

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

<b>Submission date</b> 10/06/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/06/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/07/2023	<b>Condition category</b> Other	<input type="checkbox"/> 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?

Heini Kari

heini.kari@helsinki.fi

## Contact information

### Type(s)

Scientific

### Contact name

Ms Heini Kari

### ORCID ID

<https://orcid.org/0000-0002-2061-2552>

### Contact details

Division of Pharmacology and Pharmacotherapy (7th floor)

Faculty of Pharmacy

Viikinkaari 5 E (PL 56)

University of Helsinki, Helsinki, Finland

Helsinki

Finland

00014

+358 (29)41911

heini.kari@helsinki.fi

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### 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  $\geq 75$  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  $\geq 75$  years
3.  $\geq 7$  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**

**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?
<a href="#">Results article</a>		30/06/2022	19/07/2023	Yes	No
<a href="#">Other publications</a>	People-centred care model (PCCM) development for RCT, Care Plan 2100	05/02/2022	19/07/2023	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes