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Effectiveness and cost-effectiveness of comprehensive care for older people in primary care

Submission date
10/06/2020

Recruitment status
No longer recruiting

Registration date
11/06/2020

Overall study status
Completed

Last Edited
19/07/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The number of older people with multiple chronic conditions and complex health needs will increase rapidly over the coming decades. Effective and cost-effective patient care models are needed to support older people to maintain their quality of life (QoL) and physical performance to live longer independently in their own homes.

Who can participate?
Home-dwelling older adults (age 75 years or above), that use at least seven prescribed medicines, dietary supplements or lotions/creams.

What does the study involve?
The intervention comprises an at-home patient interview, health review, pharmacist-led clinical medication review, an interprofessional team meeting, and nurse-led care coordination and health support. The usual care group patients (control group) receive usual care at the health centre. Quality of Life (SF-36) and physical performance are measured at the baseline and at the 1-year and 2-year follow-ups for all the participants.

What are the possible benefits and risks of participating?
Taking part could help improve future care of the older people. For intervention group the benefits are e.g. that comprehensive medication and health reviews are performed, care and medication plans are created/updated, and named nurse will work as a care coordinator for them. There are no anticipated risks to taking part in the study, but quality of life and physical performance tests will take some time.

Where is the study run from?
The study is conducted in collaboration with Tornio primary health care centre, (setting and intervention providers; GPs, nurses and a pharmacist), Alatornio community pharmacy (intervention provider; a pharmacist), and the Faculty of Pharmacy, University of Helsinki (intervention providers and researchers).

When is the study starting and how long is it expected to run for?
The study started in October 2014 and run until May 2018.

Who is funding the study?
1. The Foundation of Vappu and Oskari Yli-Perttula (Finland) (Funding of the research project execution and researchers travel costs)
2. Tornio city (Finland) (Funding of the research project execution)
3. The Association of the Finnish Pharmacies (AFP) (Finland) (One year funding of Heini Kari's doctoral studies)
The researchers are independent of the funders.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
OMA21

Study information

Scientific Title
Care Plan 2100 - Developing and evaluating a people-centred care model

Acronym
PCCM

Study objectives
People-centred care has positive effect on physical functioning and quality of life in older adults with lower costs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/04/2014, regional North Ostrobothnia Hospital District (Finland) ethics committee (PPSHP:n alueellinen eettinen toimikunta, Yhtymähallinto N5 (1 krs.), PL 10, 90029 OYS, Finland; +35840 773 1529, minna.makiniemi@ppshp.fi), ref: 32/2014

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Care for older people

Interventions
Effectiveness and cost-utility of a people-centre care model in primary care for multimorbid, community-living older people aged ≥75 years are compared to usual care in the health centre (RCT). The intervention comprises an at-home patient interview, health review, pharmacist-led clinical medication review, an interprofessional team meeting, and nurse-led care coordination and health support.

Intervention group: The intervention comprised an at-home patient interview, health review, pharmacist-led clinical medication review, an interprofessional team meeting, and nurse-led care coordination and health support.

Usual care group (control group): The usual care group patients received usual care at the health centre. Usual care is accessed and utilised by the patient on her/his own initiative. However, the electronic medication lists of the patients in the usual care group were reviewed by a pharmacist to ensure there were no serious interactions or other potential drug-related problems that could have been life-threatening. In such a case, the patient would have been contacted, directed to appropriate healthcare services and withdrawn from the RCT.

Quality of Life (SF-36) and physical performance are measured at the baseline and at the 1-year and 2-year follow-ups. The SF-36 data are transformed into SF-6D scores to calculate quality-adjusted life years (QALYs). Healthcare resource use are collected and transformed into costs and the ICER is calculated.

Follow-up time for each group was 2 years.

Randomisation: An envelope method was used, in which an envelope was randomly selected from a box of randomly mixed closed envelopes, containing the group designation, and opened, and the group allocation was recorded.

Intervention Type
Mixed

Primary outcome(s)
1. Quality of Life (SF-36) and physical performance are measured at the baseline and at the 1-year and 2-year follow-ups. The SF-36 data are transformed into SF-6D scores to calculate quality-adjusted life years (QALYs).
2. Healthcare resource use is collected and transformed into costs and the ICER is calculated at the 1-year and 2-year follow-ups

Key secondary outcome(s))
Physical dimension component summary in the SF-36 at the baseline and at the 1-year and 2-year follow-ups

Completion date
31/05/2018

Eligibility

Key inclusion criteria
1.Home-dwelling outpatients
2. Aged ≥ 75 years
3. ≥ 7 prescribed medicines, dietary supplements or lotions/creams identified through the health centre patient records
4. Living in Tornio

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
323

Key exclusion criteria

1. Appointed a guardian of interests
2. Living in a care home
3. Appointed to a hospital ward at the time of identification
4. Geriatrician-completed clinical medication review in the last two years

Date of first enrolment
01/10/2014

Date of final enrolment
31/05/2016

Locations

Countries of recruitment
Finland

Study participating centre
Tornio Primary Health Care Centre
Sairaalakatu 1
Tornio
Finland
95400

Sponsor information

Organisation
University of Helsinki

ROR
https://ror.org/040af2s02

Funder(s)

Funder type
Research organisation

Funder Name
The Foundation of Vappu and Oskari Yli-Perttula

Funder Name
Tornio city

Funder Name
The Association of the Finnish Pharmacies (AFP)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as participant consent forms and ethics approval did not include permission for open public access data, and due to change of individual participant identification.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/06/2022	19/07/2023	Yes	No
Other publications	People-centred care model (PCCM) development for RCT, Care Plan 2100	05/02/2022	19/07/2023	Yes	No