

Horizon 2020 Project ValueCare: Value-based methodology for integrated care supported by Information and Communication Technology

Submission date 15/09/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/11/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/01/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The Information and Communication Technology (ICT) enabled value-based methodology for integrated care (ValueCare) approach aims to deliver efficient outcome-based, integrated health and social care to older persons with multimorbidity, mild to moderate cognitive impairment, and frailty. In comparison with 'usual care', the ValueCare approach is expected to achieve more favourable outcomes for older persons (65 years and older), their informal caregivers, and health and social care practitioners. This study aims to examine the effectiveness and implementation of ValueCare in seven large-scale pilots in Europe including Athens, Greece; Coimbra, Portugal; Cork/Kerry, Ireland; Rijeka, Croatia; Rotterdam, the Netherlands; Treviso, Italy, and; Valencia, Spain.

Who can participate?

Older persons (aged 65 years and older), their informal caregivers, and health and social care practitioners based in the participating areas.

What does the study involve?

Each pilot site will design an integrated care pathway based on the ValueCare model for the target population. The assessment and personalized care plan will be enhanced by a mobile health application (i.e., the ValueCare app) for older persons. If the patient provides consent, informal caregivers and health and social care practitioners can have access to a web-based application (i.e., the ValueCare web application) that monitors the progress of the patient.

Data will be collected in pilot sites at inclusion (before ValueCare), after 12 months, and after 18 months to assess the benefits of the ValueCare approach versus usual care. Information on indicators of health, wellbeing, and quality of life; lifestyle behaviour; health care use; perceived carer burden; and (job) satisfaction will be collected. In addition, the acceptability, appropriateness, feasibility, fidelity and costs of the ValueCare approach will be measured.

What are the possible benefits and risks of participating?

Benefits

By participating in this study, patients are contributing to the development of the future health care provided to older persons.

Risks

As this is a non-invasive study, no significant risks for participants are foreseen. However, if a certain risk occurs in a pilot site, there is a related policy available, including guidance on ethical procedures how to deal with them, as they arise.

Where is the study run from?

Erasmus MC (The Netherlands)

When is the study starting and how long is it expected to run for?

From April 2021 to April 2024

Who is funding the study?

The European Commission, Horizon 2020 call Digital Transformation in Health and Care

Who is the main contact?

Prof Hein Raat

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Study website

projectvaluecare.eu

Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Horizon 2020 Grant Agreement number 875215

Study information

Scientific Title

'Value-based methodology for person-centred, integrated care supported by Information and Communication Technologies' (ValueCare): a preventive integrated health and social care approach for older persons' care in seven European countries

Acronym

ValueCare

Study objectives

Older persons in the intervention group (i.e. individuals receiving ValueCare) will have more favourable results with regard to indicators of health, wellbeing, and quality of life; lifestyle behavior; and reduced health care use compared with older persons participating in the comparison group (i.e. individuals receiving 'usual care'). With respect to the informal caregivers and health and social care practitioners, lower caregiver burden, and improved wellbeing and (job) satisfaction among participants in the intervention group are expected. Furthermore, it is expected that the costs of care for the intervention group will be lower, compared to the comparison group.

Ethics approval required

Ethics approval required

Ethics approval(s)

1. Approved 26/11/2021, Medische Ethische Commissie (MEC) – Erasmus Medical Center Rotterdam (Erasmus MC, Room Ae-337, Dr. Molewaterplein 40, Rotterdam, 3015 GD, Netherlands; +31 (0)10-70 34428, +31 (0)10-70 33625; metc@erasmusmc.nl), ref: 20210727
2. Approved 18/04/2022, Ethics and Conduct committee (Athens Medical Center, Athens, 15125, Greece; +30 2106198100; info@iatriko.gr), ref: E.Σ. 86/ 12-04-22
3. Approved 24/03/2022, Comissão da Administração Regional de Saúde do Centro (no address provided, Coimbra, no zip code provided, Portugal; no telephone number provided; noemail@provided), ref: 13-2022
4. Approved 11/08/2021, University College Dublin Human Research Ethics Committee (UCD HREC) and Clinical Research Ethics Committee of the Cork Teaching Hospital (CREC) (no address provided, Cork, no zip code provided, Ireland; no telephone number provided; noemail@provided), ref: LS-21-69-Darley
5. Approved 31/08/2021, The Ethical Committee—Faculty of Medicine, University of Rijeka (no address provided, Rijeka, no zip code provided, Croatia; no telephone number provided; noemail@provided), ref: 2170-24-04-3-21-11

