ISRCTN25089186 https://doi.org/10.1186/ISRCTN25089186

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

Submission date	**Recruitment status**	[_] Prospectively registered
15/09/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/11/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
27/01/2025	Other	[X] 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
h.raat@erasmusmc.nl

Contact information

Type(s)
Public

Contact name
Prof Hein Raat

ORCID ID
https://orcid.org/0000-0002-6000-7445

Contact details
Wytemaweg 80
Rotterdam
Netherlands
3000 CA
+31107038580
h.raat@erasmusmc.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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: Ε.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 Commit tee 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

Study type(s)
Quality of life

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(s)
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

Key secondary outcome(s))
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) (Bouwmans et al., 2015) at 18 months

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

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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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
Distomou 5-7
Marousi
Athens
Greece
15125

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
46024

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
Braće Branchetta 20/1
Rijeka
Croatia
51000

Study participating centre
Caritas Diocesana de Coimbra
Rua Dom Francisco de Almeida, nº 14
Coimbra
Portugal
3030-382

Study participating centre
University College Dublin, School of Medicine
Belfield
Dublin 2

Ireland
0000

Sponsor information

Organisation
Erasmus MC

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, Horizon 2020 Framework Programme (H2020), Rahmenprogramm Horizont 2020, Horizont 2020, Programa Marco Horizonte 2020, Horizonte 2020, Programme-cadre Horizon 2020, Orizzonte 2020, Programma quadro Orizzonte 2020, H2020

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes