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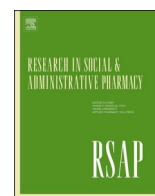
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# Effectiveness and cost-effectiveness of a people-centred care model for community-living older people versus usual care — A randomised controlled trial

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## ABSTRACT

**Background:** There is a need for effective and cost-effective interprofessional care models that support older people to maintain their quality of life (QoL) and physical performance to live longer independently in their own homes.

**Objectives:** The objectives were to evaluate effectiveness, QoL and physical performance, and cost-utility of a people-centred care model (PCCM), including the contribution of clinically trained pharmacists, compared with that of usual care in primary care.

**Methods:** A randomised controlled trial (RCT) with a two-year follow-up was conducted. The participants were multimorbid community-living older people, aged  $\geq 75$  years. 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. At the baseline and at the 1-year and 2-year follow-ups, QoL (SF-36, 36-Item Short-Form Health Survey) and physical performance (SPPB, Short Performance Physical Battery) were measured. Additionally, a physical dimension component summary in the SF-36 was calculated. The SF-36 data were transformed into SF-6D scores to calculate quality-adjusted life-years (QALYs). Healthcare resource use were collected and transformed into costs. A healthcare payer perspective was adopted. Incremental cost-effectiveness ratio (ICER) was calculated, and one-way sensitivity analysis was performed.

**Results:** No statistically or clinically significant differences were observed between the usual care ( $n = 126$ ) and intervention group ( $n = 151$ ) patients in their QoL; at the 2-year follow-up the mean difference was  $-0.02$ , (95 % CI  $-0.07; 0.04$ ,  $p = 0.56$ ). While the mean difference between the groups in physical performance at the 2-year follow-up was  $-1.02$ , ( $-1.94; -0.10$ ,  $p = 0.03$ ), between the physical component summary scores it was  $-7.3$ , ( $-15.2; 0.6$ ,  $p = 0.07$ ). The ICER was  $-73\ 638\text{€}/\text{QALY}$ , hence, the developed PCCM dominated usual care, since it was more effective and less costly.

**Conclusions:** The cost-utility analysis showed that the PCCM including pharmacist-led medication review dominated usual care. However, it had no effect on QoL and the effect towards physical performance remained unclear.

## 1. Background

The ageing population in developed countries will dramatically

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### Abbreviations

ASCOT	Adult Social Care Outcome Toolkit
CCM	Chronic Care Model
CHEERS	Consolidated Health Economics Evaluation Reporting Standards
CI	Confidence interval
GFR	Glomerular filtration rate
GP	General practitioner
ICER	Incremental cost-effectiveness ratio
ITM	Interprofessional team meeting
ITT	Intention-to-treat
PCCM	People-centred care model
QALY	Quality-adjusted life-year
QoL	Quality of life
RCT	Randomised controlled trial
SD	Standard deviation
SF-36	36-Item short-form health survey
SF-6D	Six-dimensional health state short form
SPPB	Short physical performance battery.

increase the demand for health services. More effective and cost-effective patient care models are needed to meet these demands. Indeed, new interprofessional care models should be designed to increase the comprehensiveness, integration and accessibility of care, and to encourage patients to take an active role in their own healthcare. This could be achieved through “*people-centred care* requiring that users of healthcare services have the education and support they need to make decisions and participate in their own care”.<sup>1</sup>

Providing such *integrated people-centred health services* means that “people and communities, not diseases, are at the centre of health systems, and empowering people to take charge of their own health rather than being passive recipients of services”.<sup>1</sup> Pharmacists, specialists in medications, have the potential to expand their clinical role in providing people-centred care and improving people’s health for example by promoting medication adherence, and optimising pharmacotherapy by conducting clinical medication reviews.<sup>2–6</sup> Based on the previous studies there is evidence that an isolated pharmacist-led medication review interventions cannot be assumed to have an effect on clinical outcomes such as mortality, hospital admissions and quality of life, or current evidence is inconclusive for example in terms of economic outcomes.<sup>7–9</sup> Though clinical medication reviews may improve drug-related outcomes e.g. improve drug adherence and reduce number of drugs and drug-related problems.<sup>7–11</sup> Furthermore, recently it has been found that a patient-centred clinical medication review, in which more specific attention is given to patient’s preferences, personal goals and complaints related to their health and medication during a clinical medication review, could potentially be cost-saving from a societal perspective and also slightly improve health-related QoL measured with EQ-VAS.<sup>12</sup>

People live longer and independently in their own homes; maintaining as good quality of life (QoL) and physical performance as possible is important. Furthermore, comprehensive patient care models in primary care for older people are expected to result in better outcomes and cost savings for the society by preventing or postponing the use of acute care and nursing home admissions. Effectiveness outcome results of various types of primary care interventions to improve or maintain QoL or physical performance in community-living older people have been mixed.<sup>13–14</sup> Some interventions have suggested favourable effects on QoL<sup>15–17</sup>, whereas others reported no significant effect.<sup>18–27</sup> Similarly, some interventions have improved physical functioning<sup>28–30</sup>, while others showed no effect.<sup>15,19,22,31–32</sup> Some interventions have shown potential to be cost-effective<sup>15–16,30,33–34</sup>, others have not