6. Approved 03/03/2022, Comitato Etico per Sperimentazione Clinica delle province di Treviso e Belluno (no address provided, Treviso, no zip code provided, Italy; no telephone number provided; noemail@provided), ref: 1159/CE Marca

7. Approved 07/05/2020, Comisión de Ética en Investigación Experimental de la Universitat de València (no address provided, Valencia, no zip code provided, Spain; no telephone number provided; noemail@provided), ref: no ref provided

Study design

Multicenter specific pre-post controlled non-randomized study design

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Older persons living with medical conditions, disabilities, frailty, and/or mild to moderate cognitive decline

Interventions

In the intervention condition, the ValueCare approach will be applied. In the control condition 'usual care' is applied. Each pilot site will design an integrated care pathway based on the ValueCare model for the target population. In all pilots the value-based care approach is applied, which is a specific application of 'outcome-based care delivery' developed by the International Consortium for Health Outcomes Measurements (ICHOM: www.ichom.org). This entails that a self-reported questionnaire will be administered to assess the physical, mental, and overall well-being of the participants. The aim of this assessment is to identify the individual care needs of older persons, and to monitor and discuss the outcomes with the patient and their caregiver. Based on the assessment's outcomes and detected needs, each patient will be given a personalized care plan which is co-produced by the patient, their caregiver, and care team members. The shared care plan will be periodically reviewed and can be adjusted in line with people's health and wellbeing. The stakeholders involved in the ValueCare pathway, including patients and care providers, are supported by the ValueCare technical solution. The assessment and personalized care plan will be enhanced by a mobile health application (i.e., the ValueCare app) for older persons. If the patient provides consent, informal caregivers and care team members can have access to a web-based application (i.e., the ValueCare web application) that monitors the progress of the patient. Data will be collected at baseline (T0), after 12 months (T1), and after 18 months (T2) by using self-reported questionnaires.

Intervention Type

Not Specified

Primary outcome measure

Health-related quality of life (HR-QoL) score measured using the PROMIS Scale v1.2 – Global Health (PROMIS-10) at baseline, 12, and 18 months

Secondary outcome measures

1. Loneliness measured using the UCLA 3-Item Loneliness Scale (Hughes et al., 2004) at baseline, 12, and 18 months
2. Alcohol consumption measured using one item of the International Consortium for Health Outcomes Measurement (ICHOM, 2016) at baseline, 12, and 18 months
3. Smoking status measured using one item of the ICHOM at baseline, 12, and 18 months
4. Nutrition and undernutrition measured using the SNAQ65+ (Wijnhoven et al., 2012) at baseline, 12, and 18 months
5. Physical activity measured using one item of the SHARE-Frailty instrument (Romero-Ortuno, 2011) and one item of the Internal Physical Activity Questionnaire (IPAQ) on sitting time (Lee et al., 2011) at baseline, 12, and 18 months
6. Frailty measured using the 15-item Tilburg Frailty Indicator (Gobbens, 2010) at baseline, 12, and 18 months
7. Falls-related quality of life measured using the reported number of falls in the previous year and fear of falling on the Visual Analogue Scale for Fear of Falling (Chang & Ganz, 2007) at baseline, 12, and 18 months
8. Medication intake and use measured using the Medication Risk Questionnaire (MRQ-10) (Barenholtz Levy, 2003) at baseline, 12, and 18 months
9. Activities of daily living measured using the modified 10-item Barthel Index (Collin et al., 1988) at baseline, 12, and 18 months
10. Co-morbidities measured using one item of the ICHOM at baseline, 12, and 18 months
11. Health and social care utilization measured using the modified SMRC Health Care Utilization questionnaire (Lorig et al. 2001) at baseline, 12, and 18 months
12. Time spent on providing informal care measured using the iMTA Valuation of Informal Care Questionnaire (iVICQ) (Hoefman et al., 2013) at baseline, 12, and 18 months
13. Carer burden measured using the 4-item Zarit Burden Interview (ICHOM, 2016; Bedard et al., 2001) at baseline, 12, and 18 months
14. Control over daily life measured using the Adult Social Care Outcomes Toolkit (Netten et al., 2012) at baseline, 12, and 18 months
15. Working conditions of care team practitioners measured using the Culture of Care Barometer tool (Rafferty et al., 2017) at baseline, 12, and 18 months
16. Job satisfaction of care team members measured using the Minnesota Satisfaction Questionnaire - Short Form (Weiss et al., 1977) at baseline, 12, and 18 months
17. Work-related burnout measured using the Copenhagen Burnout Inventory (Kristensen et al., 2005) at baseline, 12, and 18 months
18. Body Mass Index (BMI) measured by asking about length and weight (ICHOM, 2016) at baseline, 12 and 18 months
19. Quality of life measured using the EQ-5D-5L measure (Herdman et al., 2011) at baseline, 12 and 18 months

