social care providers). The second objective is to evaluate different dimensions of the 'process'. The following research questions were defined:

1. What are the effects of the ValueCare approach for older persons with regard to indicators of health (risks) and wellbeing, functioning, and care use?
2. What are the effects of the ValueCare approach for informal caregivers (e.g. family members, friends) and health and social care providers in terms of burden, wellbeing and (job) satisfaction?
3. What are the effects of the ValueCare approach on (care) costs?
4. What is the reach of the target population by the ValueCare approach, to what extent are stakeholders engaged and satisfied with the ValueCare approach as a whole?

1.3   Study hypotheses

Our hypothesis is that older persons in the intervention group ('ValueCare approach') have more favourable results with regard to indicators of health (risks) and wellbeing, functioning, and care use, in comparison with older persons of the control group ('usual care'). Furthermore, we hypothesize that there are more favourable (care) costs in the intervention group, in comparison with the control group. With respect to informal caregivers and health

and social care providers, we expect a lower carer burden, and improved wellbeing and (job) satisfaction among participants in the intervention group, compared to the control group.

Our aim is a reach of participants in the intervention group of 70% or higher, and a satisfaction score of 7 or higher on a 1-10 scale for the ValueCare approach.

2   Methodology

2.1   Study design

The evaluation of the ValueCare approach has a specific pre-post controlled design (Miller et al., 1989). Data will be collected during baseline-measurement at inclusion (T0), and during follow-up measurements 12 months (T1) and 18 months (T2) after inclusion. The ValueCare target group consists of older people with chronic health conditions (e.g. cardiovascular diseases, diabetes), frailty or (mild) cognitive impairment, their families (e.g. informal carers) and health and social care providers. Each pilot site defines the specific target group for their intervention. Both at baseline and at follow-up, all participating older adults will be asked to complete a questionnaire. In addition, caregiver-reported data and health and social care professional-reported data will be collected. The exposure of older adults to the ValueCare approach during the follow-up period will be measured by the follow-up questionnaire and by using clinical data provided by health care organisations. Data collection is planned to start in August 2021 (M20).

2.2   Setting

Pilot sites have been selected based on the following criteria: (i) geographical coverage, (ii) diversity in health care systems and assistance models, representing public and private models, and; (iii) region-based. Table 1 presents an overview of each pilot site, including population size, health system financing model and target group.

Table 1: Pilot site characteristics.

Pilot site	Population	Health system financing model	Target group
Rijeka (Croatia)	128,345[1]	Public financing – Social Health Insurance (mixed Bismarck)	Older people who had a heart attack and finished their rehabilitation in the clinic. (Ps, the exact target group is now being discussed)
Athens (Greece)	664,046[2]	Public health system based on Beverige model	Older patients with a neurological condition (e.g. Multiple Sclerose (MS), Parkinson's disease, stroke) and/or co-morbidities and living independently in the community after hospitalization. (Ps, the exact target group is now being discussed)

---

[1] Census of population: Croatia [https://www.dzs.hr/default_e.htm]. Accessed 5 June 2020.

[2] Census of population: Athens [https://www.statistics.gr/en/greece-in-figures]. Accessed 5 June 2020.

Cork/Kerry (Ireland)	147,707[3]	Public-private mix in financing and provision of healthcare	Older persons (≥75 years old) with mild to moderate frailty
Treviso (Italy)	85,200[4]	Public and universal welfare system	Older citizens with mild cognitive impairments, hypertension or diabetes type 2
Coimbra (Portugal)	143,397[5]	Public-private mix in financing based on Enthovens' model of managed competition[6][1].	Older citizens with none to mild cognitive impairment, co-morbidities and a lack of social support.
Valencia (Spain)	800,666[7]	Public and universal welfare system	Older people wild mild to moderate frailty and their families
Rotterdam (the Netherlands)	638,714[8]	Public and universal welfare system	Older people that suffered ischemic stroke

2.3   Intervention condition and control condition

Intervention condition

In the intervention condition, the ValueCare intervention will be applied. This entails value-based social and health integrated care approach supported by a digital solution. The ValueCare intervention promotes health and (social) functioning of older citizens, supports informal caregivers, and improves professionals' working conditions.

In WP2 (together with WP3 and the other WPs), the ValueCare intervention will be adapted for use in seven countries. In the first step, co-design activities with end-users (older people and their families, and health and social care professionals) and stakeholders will be held in each site to adapt the 'value-based care approach', and to make a selection/adaptation of ICT tools to be used in the 7 countries to support integrated health/social care (i.e. the 'digital solution').

The 'value-based care approach': this is a specific application of 'outcome-based care delivery', as it was developed by ICHOM (www.ichom.org) to choose the care, and to monitor the progress of care by measuring and discussing with the patient/client the outcomes of the 'measures that matter most to the patient/client in his/her specific situation'. In the intervention condition, the 'value-based care approach' will be implemented to choose, fine-tune and monitor the integrated health/social care pathways.

---

[3] Census of population: Cork/Kerry [https://www.cso.ie/en/census/]. Accessed 5 June 2020.

[4] Census of population: Treviso [http://www.comune.treviso.it/trevisostats/]. Accessed 5 June 2020.

[5] Census of population: Coimbra [https://www.ine.pt/xportal]. Accessed 5 June 2020.

[6][1] M. Kroneman et al., *Health Systems in Transition,* Netherlands Health system review. *18*(2), 2016.

[7] Census of population: Valencia [http://www.valencia.es/ayuntamiento/webs/estadistica]. Accessed 5 June 2020.

[8] Census of population: Rotterdam [http://statline.cbs.nl/]. Accessed 5 June 2020.

The ICT tools ('digital solution'): the IT team (WP3), together with the stakeholders and other WPs, will select and adapt existing digital solutions that can support all involved stakeholders in the integrated health/social care pathways; the end-user preferences in the seven countries are taken into account.

In the second step, the development and deployment of the ValueCare intervention, especially with regard to the ICT tools ('digital solution') will be finalized to be used in the seven countries based on the user requirements, security, performance, interoperability, third-party integrations, maintainability, portability and architecture design. As a result of the first and second step, a general framework of the ValueCare intervention is established. In the third step, pilot sites in seven countries will adapt the general framework to their context and will define a specific plan to implement the ValueCare intervention. In step four, the pilot sites in the seven countries implement this in the intervention condition.

Control condition

In the control condition, 'usual care' is applied.

2.4   Procedures

Before the implementation of the ValueCare approach, pilot sites will work on some preparatory activities. First, all pilot sites will apply for ethical approval at their local Ethical Review Board. The study protocol will be registered; for example at the Clinical Trial registry (https://www.clinicaltrialsregister.eu/). Second, pilot sites will build community connections with local stakeholders who will be involved in the ValueCare approach. The establishment of an engagement strategy - as detailed in WP2 deliverable 2.3 - will support local communication flows. Pilot sites can adapt the engagement strategy to their national context and target groups. In each pilot site, the specific target group will be recruited with support of local public administrations and health and social service providers. Third, each pilot site offers training activities to their target groups. For health and social care professionals, this includes training on how to implement the ValueCare approach in practice and how to use the ValueCare digital solution. Patients and their families are offered a training package with respect to the use of the ValueCare digital solution.

2.5   Study population and recruitment

We aim to include a total of 1765 to 1800 participants for evaluation in the pilot sites in the seven countries combined. Recruitment will take place in two parts.

Part A: In part A, we aim to include 1680 participants (older people/patients) in total; 120 participants in the intervention group and 120 participants in the control group in each pilot site. Study participants will be included if they meet the following inclusion criteria: (i) are an older adult (≥65 years of age), (ii) have a confirmed diagnosis of the targeted chronic condition at the time of enrolment, (iii) are community-dwelling (not in long-term care), or are temporarily in a hospital or institution and are expected to be referred to outpatient rehabilitation services, (iv) are able to give informed consent. Participants who are not able to comprehend the information provided in the local language or cannot cognitively evaluate the risks and benefits of participation are not eligible as this inflicts making an informed decision regarding participation. Pilots will recruit participants with the support of public administrations and social and health services providers involved in each pilot site. All

invited older adults will receive project information, an informed consent form and baseline questionnaire. Older adults who are willing to participate are requested to complete the baseline questionnaire and sign the informed consent form. This information can be returned to the researchers using the ValueCare digital solution (i.e. a mobile or web-based application) or by post such as by using a pre-paid envelope. Older adults who provide informed consent and complete the baseline questionnaire are enrolled in the study. Enrolled participants are able to stop their participation at any time.