<sup>18–19,21,24–25,27</sup> For example, Sahlen et al.<sup>16</sup> found preventive home visits supporting well-being and physical activity of older people to be cost-effective with willingness-to-pay about €14 000 per gained quality-adjusted life year (QALY), and Melis et al.<sup>15</sup> suggested that multidisciplinary intervention model for community-living older people was cost-effective at a willingness-to-pay of €34 000. Liimatta et al.<sup>34</sup> suggested that a multiprofessional preventive home visit intervention appeared to have positive effects on health-related quality of life without additional costs. On the contrary, Brettschneider et al.<sup>18</sup> found that the probability of an incremental cost-effectiveness ratio (ICER) for preventive home visits based on multidimensional geriatric assessment to be <€50 000 per QALY was only 15 %, and Uittenbroek et al.<sup>27</sup> who evaluated the cost-effectiveness of an integrated primary care service for older adults estimated that the ICER was €188 975 for an additional QALY gained, and at a willingness-to-pay €20 000 for a QALY gained, the probability of the intervention to be cost-effective was 1%.

In general, these interprofessional interventions and studies focusing on improving or maintaining QoL or physical performance in community-living older people in primary care sector have not included comprehensive contribution of clinically trained pharmacists. If the pharmacist has been involved in the care team, the role has usually been minor compared to that of other healthcare professionals, and, for example, had included patient record based medication review [e.g. 26]. However, a systematic review suggests that inclusion of clinically trained pharmacists in general practice teams could be cost-effective, for example, for reducing cardiovascular risk in patients with type 2 diabetes, including pharmacist’s contribution in evaluating the medication regimen and medical history, and making recommendations to the prescribing physician.<sup>35</sup> Indeed, health economic studies are still scarce, the follow-up periods have been relatively short, and long-term health effects of the interprofessional interventions are unknown in primary care for the aged.<sup>14,36</sup>

An interprofessional *people-centred care model (PCCM)* for multi-morbid older people and healthcare professionals supporting them in primary care was developed for, and implemented in, this study. The framework of the PCCM was based on the Chronic Care Model (CCM), an organisational approach for chronic care management in primary care settings.<sup>37,38</sup> The CCM advocates a change from the traditional acute care model of primary healthcare to a model that addresses collaborative, person-centred approach to improve chronic disease management. The key professionals providing care in the PCCM were clinically trained pharmacists, named nurse and GPs. The aim of this study was to evaluate real-world health outcomes, quality of life and physical performance, and cost-utility of a PCCM in primary care compared with that of usual care.

## 2. Methods

### 2.1. Study design

The study was a prospective longitudinal randomised controlled trial (RCT; Care Plan 2100) in primary care setting in Tornio (a town with 22 000 inhabitants), Finland, with a two-year follow-up (October 2014 to May 2018). The RCT was conducted in collaboration with Tornio health centre, the only public health centre in Tornio (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; three pharmacists). There are two community pharmacies in Tornio serving approximately 22 000 inhabitants. The reasons for selecting Alatornio pharmacy as a partner in this study included the pharmacy’s previous collaboration with the health centre, and access to a pharmacist who was accredited to complete clinical medication reviews and willing to work part-time with the health centre team. The size of Alatornio pharmacy measured by the number of dispensed prescriptions per year is above the average for community pharmacies in Finland.

The study protocol was approved by the regional North Ostrobothnia Hospital District, Finland, ethics committee (32/2014). Written, informed consent was obtained from all participants in the study. The RCT study adheres to CONSORT guidelines, and it was retrospectively registered in the ISRCTN registry (ISRCTN89081244, <https://doi.org/10.1186/ISRCTN89081244>). The study perspective of the cost-effectiveness analysis is Finnish health care payer perspective. The Consolidated Health Economics Evaluation Reporting Standards (CHEERS) statement was followed in reporting on cost-effectiveness.<sup>39</sup>

## 2.2. Study participants and randomisation

The sample size calculation was based on the primary outcome variable (SF-6D). A subgroup of 136 patients would provide the 80 % power (two-tailed  $\alpha$ -error 5 %) to detect clinically important differences ( $\Delta 0.041$ )<sup>40</sup> in the SF-6D score between the groups, when the standard deviation of SF-6D was 0.12.

Consenting patients were enrolled to the study between October 2014 and May 2016. Home-dwelling outpatients aged  $\geq 75$  years with  $\geq 7$  prescribed medicines, dietary supplements or lotions/creams were identified through the Tornio health centre patient records (Pegasos, CGI, Finland). The exclusion criteria were: living in a care home; having been admitted to a hospital ward at the time of identification; having been appointed a guardian of interests; not a Finnish citizen (Tornio is a border town); not living in Tornio; or having had a geriatrician-completed clinical medication review in the last two years. The inclusion/exclusion criteria were set to identify multimorbid older people, who were likely to need clinical medication and health reviews, and support provided by a named nurse, and potentially benefit from the intervention in terms of maintaining their quality of life and physical functioning. The researchers had only access to Tornio health centre data, which was the reason why the participants were limited to Finnish citizens living in Tornio. Eligible patients were selected at random by using Microsoft Excel (2013) and approached and recruited in six rounds. During each recruitment round around 150 patients were sent a patient recruitment information letter: a cover letter; information on the study; informed consent form; and a prepaid self-addressed return envelope. Consenting patients were randomly allocated to the intervention ( $n = 150$ ) and usual care groups ( $n = 150$ ): an envelope method was used, in which an envelope was randomly selected from a box of 30 randomly mixed envelopes, containing the group designation, and opened, and the group allocation was recorded. The used envelopes were returned in random order to the same box. This process was iterated until the maximum number of participants ( $n = 300$ ) had been recruited. No patient subgroups were defined.

