Research and Theory

The effects of integrated home care and discharge practice on functional ability and health-related quality of life: a cluster-randomised trial among home care patients

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Abstract

Objectives: The aim was to evaluate the effects of integrated home care and discharge practice on the functional ability (FA) and health-related quality of life (HRQoL) of home care patients.

Methods: A cluster randomised trial (CRT) with Finnish municipalities (n=22) as the units of randomisation. At baseline the sample included 669 patients aged 65 years or over. Data consisted of interviews (at discharge, and at 3-week and 6-month follow-up), medical records and care registers. The intervention was a generic prototype of care/case management-practice (IHCaD-practice) that was tailored to municipalities needs. The aim of the intervention was to standardize practices and make written agreements between hospitals and home care administrations, and also within home care and to name a care/case manager pair for each home care patient. The main outcomes were HRQoL—as measured by a combination of the Nottingham Health Profile (NHP) and the EQ-5D instrument for measuring health status—and also Activities of Daily Living (ADL). All analyses were based on intention-to-treat.

Results: At baseline over half of the patient population perceived their FA and HRQoL as poor. At the 6-month follow-up there were no improvements in FA or in EQ-5D scores, and no differences between groups. In energy, sleep, and pain the NHP improved significantly in both groups at the 3-week and at 6-month follow-up with no differences between groups. In the 3-week follow-up, physical mobility was higher in the trial group.

Conclusions: Although the effects of the new practice did not improve the patients' FA and HRQoL, except for physical mobility at the 3-week follow-up, the workers thought that the intervention worked in practice. The intervention standardised practices and helped to integrate services. The intervention was focused on staff activities and through the changed activities also had an effect on patients. It takes many years to achieve permanent changes in every worker's individual practice and it is also likely that changes in working practices would be visible before effects on patients. The use of other outcome measures, such as the use of services, may be clearer in showing a positive impact of the intervention rather than FA or HRQoL.

Introduction

This study focused on older people's managing at home after a hospital stay. The main interest was to evaluate the effects of integrated home care and discharge practice (IHCaD practice). Efficiency has become a more visible part of public service systems since the 1990s. Hospitals have increased their efficiency and consequently the average length of stay has shortened[1]. An increased risk for home care complications after a hospital stay has been found in cases of people living alone, multiple chronic illnesses, and lack of social support [1–3]. It is also known that

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[1] Information retrieved from the Finnish care registers for social welfare and health care (Hilmo), years 2001–2004 STAKES, National Research and Development Centre for Welfare and Health, Helsinki, Finland.

there are problems with the information transfer across organisational boundaries, in the co-ordination of care, and in the integration of services between hospital and home care and between health and social care [2, 4].

The patients' needs are complex and the care approach has changed from individual consultations to multiprofessional teamwork [2, 4–6]. There is some evidence that a more integrated healthcare system may improve efficiency and patient treatment [7]. The need for co-operation between different professionals and the need for integration of services is continuously growing. New interventions like case/care management, discharge and integrated care programmes and multidisciplinary team work [2, 7–11] have been developed to support the discharge of older people from hospital and their managing at home. Although interventions have improved patients' functional ability and the quality of care as well as decreased re-admissions and hospitalisations, the results are contradictory, while clear beneficial effects have not always been found [2, 7, 10]. In many studies there is a lack of either randomisation or a control group. Even in randomised studies there are methodological problems, such as not being able to avoid co-intervention, sample sizes being small and the lack of adequate power to detect the effects of an intervention [10, 12–14].

To our knowledge, discharge and home care interventions have not been previously studied using a cluster randomised trial (CRT), although this is a suitable design when an intervention influences changes in practice and affects groups of people rather than individuals [15, 16]. The aim of the study was to evaluate the effects of integrated home care and discharge practice (IHCaD-practice) on the functional ability (FA) and health-related quality of life (HRQoL) of home care patients using a CRT.

Methods

Design and settings

The effects of the new practice were evaluated using a CRT in 22 Finnish municipalities. Each municipality formed its own cluster.

Municipalities' recruitment and randomisation

This study belongs to the series of studies called 'Integrated Services in the Practices of Home Care and Discharge' [17]. The results of earlier studies were used as a basis for formulating criteria for the municipality-pairs for this study. Municipalities were chosen from the total number of Finnish municipalities (n = 448 as of 2001), with the minimum number of inhabitants set at over 10,000 (capital city was excluded). Municipality pairs were recruited by mail based on the following criteria for pairing:

1. the populations in municipalities were similar,
2. the pathways of patient care (= care episode) were similar,
3. the proportion of patients discharged from hospital to home were similar and
4. the administration structures of health and social care were similar.

