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Urban Health Centres Europe, a preventive integrated health and social care approach for active and healthy ageing among community-dwelling older citizens, adapted to five European settings

Submission date
27/02/2017

Recruitment status
No longer recruiting

Registration date
13/03/2017

Overall study status
Completed

Last Edited
05/06/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Background and study aims
By 2050, the number of Europeans over 65 will double and the number of over 75 will almost triple, causing a steep increase in demand for care. Care is currently characterised by a professional approach, where health and social care are isolated from each other. Urban Health Centres Europe (UHCE) is a European research project which started in January 2014. It promotes integrated health and social care, early detection of frailty, management of polypharmacy (the use of four or more medications), the prevention of falls and management of loneliness for active and healthy ageing in European cities. The aim of this study is to compare this approach with the usual care for community-dwelling older citizens aged 75 and older.

Who can participate?
People aged 75+ who are living independently

What does the study involve?
The intervention and control sites (GP practices or primary care centers) are located in different areas of the city. Participants are allocated to the intervention and control groups based on their location (whether they live in the area of the control or intervention site). In Pallini participants are randomly allocated into the intervention and control groups. The control group receives usual care, and no care plan is made or carried out based on the assessment. The intervention group receives the UHCE approach, which starts with an assessment of frailty and fall risks, medication risks and loneliness in order to identify priorities for prevention and care. The results of the assessments are discussed with the older person, a person in charge of care coordination (nurse practitioner or other) and a physician. A decision on a (preventive) care plan is made, which can include frailty action (based on the judgement of a physician), fall prevention actions (including exercise groups, home hazard identification or other actions based on the judgement of a physician), actions addressing medication risk and polypharmacy (including appropriate

prescribing and adherence action or other actions based on the judgement of a physician) and actions addressing loneliness (including support groups, social activities, or other actions based on the judgement of a physician). The care coordinator (usually a nurse or a trained physician assistant) coordinates and monitors the progress of the care plan under the supervision of the physician. Follow-up appointments are scheduled if needed. The care coordinator monitors the compliance and success of care. Healthy lifestyle, fall risk, medication risk, loneliness, frailty, hand-grip strength, mid-upper arm circumference, level of independence and quality of life are measured at the start of the study and after 12 months.

What are the possible benefits and risks of participating?
Participants benefit from receiving a health assessment and appropriate follow-up care such as exercise groups or social activities, based on their wishes and in consultation with their healthcare provider. There are no risks associated with participating, the assessment takes about 1 hour, and follow-up care is advised by the participant's healthcare provider and is always in agreement with the participant.

Where is the study run from?
1. Zorg op Noord (Netherlands)
2. Polibienestar Research Institute - Universitat de València (Spain)
3. Municipality of Pallini (Greece)
4. University of Manchester (UK)
5. University of Rijeka, Faculty of Medicine (Croatia)

When is the study starting and how long is it expected to run for?
January 2014 to December 2017

Who is funding the study?
The Third EU Health Programme

Who is the main contact?
1. Prof. Hein Raat (scientific) (h.raat@erasmusmc.nl)
2. Ms Carmen Franse (public)

Study website
http://uhce.eu

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
104072-2075

Study information

Scientific Title
Urban Health Centres Europe, a preventive integrated health and social care approach compared with usual care for community-dwelling older citizens aged 75 years and older aimed at healthy and active ageing

Acronym
UHCE

Study objectives
1. In the intervention group, compared to the control group there will be more favourable lifestyles (physical activity, smoking, alcohol use), less fall and medication risks, higher level of independence, less frailty and more favourable health-related quality of life
2. In the intervention group, compared to the control group there will be less use of ambulatory and residential health and social care
3. In the intervention group the reach will be 70% or higher, and appreciation of 7 or higher on a 1-10 scale