Part B: In part B, we aim to include 50-70 family members and caregivers (e.g. family members, friends); 30-40 professionals who work with older adults having the targeted chronic condition in either health or social care context; and 5-10 organisational and/or IT experts per pilot site. Recruitment takes place with the support of the engagement strategy. The procedure regarding study information, informed consent and data collection is similar as for the older adults in part A. Informal caregivers, health and social care professionals, and experts who provide informed consent and complete the baseline questionnaire are enrolled in the study. Enrolled participants are able to stop their participation at any time.

2.6 Data-collection and measurements

Data will be collected through questionnaires completed by self-report and filled out by older adults, informal caregivers (e.g. family members, friends) and health and social care professionals. Both primary and secondary outcome measures are included in the questionnaires. The questionnaires can be completed on paper or digitally through a secured mobile or web-based application. The baseline questionnaire is currently being developed by WP5.

The instruments used are partly based on the Standard Set for Older Person (ICHOM, 2016; Akpan et al., 2018) and the Standard Set for Overall Adult Health (ICHOM, 2019) developed by the International Consortium for Health Outcomes Measurements (ICHOM). In addition, pilot sites can apply particular ICHOM Standard Sets according to the specific chronic condition of their target population, such as the ICHOM Stroke Set or the ICHOM Diabetes Set. The outcome measures are described below. The instruments for which no validated translations are available are translated (forward and backward translations). Translations are discussed by the study team and adapted when needed. Before the start of the study, the questionnaire will be pilot-tested in all pilot sites to assure its user-friendliness in terms of appropriateness, comprehensibility and length.

2.6.1 Outcome measures

We evaluate the effects of the ValueCare intervention with regard to indicators of health (risks) and wellbeing, functioning, and care use. That is: health-related quality of life (HR-QoL), overall health, fall risk, appropriate medication use, loneliness, happiness, frailty, autonomy and control, participation and decision making, time spent in the hospital, carer burden and costs.

The ICHOM Standard Set for Older Person will be applied to measure part of these outcomes (ICHOM, 2016). Overall health is measured by the PROMIS Scale v1.2 – Global Health (Katzan & Lapin, 2018), the WHO (Five) Wellbeing Index (Topp et al., 2015), and the WHO Disability Assessment Schedule 2.0 (WHO-DAS 12) (Üstün et al., 2010). Fall risk is measured by the number of falls in the previous year and how many falls have resulted in any form of medical attention or hospitalization (Chang & Ganz, 2007). Appropriate medication use includes

questions regarding the number of prescribed medications, adverse drug events and whether medications make the patient unwell. The UCLA 3-Item Loneliness Scale is used to measure loneliness and isolation (Hughes et al., 2004). Frailty is tracked via the Canadian Study on Health and Aging Clinical Frailty Scale, that measures frailty on a scale from 1 (robust health) to 7 (complete functional dependence on others) (Rockwood et al., 2005). Autonomy and control over daily life is measured via the Adult Social Care Outcomes Toolkit (Netten et al., 2012). Participation and decision making includes questions regarding care experience and a participant's confidence in: i) the ability to cope with own health, ii) role as participant in care, and iii) healthcare professionals (Akpan et al., 2018). Time spent in the hospital is measured by the number of hospital admissions, readmissions and the total time spent in hospital over the past 12 months. Health-related quality of life (HR-QoL) is measured with the PROMIS Scale v1.2 – Global Health representing physical health, pain, fatigue, mental health, social health, and overall health (Katzan & Lapin, 2018).

Additionally, carer burden is measured among informal caregivers (e.g. family members). The 4-item screening Zarit Burden Interview tool is used to track carer reported burden (Bedard et al., 2001). Working conditions of health and social care professionals are measured using the Culture of Care Barometer tool (Rafferty et al., 2017) For the assessment of wellbeing among health and social care professionals, two dimensions will be considered: job satisfaction measured using the Minnesota Satisfaction Questionnaire (Weiss et al., 1977) and burnout using the Copenhagen Burnout Inventory (Kristensen et al., 2005).