Two municipalities were matched by researchers according to the above criteria and were then recruited together. All participating municipalities signed a written agreement. Furthermore, all hospitals serving the participating municipalities were involved in the study. (Table 1)

The municipality-pairs were randomised to a trial (n = 11) or to a control group (n = 11) after the pilot study (Figure 1). The purpose of the pilot study was to ensure the success of the randomisation before the follow-up study had begun. The randomisation was carried out by researchers using a lottery. Hospital and home care staff and the interviewers were aware of which group the municipality belonged to, but patients were not.

Sample

Power calculations were performed for the two main outcome variables: HRQoL using a population-based sample of the HRQoL instrument (the 15D) [18] and success in discharge from hospital to the patient's home[2]. The power calculation took into account that randomisation focused on a patient cluster (municipalities) and not on a single patient [15]. We assumed an intra-cluster correlation (ICC) of $\rho = 0.05$. According to the calculation, an adequate power ($\alpha = 0.05$, $\beta = 0.20$) to detect significant changes in both outcome variables can be reached by a sample of 22 clusters (11 per group) and 35 patients in each cluster (n = 770). The study design and the flow of participants are shown in Figure 1.

The interviewers recruited patients to the study between October 2002 and July 2003. A two-stage filter was used to include or exclude patients. At the first stage, study candidates were included (in the

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[2] Information retrieved from the Finnish care registers for social welfare and health care (Hilmo), year 1997, STAKES, National Research and Development Centre for Welfare and Health, Helsinki, Finland.

Table 1. Characteristics of study population and municipalities at baseline

	Intervention group	Control group	p
Study population	n=354	n=314	
Age, mean (sd)	81.7 (6.5)	81.7 (7.1)	ns
Gender, women (%)	73.7	74.1	ns
Marital status, widowed (%)	51.1	48.9	ns
Education, <7 years (%)	85.3	86.4	ns
Living status, alone (%)	75.5	73.0	ns
Children, 'yes' (%)	80.2	83.7	ns
Number of diagnoses, mean (sd)	4.1 (2.25)	3.8 (1.91)	0.046
Study municipalities	n=11	n=11	
Size			
10,000–21,000	2	3	
21,001–35,000	5	5	
35,001–96,000	4	3	
Structure of health and social care			
Combined	3	3	
Study hospitals (26)			
University hospitals (tertiary level)	4	3	
Regional hospitals (secondary level)	5	5	
Health centre hospitals (primary level)	11	11	

order of their arrival) if they were aged 65 years or older, lived in the study municipalities, and were admitted to hospital from home. If the primary admission diagnosis was cancer, dementia or some psychiatric diagnosis, the patient was excluded. Final selection was made at discharge based on the following criteria: the preliminarily chosen patient had to be discharged back home with regular home care services. Those patients who were unable to answer the Short Portable Mental Status-test (SPMSQ-test) [19] were excluded.

Intervention

In Finland, the municipalities (n=448, year 2001) have a legislative responsibility to arrange health and social care for their citizens [20, 21]. Home care is provided by home help service units (under social welfare) or home nursing units (under health care) either together or separately. Primary health care is served by municipal health centres including various outpatient offices and bed wards (primary level). For specialist medical treatment, Finland is divided into 20 hospital districts. Each municipality is a member of a hospital-district joint authority, which is responsible for organising specialised medical and hospital (tertiary and secondary level) treatment in its own district [22] (see Figure 1). Home care patients are discharged to home from specialised care hospitals directly or via health centre wards.

There are some common problems in home care and discharging practices in Finland, such as shortcomings in the flow of information (between different professionals and between hospital and home care, particularly at a specialised care level), a lack of clarity on responsibilities and the distribution of work (particularly in discharging a patient from hospital to home care), a reactive as opposed to proactive way of working (ad hoc discharges from hospital to home) and a lack of integration in home care services (especially for a patient with multiple service needs) [23, 24].

One aim of the intervention was to standardise practices and make written agreements between hospital and home care and within home care, which defined practices, responsibilities and support tools. At the same time the patient's whole care chain from home to hospital and from hospital to home was described in writing and made available to all those involved in the care chain. Previous to the intervention, only a part of the chain, for example, from hospital discharge to home, has been described, though not in as much detail, while home care responsibilities in particular were hardly ever mapped in the care chain.