## 2.3. Intervention

The purpose of the people-centred care model (PCCM) was to recognise and treat each patient as a person, encourage her/his active role in collaborative health goal setting and empower multimorbid patients to live well with long-term conditions. At baseline, the PCCM comprised: an at-home patient interview by a named nurse and a pharmacist; completing health (the named nurse) and clinical medication (a pharmacist) reviews; and agreeing on the care and medication plan based on the patient's care targets and needs at an interprofessional team meeting (ITM) (the named nurse, a pharmacist and a GP). During the two years of follow-up, care coordination and health support were provided by the named nurse.

To support the intervention group patients to prepare for the at-home interviews, a self-care evaluation questionnaire was sent to them. The patients were encouraged to mention any health, social and medicine related issues important to them and any health-related goals towards which they wanted to work.

During the at-home interview the pharmacist compared the health centre medication list to the patient's actual use of prescription and

over-the-counter drugs, and dietary supplements. The patient's experiences and medicines use were discussed: background details (e.g. drug allergies); therapy control, experienced drug-related problems, potential adverse drug reactions, drug administration problems, any concerns with drugs, and health history (e.g. exercise and nutrition). The pharmacist completed a clinical medication review report, utilising the primary care clinical records; the procedure has been described elsewhere.<sup>41</sup>

During the same at-home interviews, the named nurse, also utilising the primary care clinical records, discussed health-related issues and goals with the patients to build therapeutic partnership with the patient and empower her/him to take charge of her/his own health. The nurse completed a health review report.

At the ITM, the nurse, a pharmacist and a GP reviewed the completed reports, discussed the drug related problems (DRPs) and health-related issues, made decisions on patient care based on the patient's preferences and the pharmacist's and the nurse's recommendations and created a care plan for each patient. The care plan comprised patient details, including short personal history and diseases, patient's own view of her/his well-being, patient-oriented health goals, self-care advice, medication and health plan and significant health-related information for healthcare providers.

After completing and sending the care plan to the patient, either the nurse or a pharmacist contacted the patient to discuss the care plan and its goals in detail. Additionally, the patients were given a direct phone number to the named nurse and were told that they could contact him during office hours and receive support in health-related issues and coordination of care. Along with the intervention, usual care was also provided at the health centre.

## 2.4. Usual care

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 if no chronic illness such as asthma or severe heart condition exists. Usual care within the existing health system does not include in-depth clinical medication and health reviews, which were part of the intervention, care plans completed in team meetings nor coordination of care by a healthcare professional. However, after each recruitment round and randomisation and allocation to groups, 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 DRPs 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. The healthcare professionals providing usual care were those who worked in the Tornio health centre and involved same professionals who provided care for the intervention group patients.

## 2.5. Outcome measurements

The primary health outcome was quality of life (QoL, SF-36) and secondary health outcome was physical performance (SPPB, and physical dimension component summary of SF-36). At the baseline and at the 1-year and 2-year follow-up, the QoL, using the 36-Item Short-Form Health Survey (SF-36)<sup>42</sup> was administered, and physical performance, using the Short Performance Physical Battery (SPPB),<sup>43</sup> was measured by a study nurse. The SF-36 data were converted into SF-6D; a generic preference-based single index measure of health (scale 0–1) that can be used to generate quality-adjusted life-years (QALYs) to be used in cost-utility analysis.<sup>44–45</sup> The United Kingdom population based utility weights were applied.<sup>44</sup> The SF-6D includes six health-related quality of life dimensions: physical functioning, role limitations, social functioning, bodily pain, mental health, and vitality. Additionally, a physical dimension component summary in the SF-36 was calculated.<sup>46</sup>

## 2.6. Healthcare and intervention resource use and costs

Healthcare resource use over a follow-up period of one year and two years were collected for all participating patients from the health centre patient records (Pegasos, CGI, Finland). These included e.g. primary care (Tornio health centre) and secondary care (Länsi-Pohja central hospital) data, comprising *primary care* GP and nurse planned appointments, emergency appointments, phone calls, and inpatient care at the health centre, *secondary care* outpatient and inpatient care, and home care, home care services and sheltered housing services. The full list of included healthcare resource use is given in [Supplementary Table 1](#). The mean time used to provide the intervention was calculated from the healthcare records completed by the named nurse, the pharmacists and the GPs. These include time for phone calls to the patient (named nurse/pharmacist), time for travelling to patient at-home interview (named nurse and pharmacist), at-home interview (named nurse and pharmacist), clinical medication review (pharmacist), ITM (named nurse, pharmacist and GP), conducting medication plan (pharmacist) and conducting care plan (named nurse). Travel expenses (by car) to at-home patient interview were included. All unit costs were determined using the national unit costs for Finland provided by The Finnish Institute for Health and Welfare,<sup>47</sup> except the hourly wage for pharmacists (health centre pharmacist and community pharmacist), which was assessed using the General collective agreement for municipal personnel ([Supplementary Table 1](#)). The costs are those of the Finnish public healthcare service provider. All costs were converted to year 2017 costs using Price index of public expenditure, municipal health services and Index of wage and salary earnings.<sup>48</sup> Costs were calculated by multiplying the number of healthcare services utilisation units with cost prices of each unit. The costs are presented in Euros (€). The yearly total costs per patient were calculated as a sum of all cost categories, and aggregated to estimate mean total costs per person per year. No discounting was applied due to the relatively short time-horizon.