Cost measures:

1. Productivity losses measured using the iMTA Productivity Cost Questionnaire (iPCQ) (Bouwman et al., 2015) at 18 months

Implementation outcomes will be measured in terms of acceptability, appropriateness, feasibility, fidelity, and costs.

Overall study start date

01/04/2021

Completion date

30/04/2024

Eligibility

Key inclusion criteria

1. Older persons:

1.1. Aged ≥ 65 years

1.2. Have a confirmed diagnosis of the targeted chronic condition at the time of enrolment

1.3. Community-dwelling (not living in long-term care facilities) or are temporarily in a hospital or institution and are expected to be referred to outpatient rehabilitation services

1.4. Able to give informed consent

2. Informal and formal caregivers:

2.1. Informal caregivers (e.g., relatives, friends) of participating older persons will be approached to participate in the study

2.2. Health and social care practitioners who work with older persons having the targeted condition in each pilot site will be approached to participate in the study

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

We aim to include 1680 older persons in total: 120 participants in the intervention group and 120 participants in the control group in each pilot site. In addition, 50-70 informal caregivers and 30-40 health and social care practitioners will be included in the intervention group.

Key exclusion criteria

Unable to comprehend the information provided in the local language or cannot cognitively evaluate the risks and benefits of participation

Date of first enrolment

01/11/2021

Date of final enrolment

31/07/2023

Locations

Countries of recruitment

Croatia

Greece

Ireland

Italy

Netherlands

Portugal

Spain

Study participating centre**Erasmus Medical Center**

Dr. Molewaterplein 40

Rotterdam

Netherlands

3015 GD

Study participating centre**Athens Medical Center**

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Marousi

Athens

Greece

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Study participating centre**Fundación de la Comunidad Valenciana para la Promoción Estratégica el Desarrollo y la Innovación Urbana**

Calle Juan de Verdeguer, 16

Valencia

Spain

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Study participating centre**Azienda ULSS n.2 Marca Trevigiana**

via S. Ambrogio di Fiera, 37

Treviso

Italy

31100

Study participating centre
University of Rijeka, Faculty of Medicine
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Study participating centre
Caritas Diocesana de Coimbra
Rua Dom Francisco de Almeida, nº 14
Coimbra
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Study participating centre
University College Dublin, School of Medicine
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Sponsor information

Organisation
Erasmus MC

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Sponsor type
University/education

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ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Government

Funder Name

Horizon 2020 Framework Programme

Alternative Name(s)

EU Framework Programme for Research and Innovation H2020, Horizon 2020, Rahmenprogramm Horizont 2020, Programa Marco Horizonte 2020, Programme-cadre Horizon 2020, Programma quadro Orizzonte 2020, Program ramowy Horyzont 2020, Horizont 2020, Horizonte 2020, Orizzonte 2020, Horyzont 2020, Horizon 2020 Framework Programme (H2020), H2020

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed jour.

Intention to publish date

31/03/2025

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	in Valencia (Spain)	31/05/2024	28/06/2024	Yes	No
Protocol article	in Rijeka (Croatia)	03/01/2025	27/01/2025	Yes	No