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Netherlands: Medische Ethische Toetsings Commissie (METC) – ErasmusMC Rotterdam, 08/01/2015, ref: MEC-2014-661
2. UK: NRES Committee West Midlands - Coventry & Warwickshire, 06/03/2015, ref: 15/WM/0080
3. UK: NRES Committee South Central – Berkshire B, 29/20/2014, ref: 14/SC/1349
4. Spain: Comisión de Investigación - Consorcio Hospital General Universitario de Valencia, 29/01/2015, ref: CICHGUV-2015-01-29-01
5. Croatia: The Ethical Committee - Faculty of Medicine University of Rijeka, 07/04/2014, ref: 2170-24-01-14-02
6. Greece: The Ethics and Scientific board - Latriko Palaiou Falirou Hospital, 04/03/2015, ref: 20150304-01

Study design
All pilot cities except for Pallini: non-randomized pre-post controlled design
Pallini: randomized design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Healthy lifestyles, fall risk, medication risk and loneliness level, frailty, level of independence, and health-related quality of life

Interventions
The evaluation of UHCE has a specific pre-post controlled design in all pilot cities except for Pallini. The intervention and control sites (GP practices or primary care centers) are located in different areas of the city. Participants are allocated to intervention and control groups based on their location (whether they live in the area of the control or intervention site). In Pallini a randomized design was used; all eligible patients of the Municipal Health and Social Services were randomized (by using a random numbers table) into intervention and control groups. The intervention group receives the UHCE approach. The control group receives usual care, no care plan is made or executed based on the assessment.

UHCE starts with a frailty assessment and an assessment of fall risks, medication risks and loneliness in order to identify priorities for prevention and care of the older citizens joining UHCE. Frailty is measured with the Tilburg Frailty indicator. Fall risk is measured following the

protocol developed by Dutch research institute Veiligheid.nl. Medication risk measured is currently taking 5 or more different medicines and/or difficulty to take the medicines as prescribed. Loneliness is measured with the social subscale of the Tilburg Frailty Indicator.

The results of the assessments will be discussed with the older person, a person in charge of care coordination (nurse practitioner or other) and a physician. A decision on a (preventive) care plan will be made, using evidence based “care pathways” (interventions) that were described in the UHCE template, with contextual adaptations to each of the five participating pilot cities. The main UHCE (preventive) care pathways are: frailty action (based on the judgement of a physician), multifactorial fall prevention actions (which included exercise groups, home hazard identification or other actions based on the judgement of a physician), actions addressing medication risk and polypharmacy (which included appropriate prescribing and adherence action or other actions based on the judgement of a physician) and actions addressing loneliness (which included support groups, social activities, or other actions based on the judgement of a physician).

The care coordinator (usually a nurse or a trained physician assistant) will coordinate and monitor the progress of the care plan under the supervision of the physician. Follow-up appointments are scheduled if needed. The care coordinator will monitor the compliance and success of care. The general UHCE template is adjusted in accordance with national standards and the local setting of five pilot cities (Manchester, Pallini, Rijeka, Rotterdam and Valencia).

Data will be collected at baseline (T0); this will be done simultaneously with the frailty assessment after participants have provided written informed consent, and after 12 months (T1). Data collection is done with the use of a questionnaire; which includes the UHCE assessment, outcome and other measures. Two non-invasive measurements (hand-grip strength and mid-upper arm circumference, see below) are additionally performed and written down in the questionnaire.

Intervention Type
Other

Primary outcome measure
Measured at baseline and 12 months:
1. Healthy lifestyle is measured with one item on physical activity, two items on smoking, and three items of the AUDIT-C24 on high-risk alcohol use
2. Fall risk is measured by two items on (the number of) falls in the previous year, a single item asking whether or not the person is afraid of falling, and fear of falling while performing several daily activities as measured by the 7-item Falls Efficacy Scale International (FES-I) short version
3. Medication risk is measured with 10 items of the Medication risk questionnaire (MRQ-10), a tool developed for use by elderly patients to identify who is at increased risk of potentially experiencing a medication-related problem
4. Loneliness is measured with the short 6-item version of the Jong Gierveld loneliness scale, which measures the degree of what one wants in terms of interpersonal affection and intimacy, and what one has
5. Frailty is measured with the 15-item Tilburg Frailty indicator, that includes questions on physical, psychological and social components of frailty, physical frailty is additionally measured with the SHARE-Frailty instrument which is an instrument that was developed and validated in an European population, SHARE-frailty includes hand-grip strength measurement and physical frailty is also measured with a measurement of the mid-upper arm circumference (MUAC), a measure for malnutrition