## 2.7. Data handling and statistics

The collected data were entered into Microsoft Excel (2016) and SPSS (version 25) databases. The quality of the data entries was checked before starting the analyses. For the SF-36-data, the imputation strategy of replacing missing values with the mean of the same sample dimension was used.<sup>46</sup> Potentially missing cost data was not imputed; available cases were analysed.

Descriptive statistical analyses were performed. The intervention and usual care group characteristics and measurements at the baseline were compared using chi-squared test for nominal data and *t*-test for normally distributed ratio data. Primary analyses were based on the intention-to-treat (ITT) principle, and comparisons were between the randomised groups. Furthermore, within group comparisons were performed. Statistical and clinical differences between and within the intervention group and the usual care group were analysed using group means, standard deviations and *t*-tests (independent *t*-test for between group analysis and paired-samples *t*-test for within group analysis). Statistical significance was set at  $p \leq 0.05$ .

The outcome measure of cost-effectiveness analysis was the incremental cost-effectiveness ratio (ICER).<sup>49</sup> The QALYs were calculated to combine quality of life scores (scale 0–1) and quantity of time using area under the curve method.<sup>49,50</sup> Finally, the ICER was calculated as:

$$ICER = \frac{C_1 - C_0}{E_1 - E_0} = \frac{\Delta C}{\Delta E}$$

where  $C_1$  and  $E_1$  are the cost and the effectiveness (measured as QALYs) in the intervention group and  $C_0$  and  $E_0$  are the cost and the effectiveness in the usual care group. For the ICER calculation, only patients with data for both costs and outcomes were included. One-way sensitivity analysis, in which one value (costs or QALYs of intervention or usual care

group) is varied by a given amount, and the impact of the change in the parameter on the ICER result was calculated. The threshold chosen was based on discussions with health economic experts, which led to the choice of pragmatic  $\pm 20\%$ .<sup>51</sup>

## 3. Results

### 3.1. Participant recruitment and baseline characteristics

In total, 2324 eligible patients were identified and 831 recruitment letters were sent. 323 patients (39%) returned the recruitment letter: 174 patients were randomised to the intervention and 149 to the usual care group ([Fig. 1](#)). Before starting the intervention, 46 patients were excluded (see [Fig. 1](#), CONSORT flow chart for reasons of exclusions), and finally, at the baseline, 151 patients were in the intervention and 126 in the usual care group. At one-year follow-up, there were 141 intervention and 124 usual care group patients, and at two-year follow-up, 124 and 112 patients, respectively.

At the baseline, there were no significant differences in patient characteristics or in the SF-6D scores between the intervention and the usual care group ([Table 1](#)). However, while the SPPB scores were different in the intervention and usual care group,  $8.4 \pm 3.0$  and  $7.6 \pm 3.0$ , respectively, ( $p = 0.04$ ), no significant difference was found in the SF-36 physical component summary scores. Altogether, there were 16 individual missing values in the SF-36-data that were imputed.

### 3.2. Health outcomes

At the one-year follow-up, the results of the Quality of Life (SF-6D), physical performance (SPPB) and physical dimension component summary score (SF-36) did not differ between the intervention and the usual care groups ([Table 2](#)). At the two-year follow-up, the physical performance in the intervention group was significantly ( $p = 0.03$ ) higher than in the usual care group. Within both groups, all health outcome results were significantly lower at the two-year follow-up than at the baseline. The deterioration in health outcomes did not differ statistically or clinically between the groups.

### 3.3. Costs

In the first year, the mean total costs were €6788 (SD €11 999) in the usual care group and €5416 (€10 036) in the intervention group ([Supplementary Table 1](#)); the difference was not statistically significant ( $p = 0.31$ ). In the second year, the costs were €8185 (€13 539) and €7625 (€15 078) ( $p = 0.76$ ), respectively. The mean total costs for the two-year follow-up period were €14 454 (€21 097) and €12 315 (€22 587) ( $p = 0.42$ ), respectively. The intervention costs were €207 per intervention group patient.

### 3.4. Cost-utility of the intervention

The mean total costs for usual care and intervention groups were €14 454 and €12 315, while mean QALYs were 1.4454 and 1.4745, respectively ([Table 3](#)). Consequent ICER in base case was  $-73\,638$  €/QALY, which suggests that the intervention dominates usual care, since it was more effective and less costly. One-way sensitivity analysis results are shown in [Table 3](#).