Other outcomes we measure are incremental quality of life years and costs to evaluate the cost-effectives of the VALUECARE intervention. Quality of life impact in patients and professionals will be measured in the control group and compared with the intervention group using Quality-Adjusted Life Years (QALYs) (Cleemput et al., 2011). This will be complemented with questions regarding health-related quality of life (HR-QoL) measured by the ICHOM standard sets. Happiness is measured by one item of the 36-Item Short Form Survey Instrument (SF-36). The costs of healthcare refers to the carer's financial burden. It considers the loss of productivity and income, besides health-care costs for both, the cared person and the carer, measured through the Productivity Cost Questionnaire (PCQ). It consists of a modified version of the 18-items PCQ (Bouwmans et al., 2015).

Socio-demographic characteristics include age, gender, country of birth, level of education, living status and location, life style (smoking status, alcohol use), co-morbidities and level of received care.

Participants are also asked questions regarding their activities of daily living function. This is tracked via de Barthel Index (Mahoney & Barthel, 1965). Clinical data will be used to measure BMI and assess cognitive functioning. There is an open box at the end of the questionnaire for additional remarks.

2.6.2 Process measures

The process evaluation aims to assess ValueCare's implementation and performance. We will monitor how well ValueCare is adopted and key elements are delivered, including (i) the reach of the target population and participation of stakeholders, and (ii) functioning of ValueCare pathways. In each pilot site two focus groups will be held to collect data on the implementation process. By using checklists and qualitative means (i.e. individual interviews) with front-line and relevant care staff as well as, if necessary, with older people and relatives, one researcher from EMC will do a study visit to each pilot site. Herewith,

additional data about the impact of the implemented interventions will be collected. Additionally, permanent resource and/or care use registries will be used. The process evaluation is based on the theoretical framework for public health interventions as developed by Steckler and Linnan (Steckler, 2002; Saunders, Evans & Joshi, 2005). This framework includes the following elements which are described below: reach, dose delivered and received, fidelity, satisfaction, and context.

Reach

As part of the process evaluation, we measure the proportion of the intended target population that is reached by the ValueCare approach. Reach will be determined by calculating the percentage of contacted participants that completed the ValueCare intervention. If possible, reasons for not using the intervention are recorded.

Dose delivered and received

Dose delivered measures whether the anticipated care is provided to the participant. Dose received measures the extent to which participants are participating in the care that is offered. Data on the delivery of the ValueCare approach will be collected and reasons for nonparticipation in care are reported by the health or social care provider.

Fidelity

We aim to measure to what extent the ValueCare approach is implemented as planned (fidelity). In addition, we measure to what extent the target group is satisfied with the ValueCare approach. As part of the T1 questionnaire, 3 items are included with regard to general satisfaction with professional care, social care and self-management in the past 12 months. Participants are also asked to rate the ValueCare approach as a whole on a scale of 1 to 10. Additionally, qualitative feedback from older persons, informal caregivers, and health and social care professionals will be gathered. Participants will be asked to share their experience with regard to: i) the feasibility to carry out or to adhere to the intervention, ii) acceptability of the intervention, iii) the perceived fit or relevance of the intervention, iv) the intention or action to employ the intervention. We will also ask feedback on the implementation barriers and facilitators. Each pilot site will organise focus groups at two time points: one at 8 months and one at 12 months after inclusion of the last group of participants. At each time point, one focus group will be organised with 6-8 older persons and caregivers (e.g. family members, friends) and one focus group will consist of 6–8 social and health care professionals. All professionals engaged in the ValueCare intervention are invited to participate in the focus groups. Focus groups will be audiotaped, converted into text, and translated into English for the analyses.

Context

As the ValueCare intervention is implemented in seven diverse settings in Europe, ValueCare's success depends on the context in which it is implemented. By using structured forms we make an inventory of relevant contextual factors of each pilot site in which the ValueCare approach is implemented. This includes experience of health staff, setting, resources and interventions available or newly developed.

2.7 Power considerations

In each of the seven pilot sites, 120 participants will be included in the intervention group and 120 participants in the control group. Assuming a 20% loss to follow-up between T0 and T1 (e.g. due to mortality, rehousing or not being able to participate), we expect complete data of 672 participants in the intervention group and 672 participants in the control group of each pilot site at follow-up; in total n=1344 study participants. We assume equal standard deviations in the intervention group and the control group, alpha of 0.05 and power of 0.80. Thus, given seven participating study sites with each an intervention group and control group, we applied a correction factor to account for the cluster design, assuming an average cluster size of 96 older citizens (1344/14) and an intra-class correlation coefficient of 0.02. For this expected overall sample size and assumptions, with regard to the continuous outcome measures, a difference of 0.23 SD between the intervention and the control group can be detected at follow-up. This means that both at the European level, and in addition in each pilot separately, small differences regarding the outcomes in the intervention group compared to the control group can be shown (Middel et al., 2002).

2.8 Data management and analysis

To conduct the evaluation, data from all pilot sites is combined and analysis is done at Erasmus MC. Paper questionnaires will be transferred into electronic files. Subsequently, electronic data is checked for missing or incorrect data. If an error is present in the electronic data, paper questionnaires are consulted. Responsible staff is contacted for clarification when needed. All data is handled confidentially and scientific data is stored anonymously, compliant with GDPR regulations.

Participant socio-demographic characteristics and health outcomes will be evaluated at baseline between the intervention and control group in the total study population and in each pilot site separately by means of chi-square tests for categorical variables and one-way ANOVA for continuous variables. Main effects at follow-up will be evaluated for the total study population, as per "intention to treat", using a multilevel modelling approach. Clustering effects at study site-level will be taken into account. Multilevel linear regression analyses will be conducted for continuous outcome variables with group (intervention or control) as independent variable. Multilevel logistic regression will be performed for dichotomous outcome variables. We correct effect estimates of multilevel analyses for covariates, based on literature (Metzelthin et al., 2013); age, sex, living situation, education level and the baseline status of the outcome variable. We will assess interactions between intervention condition and study site, gender, age and education level in the association between intervention condition and all outcomes (Franse et al., 2017). We consider a P-value of 0.05 or lower to be statistically significant.

Using the baseline measurement as control group, a preliminary cost-effectiveness analysis will be performed from a societal and healthcare perspective and with a time horizon of 6 months. Healthcare costs for individual participants will be determined by multiplying resource use (doctor appointments, hospital emergency rooms and hospital admissions) with corresponding unit prices. Productivity losses for individual participants (lost productivity at paid work due to absenteeism and lost productivity at unpaid work) will follow from the PCQ.

2.9   Dissemination

The communication and dissemination strategy will be developed in WP6. The exploitation, innovation and business models will be developed in WP8. As part of the communication strategy, scientific project results will be disseminated through publications in scientific peer-reviewed journals and conferences. In addition, social media and the website (https://projectvaluecare.eu/) provide a platform to further disseminate key findings of our project to all stakeholders.

An External Advisory Board will be created consisting of a group of 8 experts and representatives of stakeholders with complementary profiles and consolidated expertise. The Advisory Board will provide critical suggestions and comments throughout the project.

3   Findings and conclusions

This study aims to evaluate the effect of the ValueCare intervention with regard to indicators of health (risks), functioning, and care use in comparison with 'usual care'. We will measure health-related quality of life, overall health, fall risk, appropriate medication use, loneliness, happiness, frailty, autonomy and control, participation and decision making, time spent in the hospital, carer burden and health/care costs. A pre-post controlled design is used to explore the effects of the ValueCare approach in seven European pilot sites, including: Rijeka, Croatia; Athens, Greece; Cork/Kerry, Ireland; Treviso, Italy; Coimbra, Portugal; Valencia, Spain, and; Rotterdam, the Netherlands.