6. Level of independence is measured with the Groningen activity restriction scale (GARS), that includes 18 items on independence of activities of daily living (ADL) and instrumental activities of daily living (iADL) and additionally with the one-item Global Activity Limitation Index (GALI)
7. Health Related Quality of Life (HRQOL) is measured with the 12-item short-form (SF-12)34 35 and the full 5-item psychological well-being subscale of the SF-36

Secondary outcome measures
Measured at baseline and 12 months:
1. Use of ambulatory and residential health and social care, measured with four questions regarding the use of doctor appointments, household work, help caring (such as washing or dressing) and hospital admissions
2. Proportion of the participants contacted who participate in the UHCE approach (reach)and appreciation of UHCE, measured with a questionnaire. If possible reasons for refusal are reported.

Overall study start date
01/01/2014

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Citizens living independently
2. Aged 75 years or more
3. Are, according to their general physician, expected to be able to participate in the study for at least 6 months

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
250 in both control and intervention group of each city, so 1250 in both control and intervention groups in total

Total final enrolment
1844

Key exclusion criteria
1. Unable to comprehend the information provided in the local language
2. Unable to cognitively evaluate the risks and benefits of participation
3. Not expected to be able to make an informed decision regarding participation in the study, according the general practitioner

Date of first enrolment
01/05/2015

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
Croatia

England

Greece

Netherlands

Spain

United Kingdom

Study participating centre
Zorg op Noord
Rotterdam
Netherlands
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Study participating centre
Polibienestar Research Institute - Universitat de València
Valencia
Spain
46022

Study participating centre
Municipality of Pallini
Pallini
Greece
GR 15344

Study participating centre

University of Manchester
Manchester
United Kingdom
M13 9PL

Study participating centre
University of Rijeka, Faculty of Medicine
Rijeka
Croatia
51000

Sponsor information

Organisation
Erasmus MC

Sponsor details
Wytemaweg 80
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Netherlands
3015 CN

Sponsor type
University/education

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Government

Funder Name
The Third EU Health Programme

Results and Publications

Publication and dissemination plan

The results will be disseminated by the project team through publications in scientific journals and conferences, the aim is to publish study effects in the course of 2018. To further disseminate the knowledge to all stakeholders the trialists will use the project website (www.uhce.eu). The European Local Inclusion and Social Action Network (ELISAN) is one of the partners of the UHCE project and aids the dissemination of project results to all stakeholders via social media.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Hein Raat (h.raat@erasmusmc.nl)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		09/03/2017	13/03/2017	No	Yes
Protocol article	protocol	11/09/2017		Yes	No
Results article	results	01/12/2018		Yes	No
Other publications	cost-effectiveness analysis	13/06/2019	19/12/2019	Yes	No
Other publications	Factors associated with polypharmacy and the high risk of medication-related problems	07/11/2022	08/11/2022	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No
Results article	Mixed methods evaluation of reach, dose and experience	06/10/2019	05/06/2024	Yes	No
Results article	Primary outcome association between physical activity and health-related quality of life	01/10/2021	05/06/2024	Yes	No
Results article	cross-sectional study was performed with baseline data	01/10/2019	05/06/2024	Yes	No
Results article	physical, psychological and social frailty	12/07/2021	05/06/2024	Yes	No
Results article	socio-demographic characteristics	09/02/2021	05/06/2024	Yes	No