The intervention was a generic prototype of care/case management-practice (IHCaD-practice) [17, 25], which was tailored to fit the municipalities' administrative structure and practice codes. Multidisciplinary teamwork is further emphasised in the hospital as well as in home care practices. The home care team (representatives from home nurses and home aids and a doctor) named a working pair (cf. a care/case manager) inside the team. The care/case manager has previously been used in only a few municipalities, and not before as pair [24]. This care/case manager pair consisted of a home nurse and a home aid/helper. The care/case manager pair was assigned to
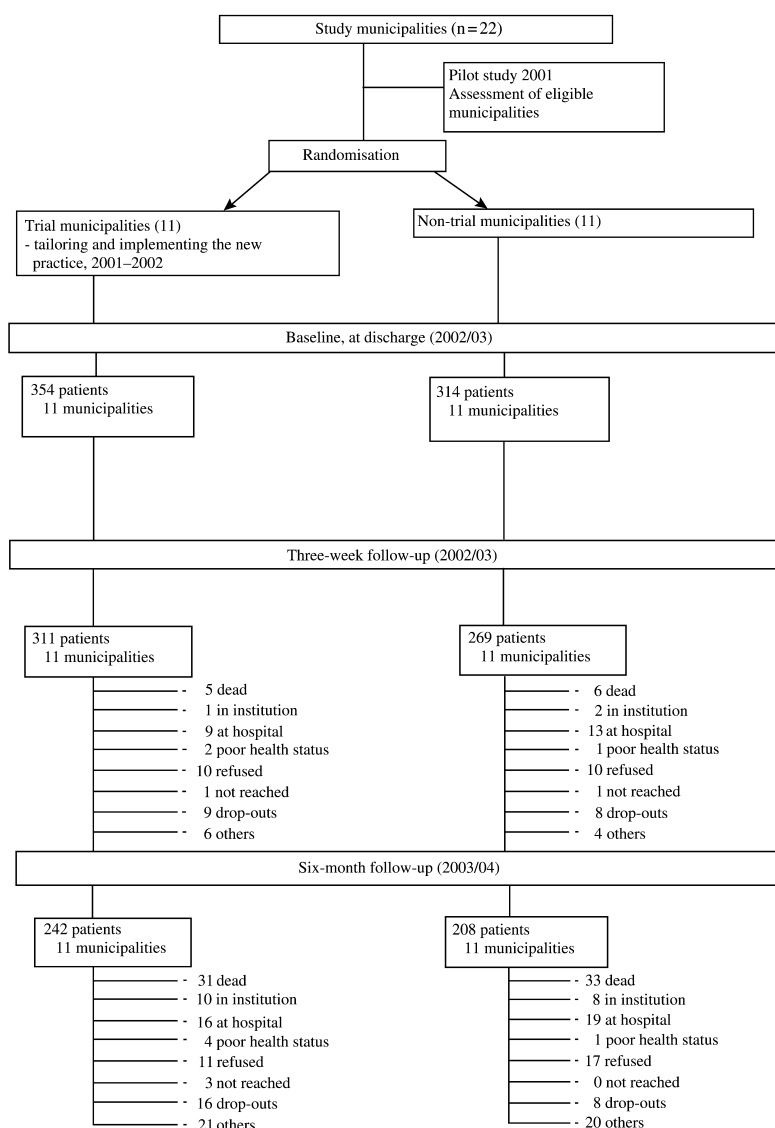
Figure 1. Study design and flow of participants.

all patients who received home care services regularly. The pair planned and integrated home care services together with the patient, with the informal care givers and with other service providers. Further, the pair participated in planning the patient's discharge from hospital to home care with hospital staff (proactive discharge planning including, among other things, home care staff consultation and meetings). We assumed that a care/case manager pair who is familiar with the patient and the service organisation and with the required information and support from multi-disciplinary team is able to integrate various home care services effectively based on the patient's needs. By offering adequate care and services at the right time it is possible to prevent or at least slow down the deterioration of patients' FA and HRQoL (Figure 2).

The IHCaD-practice [17, 25] was implemented in the trial municipalities by means of action research [26, 27]. A written prototype of the intervention practice that included the criteria and implementation instructions acted as tools for the intervention. The researchers guided and supported the municipalities in tailoring a municipality-specific practice and in devising an implementation plan (lasting for 1–1.5 years), and arranging for national seminars (4 days) and meetings at municipality level (4 days). The intervention was applied to home care and hospital staff (not to patients) and it is assumed that through the changing practices, it would also have an effect on patients. The most significant differences between the control and intervention group centred on the previous lack of a care/case manager pair, little participation of
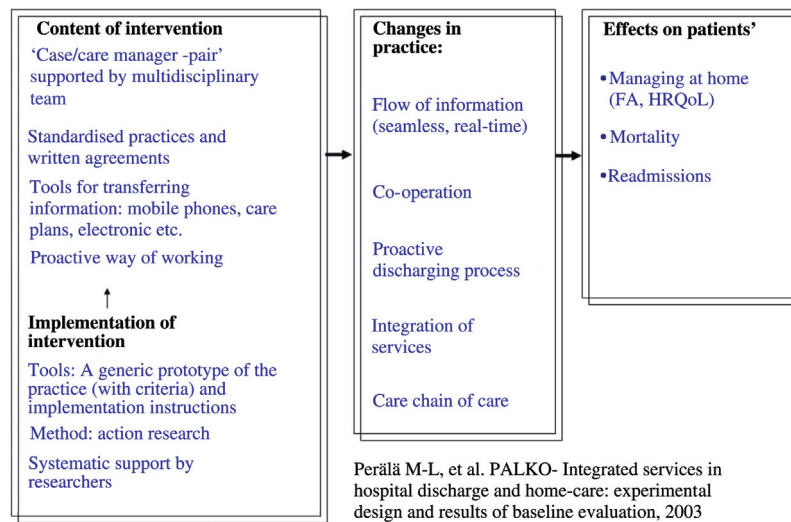
Figure 2. Intervention.