This study has several strengths. First, this research examines both the implementation and effects of the ValueCare intervention. While measures of effect provide information on whether the intervention works, insight regarding the facilitators and barriers of implementation will inform on relevant topics such as the reach of the intervention, fidelity and satisfaction. This will help to capture the complexity of the interactions between many contextual factors that influence the implementation of the intervention (Curran et al., 2012). Second, this study explores the effects of the ValueCare approach among a diverse study population in seven different European settings. The various European pilot sites included in this study provide important contextual information on the generalisability of the ValueCare approach in different European settings. By using a uniform questionnaire and measurements, and by using the ICHOM standard sets, we apply a thorough and relevant evaluation design in all countries. Third, by using co-design ValueCare will allow active participation of end-users which stimulates local ownership and acceptability of developed solutions (Sanders, 2008). A final contribution of this study concerns the ICT support to enhance integration by providing e-health communication and self-management tools. The use of ICT can increase patient ownership by allowing users to have insight in their health data (Oresktovic et al., 2015). Additionally, it fosters collaboration by facilitating interprofessional communication and communication between patients and healthcare providers which is essential for coordinating care for older persons. This provides valuable information for integrating digital solutions into routine practice in various care settings.

We also expect to encounter some challenges, especially now due to the pandemic. Having older citizens with one or more chronic conditions, frailty, or mild cognitive impairment to participate may pose a challenge (Dibartolo & McCrone, 2003). Recruitment of participants can be organized in different manners and depends on the availability and organizational resources in the local context. The engagement strategy developed in WP2 aims to increase the participation rate, including organizing open events to recruit participants. However, due to the COVID-19 pandemic these events might have to take place in an adjusted form, such as in an online environment. Furthermore, as our target group consists of older persons, it is possible that participants move to another place (e.g. nursing home), pass away during the follow-up period, or are no longer able to participate. We also foresee challenges with regard to the adoption of the ValueCare digital solution by the various stakeholders. It is possible that some elements of the digital solution are not used by older adults or professionals. Adoption depends on how digital technologies allow people to live their lives in ways that are valuable to them (Nikou et al., 2020). Therefore, the co-design process and training activities is expected to facilitate the adoption of technology by the target groups.

In summary, the results of this study will provide evidence on the effects of a new and innovative integrated care model that can potentially enhance the 'Quadruple Aim'

regarding the care for older people with a chronic condition, frailty or mild cognitive impairment. By applying integrated health/social care pathways while using the approach of 'value-based care', and using appropriate ICT tools in the current practice in seven European countries, this study is positioned to transform care delivery to older persons.

4 References

Akpan, A., Roberts, C., Bandeen-Roche, K., Batty, B., Bausewein, C., Bell, D., Bramley, D., Bynum, J., Cameron, I. D., Chen, L. K., Ekdahl, A., Fertig, A., Gentry, T., Harkes, M., Haslehurst, D., Hope, J., Hurtado, D. R., Lyndon, H., Lynn, J., Martin, M., … Banerjee, J. (2018). Standard set of health outcome measures for older persons. *BMC geriatrics*, *18*(1), 36. https://doi.org/10.1186/s12877-017-0701-3

Banerjee S. Multimorbidity: older adults need health care that can count past one. Lancet. 2014;385:587–589. doi: 10.1016/S0140-6736(14)61596-8.

Baxter, S., Johnson, M., Chambers, D. *et al.* The effects of integrated care: a systematic review of UK and international evidence. *BMC Health Serv Res* 18, 350 (2018). https://doi.org/10.1186/s12913-018-3161-3

Beard JR, Officer A, de Carvalho IA, Sadana R, Pot AM, Michel J-P, et al. The world report on ageing and health: a policy framework for healthy ageing. Lancet. 2016;387(10033):2145–54.

Bedard M, Molloy DW, Squire L et al. The Zarit Burden Interview: a new short version and screening version. Gerontologist 2001;41: 652-657

Berwick, D. M., Nolan, T. W., & Whittington, J. (2008). The triple aim: care, health, and cost. *Health affairs*, *27*(3), 759-769.

Bodenheimer, T., & Sinsky, C. (2014). From triple to quadruple aim: care of the patient requires care of the provider. *The Annals of Family Medicine*, *12*(6), 573-576.

Bouwmans, C., Krol, M., Severens, H., Koopmanschap, M., Brouwer, W., & Hakkaart-van Roijen, L. (2015). The iMTA productivity cost questionnaire: a standardized instrument for measuring and valuing health-related productivity losses. *Value in health*, *18*(6), 753-758.

Chang, J. T., & Ganz, D. A. (2007). Quality indicators for falls and mobility problems in vulnerable elders. *Journal of the American Geriatrics Society*, *55*, S327-S334.

Cleemput, I., Neyt, M., Thiry, N., De Laet, C., & Leys, M. (2011). Using threshold values for cost per quality-adjusted life-year gained in healthcare decisions. *International journal of technology assessment in health care*, *27*(1), 71-76.

Curran GM, Bauer M, Mittman B, et al. Effectiveness- implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care 2012; 50: 217–226.

Deschodt, M., Laurent, G., Cornelissen, L., Yip, O., Zúñiga, F., Denhaerynck, K., … & De Geest, S. (2020). Core components and impact of nurse-led integrated care models for home-dwelling older people: a systematic review and meta-analysis. *International Journal of Nursing Studies*, 103552.

Dibartolo, M.C. & McCrone, S. (2003). Recruitment of rural communitydwelling older adults: Barriers, challenges, and strategies, Aging & Mental Health, 7:2, 75-82, DOI: 10.1080/1360786031000072295

Eklund K, Wilhelmson K. Outcomes of coordinated and integrated interventions targeting frail elderly people: a systematic review of randomised controlled trials. Health and Social Care in the Community 2009; 17:447–58.

European Commission. (2018). "The 2018 Ageing Report: Economic and Budgetary Projections for the EU Member States (2016-2070). *Institutional Paper No. 79. Luxembourg: Publications Office of the European Union.*

Eurostat (2019). Ageing Europe: Looking at the lives of older people in the EU. Retrieved from: https://ec.europa.eu/eurostat/statistics-explained/index.php.

Everink IHJ, van Haastregt JCM, Evers SMAA, Kempen GIJM, Schols JMGA (2018a) An economic evaluation of an integrated care pathway in geriatric rehabilitation for older patients with complex health problems. PLoS ONE 13(2): e0191851. https://doi.org/10.1371/journal. pone.0191851

Everink, I. H., van Haastregt, J. C., Tan, F. E., Schols, J. M., & Kempen, G. I. (2018b). The effectiveness of an integrated care pathway in geriatric rehabilitation among older patients with complex health problems and their informal caregivers: a prospective cohort study. *BMC geriatrics*, *18*(1), 285.

Franse, C. B., van Grieken, A., Alhambra-Borrás, T., Valía-Cotanda, E., van Staveren, R., Rentoumis, T., ... & Verma, A. (2018). The effectiveness of a coordinated preventive care approach for healthy ageing (UHCE) among older persons in five European cities: a pre-post controlled trial. *International journal of nursing studies*, *88*, 153-162.

van der Heide, I., Snoeijs, S., Melchiorre, M. G., Quattrini, S., Boerma, W., Schellevis, F., & Rijken, M. (2015). Innovating care for people with multiple chronic conditions in Europe. *Brussels: ICARE4EU.*

Hughes ME, Waite LJ, Hawkley LC, Cacioppo JT (2004) A short scale for measuring loneliness in large surveys: Results from two population-based studies. Res Aging 26(6):655–672.

ICHOM (2016). Elderly Standard Set. Retrieved June 5, 2020, from: www.ichom.org

ICHOM (2019). Overall Adult Health Standard Set. Retrieved June 5, 2020, from: www.ichom.org

Looman, W. M., Huijsman, R., & Fabbricotti, I. N. (2019). The (cost-) effectiveness of preventive, integrated care for community-dwelling frail older people: A systematic review. *Health & social care in the community*, *27*(1), 1-30.

Low LF, Yap M, Brodaty H. A systematic review of different models of home and community care services for older persons. BMC Health Services Research 2011; 11:93.

Katzan, I. L., & Lapin, B. (2018). PROMIS GH (patient-reported outcomes measurement information system Global Health) scale in stroke: a validation study. *Stroke*, *49*(1), 147-154.

Kristensen, T. S., Borritz, M., Villadsen, E., & Christensen, K. B. (2005). The Copenhagen Burnout Inventory: A new tool for the assessment of burnout. *Work & Stress*, *19*(3), 192-207.