## 4. Discussion

In this RCT-based analysis the effectiveness and cost-effectiveness of the PCCM, including the contribution of clinically trained pharmacists, was compared to usual care. The ICER was  $-73\,638$  €/QALY (the intervention dominates usual care); hence, the mean total costs were lower and the generated QALYs higher in the intervention group than in the usual care group. The cost-effectiveness results were tested by the

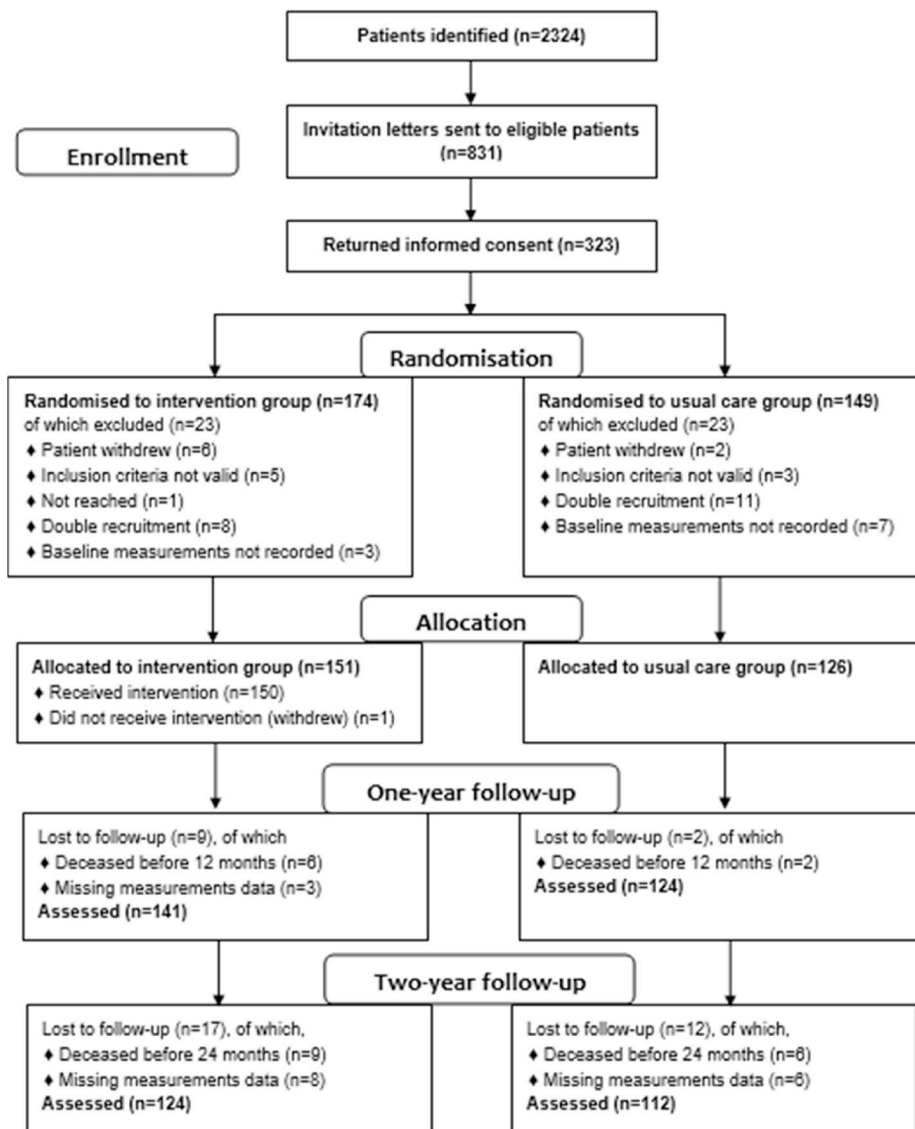


Fig. 1. Patient flow chart.

one-way sensitivity analysis, which resulted in a maximum of 25 876 €/QALY in a scenario when usual care costs were calculated to be –20% lower than in the base case analysis. Thus, even the highest ICER did not exceed 30 000 €/QALY and lies below many common international willingness-to-pay thresholds.<sup>52</sup>

While no statistically or clinically significant differences were observed between the usual care and intervention group patients in their QoL, at the two-year follow-up, the physical performance in the usual care group was significantly ( $p = 0.03$ ) lower than in the intervention group. However, there were significant differences of the SPPB between the groups at the baseline ( $p = 0.04$ ), which is why the effectiveness of the PCCM toward physical performance remained unclear. However, there were no significant differences of the SF-36 physical component summary score or in any other characteristics at the baseline, which indicates that the groups were rather comparable at the baseline, and the impact of the baseline differences of the SPPB might have been minor.

There is heterogeneity between previous care interventions, study protocols and settings, and it is difficult to determine which features within the models contribute most to positive QoL [15–17] or physical functioning [28–30] outcomes. A recent systematic review suggests that high-intensity intervention or the presence of a multidisciplinary or inter-organisational care plan was associated with positive outcomes in

primary care settings.<sup>53</sup> Interventions for older people that have shown potential to be cost-effective [15–16, 30, 33–34] and others that have not been cost-effective [18–19, 21, 24–25, 27] have all included interprofessional teamwork. In most of these interventions a nurse has been the main intervention provider and worked in collaboration with other healthcare professionals such as GPs, physiotherapists, occupational therapists, and social workers. In comparison, the strengths of this PCCM were that the interprofessional core team included also a pharmacist, the intervention included pharmacist-led clinical medication reviews and nurse-led health reviews, both with comprehensive patient interviews, and an interprofessional (a GP, a pharmacist and a nurse) face-to-face meeting on patient care, and support and care coordination by the named nurse was provided for two years. Additionally, detailed care plans based on patient-centred goal setting were completed by the interprofessional team.