Mahoney, F. I., & Barthel, D. W. (1965). Functional evaluation: the Barthel Index: a simple index of independence useful in scoring improvement in the rehabilitation of the chronically ill. *Maryland state medical journal*.

Markle-Reid, M., Valaitis, R., Bartholomew, A., Fisher, K., Fleck, R., Ploeg, J., ... & Thabane, L. (2019). Feasibility and preliminary effects of an integrated hospital-to-home transitional care intervention for older adults with stroke and multimorbidity: A study protocol. *Journal of Comorbidity*, *9*, 2235042X19828241.

Metzelthin SF, van Rossum E, de Witte LP, Ambergen AW, Hobma SO, Sipers W, Kempen GI. Effectiveness of interdisciplinary primary care approach to reduce disability in community dwelling frail older people: cluster randomised controlled trial. BMJ. 2013;347:f5264.

Miller JN, Colditz GA, Mosteller F. How study design affects outcomes in comparisons of therapy. II: Surgical. Stat Med. 1989;8(4):455–66.

Minkman, M., Ahaus, K., Fabbricotti, I., Nabitz, U., & Huijsman, R. (2009). A quality management model for integrated care: results of a Delphi and Concept Mapping study. *International Journal for Quality in Health Care*, *21*(1), 66-75.

Netten, A., Burge, P., Malley, J., Potoglou, D., Towers, A. M., Brazier, J., … & Forder, J. (2012). Outcomes of social care for adults: developing a preference-weighted measure. *Health Technology Assessment*, *16*(16), 1-166.

Niccoli, T., & Partridge, L. (2012). Ageing as a risk factor for disease. *Current biology*, *22*(17), R741-R752.

Nikou, S., Agahari, W., Keijzer-Broers, W., & de Reuver, M. (2020). Digital healthcare technology adoption by elderly people: A capability approach model. *Telematics and Informatics*, *53*, 101315.

Oelke, N. D., Suter, E., da Silva Lima, M. A. D., & Van Vliet-Brown, C. (2015). Indicators and measurement tools for health system integration: a knowledge synthesis protocol. *Systematic Reviews*, *4*(1), 99.

Oreskovic, N., Huang, T., & Moon, J. (2015). Integrating mHealth and systems science: A combination approach to prevent and treat chronic health conditions. *JMIR MHealth and UHealth*, *3*(2).

Rafferty AM, Philippou J, Fitzpatrick JM, et al. Development and testing of the 'Culture of Care Barometer' (CoCB) in healthcare organisations: a mixed methods study. BMJ Open 2017;7:e016677. doi:10.1136/ bmjopen-2017-016677

Rockwood K, Song X, MacKnight C, et al. A global clinical measure of fitness and frailty in elderly people. CMAJ. 2005;173:489–495. doi: 10.1503/cmaj.050051.

Sanders EB-N, Stappers PJ. (2008). Co-creation and the new landscapes of design. CoDesign 4(1):5–18.

Slater, H., Campbell, J., Stinson, J., Burley, M., & Briggs, A. (2017). End-user and implementer experiences of mhealth technologies for noncommunicable chronic disease management in young adults: Systematic review. *Journal of Medical Internet Research*, *19*(12). doi: 10.2196/jmir.8888.

Topp, C. W., Østergaard, S. D., Søndergaard, S., & Bech, P. (2015). The WHO-5 Well-Being Index: a systematic review of the literature. *Psychotherapy and psychosomatics*, *84*(3), 167-176.

Üstün, T. B., Chatterji, S., Kostanjsek, N., Rehm, J., Kennedy, C., Epping-Jordan, J., … & Pull, C. (2010). Developing the World Health Organization disability assessment schedule 2.0. *Bulletin of the World Health Organization*, *88*, 815-823.

Vestjens, L., Cramm, J. M., Birnie, E., & Nieboer, A. P. (2019). Cost-effectiveness of a proactive, integrated primary care approach for community-dwelling frail older persons. *Cost Effectiveness and Resource Allocation*, *17*(1), 14.

Weiss, D. J., Dawis, R. V., England, G. W., Lofquist, L. H. (1977). Manual for the Minnesota Satisfaction Questionnaire. Minneapolis, MN: Univer. of Minnesota, Vocational Psychology Department.