Integrating community pharmacists into primary care and expanding their role in order to contribute to the safe, effective, and efficient use of medicines has been recommended.<sup>54</sup> Indeed, adding clinically trained pharmacists to health care teams and providing advanced pharmacy services in community and primary care settings appear to be cost-effective.<sup>35</sup> For example, Malet-Larrea et al. (2017)<sup>55</sup> found that it could be efficient use of healthcare resources to optimise aged polypharmacy

**Table 1**

The intervention (n = 151) and usual care group (n = 126) patient characteristics and health measurements at the baseline.

Variable	INTERVENTION GROUP n = 151	USUAL CARE GROUP n = 126	P-VALUE
<b>Gender</b>	<b>n (%)</b>	<b>n (%)</b>	0.25 <sup>a</sup>
Male	58 (38)	40 (32)	
Female	93 (62)	86 (68)	
<b>Age (years)</b>	<b>Mean ±SD (range)</b>	<b>Mean ±SD (range)</b>	0.38 <sup>b</sup>
	81.0 ± 4.5 (75–98)	81.4 ± 4.3 (75–96)	
<b>GFR (ml/min)</b>	<b>Mean ±SD (range)</b>	<b>Mean ±SD (range)</b>	0.31 <sup>b</sup>
	66 ± 14 (31–98) n = 146	68 ± 16 (22–92) n = 122	
<b>MOST COMMON DIAGNOSED DISEASES</b>	<b>n (%)</b>	<b>n (%)</b>	
<b>Cardiovascular system</b> (hypertension, heart failure, coronary heart disease, arrhythmia, hypercholesterolaemia)	136 (90)	114 (92) n = 124	0.59 <sup>a</sup>
<b>Endocrine system</b> (diabetes mellitus, impaired fasting glucose, hypothyroidism)	59 (39)	59 (48) n = 124	0.16 <sup>a</sup>
<b>Malignant disease</b>	31 (21)	18 (15) n = 124	0.20 <sup>a</sup>
<b>Respiratory system</b> (asthma, chronic obstructive pulmonary disease)	28 (19)	24 (19) n = 124	0.86 <sup>a</sup>
<b>Central nervous system</b> (Alzheimer disease, diagnosed memory problems, depression)	13 (9)	18 (15) n = 124	0.12 <sup>a</sup>
<b>NUMBER OF MEDICINES ON THE MEDICATION LIST</b>	<b>Mean ±SD (range)</b>	<b>Mean ±SD (range)</b>	
Number of drugs/dietary supplements/lotions	12 ± 4.9 (6–29)	12 ± 4.9 (1–31) n = 125	0.54 <sup>b</sup>
Regular drugs	10 ± 3.9 (3–24)	10 ± 3.5 (3–21) n = 125	0.62 <sup>b</sup>
Drugs taken as required	2 ± 2.3 (0–11)	3 ± 2.5 (0–13) n = 125	0.54 <sup>b</sup>
<b>HEALTH MEASUREMENTS</b>	<b>Mean ±SD (range)</b>	<b>Mean ±SD (range)</b>	
Quality of Life (SF-6D) (Scale from worst to best 0–1)	0.77 ± 0.1 (0.31–1)	0.75 ± 0.1 (0.39–1)	0.29 <sup>b</sup>
Physical performance (SPPB) (Scale from worst to best 0–12)	8.4 ± 3.0 (0–12)	7.6 ± 3.0 (0–12)	0.04 <sup>b</sup>
Physical dimension component summary score (SF-36) (Scale from worst to best 0–100)	62.4 ± 28.8 (0–100)	56.1 ± 29.0 (0–100)	0.07 <sup>b</sup>

Intervention and usual care group patient characteristic derived from the health centre patient registers. Results of the health measurements (SF-6D, SPPB, SF-36) at the baseline.

SD, Standard Deviation.

GFR, Glomerular Filtration Rate.

SF-36/SF-6D, Short Form Health Survey.

SPPB, Short Performance Physical Battery.

<sup>a</sup> Chi-squared test.

<sup>b</sup> T-test.

patients' medication through medication reviews with follow up. In this study, the role of the pharmacist-led clinical medication review was essential along with interprofessional teamwork and care planning. The pharmacists for example identified on average five drug-related problems per patient, of which one-fifth were rated clinically significant.<sup>41</sup> Furthermore they supported and empowered the patients along with

other healthcare professionals and updated medication lists, which might result in better health outcomes or cost savings in the future.

Additionally, involving the patient in collaborative decision-making and understanding her/him more as a person than a patient were important targets of the intervention, as well as supporting of the medication adherence and providing health empowerment. It may be assumed that building trust and partnership between the patient and a healthcare professional takes time and that is why in this study the follow-up time was 24 months, which is longer than in many other previous economical evaluation studies.<sup>36</sup> It has to be recognised that implementation of PCCM to primary care organisations in order to provide comprehensive, preventive and demand-oriented care for patients requires a shift from providing disease-specific care to people-centred care, which may be time-consuming. While we could not see effects in clinical outcomes in this group of 75+ years old people, it is also worth and necessary to better try identify patients who are most likely to benefit from this kind of care interventions.

This study has several limitations. Firstly, a certain patient group in one town was studied, and the response rate was 39 %, which probably has led to a selection bias towards older people more willing and able to participate. Secondly, the analysis on healthcare costs did not consider costs of medicines purchased from community pharmacies neither the use of informal care, such as care provided by family members. However, the same type of data were (un)available for the intervention and usual care group patients. Thirdly, in this study, the intervention costs related to the work of a pharmacist were based on the hourly wage of the employed pharmacists in the health centre. However, if the community pharmacists were to work part-time in a health centre, there, indeed, would be some other related costs for the community pharmacy, and for that reason the payment should be appropriate to cover these costs. Another limitation is that since this study did not include evaluation of the 95 % confidence intervals for incremental costs and incremental QALYs, the cost-effectiveness plane of the bootstrapped ICERs nor the cost-effectiveness acceptability curve were not presented, and the baseline utility values were not controlled in estimating mean QALYs, which may have had some impact on the results.<sup>56</sup>

The major strengths of the study are that the study design was RCT, it was performed with real patients in a real setting, the power of the study were appropriate for evaluation of the primary outcome (SF-6D), and the intervention was conducted by interprofessional teams including GPs, nurses and pharmacists. However, when planning further studies, consideration should be given to power such studies to detect also other outcomes, such as prevented events or mortality. While the length of the trial was longer than in many other studies, it probably was not long enough to capture all changes in the outcomes; it is possible that some of the benefits of health interventions occur later. In the future, studies modelling the outcomes beyond the trial are recommended. Furthermore, it is possible that health interventions generate benefits that fall outside the healthcare sector and could have not been captured in this study. For example, it has been discussed that the use of preference based instruments having a wider focus on the quality of life attributes beyond health status, such as the Adult Social Care Outcome Toolkit (ASCOT)<sup>57</sup> and the ICECAP-O,<sup>58</sup> could be applied in combination with health-related quality of life instruments to better capture those dimensions of quality of life that are important to older people.<sup>36</sup>

The use of real-world setting and evidence increases the reliability of this study, but may also introduce possible bias. As this was a single-centre study, for example, the blinding of the healthcare professionals in a small town and one health centre might not have been complete during the two-year follow-up, and also usual care may have changed during the trial. However, this effectiveness and cost-effectiveness study provides a relevant contribution to the methods of economic evaluation of collaborative care complex interventions, involving primary care and local community pharmacy alongside a controlled trial. Furthermore, the results give an insight into the quality of life, physical performance, and use of healthcare services and related costs among the older people.

**Table 2**

The health outcome results and their comparison between the usual care group and intervention group, difference of the change in health outcome results between the groups, and comparison of the health outcome results within the groups.

	The health outcome results and their comparison <i>between</i> the usual care group and intervention group		Difference of the change in health outcome results <i>between</i> the usual care group and intervention group <sup>a</sup>			Comparison of the health outcome results <i>within</i> the usual care group and intervention group		
	1 year Mean±SD, n	2 year Mean±SD, n	Baseline to 1 year Difference (Usual care-intervention), n	1 year to 2 years Difference (Usual care-intervention), n	Baseline to 2 years Difference (Usual care-intervention), n	Baseline and 1 year Mean change, (95 % CI) <sup>b</sup> , p-value, n	1 and 2 years Mean change, (95 % CI) <sup>b</sup> , p-value, n	Baseline and 2 years Mean change, (95 % CI) <sup>b</sup> , p-value, n
<b>Quality of Life (SF-6D)</b>								
Usual care group	0.72 ± 0.17, n = 124 <sup>c,e</sup>	0.70 ± 0.21, n = 118 <sup>f</sup>	n = 124	n = 116	n = 120 <sup>g</sup>	-0.02, (-0.05; 0.00), p = 0.07, n = 124	-0.03, (-0.06; 0.00), p = 0.03, n = 116	-0.07, (-0.11; -0.03), p < 0.01, n = 120 <sup>g</sup>
Intervention group	0.74 ± 0.20, n = 147 <sup>c</sup>	0.71 ± 0.25, n = 133 <sup>f</sup>	n = 147	n = 133	n = 139 <sup>g</sup>	-0.03, (-0.06; 0.00), p = 0.07, n = 147	-0.06, (-0.09; -0.02), p = 0.01, n = 133	-0.08, (-0.13; -0.04), p < 0.01, n = 139 <sup>g</sup>
Mean difference, (95 % CI) <sup>b</sup> , p-value	-0.01, (-0.06; 0.03), p=0.62	-0.02, (-0.07; 0.04), p=0.56	0.004, (-0.04; 0.04), p=0.85	0.03, (-0.02; 0.07), p=0.31	0.01, (-0.05; 0.07), p=0.65			
<b>Physical performance (SPPB)</b>								
Usual care group	7.67 ± 3.2, n = 121	6.95 ± 3.6, n = 111	n = 121	n = 111	n = 111	-0.03, (-0.36; 0.29), p = 0.84, n = 121	-0.87, (-1.27; -0.46), p < 0.01, n = 111	-0.88, (-1.34; -0.43), p < 0.01, n = 111
Intervention group	8.26 ± 3.4, n = 140 <sup>d</sup>	7.98 ± 3.5, n = 123 <sup>d</sup>	n = 140	n = 123	n = 123	-0.15, (-0.44; 0.21), p = 0.48, n = 140	-0.50, (-0.82; -0.17), p < 0.01, n = 123	-0.62, (-0.95; -0.28), p < 0.01, n = 123
Mean difference, (95 % CI) <sup>b</sup> , p-value	-0.60, (-1.41; 0.22), p=0.15	-1.02, (-1.94; -0.10), p=0.03	0.08, (-0.38; 0.54), p=0.73	-0.37, (-0.88; 0.14), p=0.16	-0.27, (-0.82; 0.29), p=0.35			
<b>Physical component summary score (SF-36)</b>								
Usual care group	53.2 ± 29, n = 122	46.3 ± 31, n = 112	n = 122	n = 112	n = 112	-4.1, (-7.0; -1.1), p = 0.01, n = 122	-9.0, (-12.5; -5.1), p < 0.01, n = 112	-13.0, (-16.9; -9.1), p < 0.01, n = 112
Intervention group	57.3 ± 29, n = 141	53.5 ± 31, n = 123 <sup>d</sup>	n = 141	n = 123	n = 123	-5.5, (-8.2; -2.7), p < 0.01, n = 141	-5.6, (-8.3; -2.9), p < 0.01, n = 123	-11.2, (-14.2; -8.1), p < 0.01, n = 123
Mean difference, (95 % CI) <sup>b</sup> , p-value	-4.1, (-11.2; 3.0), p=0.25	-7.3, (-15.2; 0.6), p=0.07	1.4, (-2.6; 5.4), p=0.49	-3.4, (-7.8; 1.0), p=0.13	-1.81, (-6.7; 3.0), p=0.46			

CI, Confidence interval; SD, Standard Deviation; SF-36/SF-6D, Short Form Health Survey; SPPB, Short Performance Physical Battery.

<sup>a</sup> Negative difference between intervention and usual care groups means that the intervention group health outcomes decreased less than the usual care group health outcomes during the follow-up period.

<sup>b</sup> 95 % confidence interval for the difference in means.

<sup>c</sup> Two measurements not having been recorded.

<sup>d</sup> One measurement not having been recorded.

<sup>e</sup> If deceased between 0–12 months SF-6D is valued 0.

<sup>f</sup> If deceased between 12–24 months SF-6D is valued 0.

<sup>g</sup> If deceased between 0–24 months SF-6D is valued 0.

The methods and results of this study could be generalized to other similar-sized primary care health centres and community pharmacies, when considering care models for multimorbid community-living older people. Starting such collaboration between primary care health centre and community pharmacy requires, for example, commitment and willingness to development, trust, pharmacists with clinical skills, and a compensation model for pharmacy services.

This study provided new evidence on the effectiveness and cost-effectiveness of the interprofessional people-centred care model, including the contribution of a clinically trained pharmacist. Decision makers could utilise these findings when deciding whether to introduce this kind of care models in primary care practice. However, further possible multi-centre studies are needed to strengthen the evidence on the effectiveness and cost-effectiveness of interprofessional people-centred care models in real-world settings and with multimorbid older people who might have complex and varying needs.

**5. Conclusion**

In conclusion, the cost-utility analysis showed that the PCCM

including pharmacist-led medication review dominates usual care, since it was more effective and less costly. However, no statistically or clinically significant differences were observed in the QoL, and the effectiveness of the PCCM toward physical performance remained unclear among community-living older people.

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**Author statement**

Heini Kari: Conceptualization, Data curation, Investigation, Methodology, Software, Formal analysis, Writing – original draft, Writing – review & editing. Nelli Äijö-Jensen: Data curation, Software, Formal



Table 3

The cost-utility of the usual care compared to intervention. Base case and sensitivity analysis results.

	Total costs, €	Incremental costs, €	Quality adjusted life years, QALYs	Incremental QALYs	Costs €/QALY	ICER, €/QALY
<b>BASE CASE</b>						
Usual care	14 454		1.4454		10 000	
Intervention	12 315	-2139	1.4745	0.029	8352	-73 638 <sup>a</sup>
<b>SENSITIVITY ANALYSIS RESULTS<sup>b</sup></b>						
<b>Usual care group</b>						
Costs +20 %						-173 151
Costs -20 %						25 876
QALYs +20 %						8226
QALYs -20 %						-6724
<b>Intervention group</b>						
Costs +20 %						11 129
Costs -20 %						-158 424
QALYs +20 %						-6603
QALYs -20 %						8047

ICER, Incremental Cost-Effectiveness Ratio.

QALY, Quality-Adjusted Life Year.

<sup>a</sup> The intervention dominates usual care; the costs are lower and more QALYs are gained.<sup>b</sup> One-way sensitivity analysis, in which one value (costs or QALYs of usual care or intervention group) is varied by  $\pm 20\%$ , and the impact of the change in the parameter on the ICER result is calculated.

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### Declaration of competing interest

The authors declare that they have no competing interests.

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### Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.sapharm.2021.07.025>.

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