home care staff in the planning of hospital discharges, and a lack of systematic agreements concerning the flow of information and co-operation.

Data collection

Three kinds of data were used: patient interviews, medical records, and care register data compiled by means of a personal identification number for the patient. In each municipality and hospital, a trained interviewer who did not work on the wards or for the home care agency and did not participate in the development of the intervention carried out the interviews. The interviewers selected eligible participants and interviewed them during 2002–2003 using a structured questionnaire at baseline, and at 3-week and 6-month follow-ups. Patients' diagnoses and medication use were obtained from medical records.

The registered data were gathered from the care registers for social welfare and health care[3], the statistics on causes of death[4] and the Sotka-municipal database for social and health statistics[5] during 2002–2004. The registry data contained information on patient care episodes, deaths and number of readmissions, as well as municipalities' health and social care structure.

[3] Information retrieved from the Finnish care registers for social welfare and health care (Hilmo), years 2001–2004 STAKES, National Research and Development Centre for Welfare and Health, Helsinki, Finland.

[4] Information retrieved from the Finnish statistics of causes of death during 2001–2004, Statistics Finland, Helsinki, Finland.

[5] Information retrieved from the Sotka –municipal database for social and health statistics in Finland, years 2001–2004, STAKES, National Research and Development Centre for Welfare and Health, Helsinki, Finland.

Variables

FA was assessed using a Finnish version of the Activities of Daily Living (ADL), which includes both basic (PADL) and instrumental (IADL) dimensions [28] FA was assessed by a 14-item score for ADL, each item yielding values from 0 (no problems) to 3 (unable to manage). Further, FA was classified into three categories (good, moderate or poor) using a method by Jylhä [28]. The HRQoL was measured with the Nottingham Health Profile (NHP) and the EQ-5D instruments. Both of these instruments are widely used and well documented and have also been validated for use in the Finnish general population [29, 30]. The NHP is composed of 38 assertions (yes/no) from which six dimensions can be derived (Table 3). The values in each dimension vary from 0 (best) to 100 (worst). The EQ-5D is a generic HRQoL instrument consisting of 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. After a weighting procedure, a general index value for HRQoL, varying between 0 (dead) –1 (best), is derived.

Ethical issues

All enrolled patients gave written informed consent. Patients were given a letter explaining the study and were assured that their care would be unaffected if they chose not to be involved. Permission for the study was obtained from the Finnish Ministry of Social Affairs and Health, while the Ethics Committee at the National Research and Development Centre for

Welfare and Health (STAKES) approved the design and implementation of the study.

Statistical analyses

All analyses were by intention to treat. To compare groups and changes in outcome variables we analysed differences in means (*t*-test), medians (Mann–Whitney *U*-test, Wilcoxon two-sample test), proportions (a comparison of proportions test) and distributions (Chi squared test). A p-value ≤ 0.05 was regarded as statistically significant. Because we used CRT there was a fear that the values were too small and confidence intervals too narrow [13, 15, 16]. To avoid cluster effects, the municipalities were matched in pairs. A summary statistic (mean, median) in outcome variables for each cluster was calculated and then the summary values in trial and control groups were compared. We used hierarchical regression models (variance component models) [31] to analyse the potential effects of the number of inhabitants or the administrative structure of care in the municipalities on patients' HRQoL or FA so as to discount possible correlating of responses among municipalities. The cluster effects in these models were weak (ICC varied between 1–5%) and not statistically significant. Therefore, these results are not presented in this paper. Missing data were excluded from the analysis. The SPSS for Windows program (V.14) and MLwin program (V1.1) were used for statistical analysis.

Results

We interviewed 669 patients at baseline, 579 at the 3-week follow-up and 449 at the 6-month follow-up (Figure 1). Despite the loss during the follow-up and the number of deceased, the structure of the study population remained similar during the follow-up period, with no differences between groups. Further, none of the clusters dropped out.

At baseline, the patients were rather old and the majority was women living alone. In terms of background characteristics, the only difference between groups was the number of diagnoses, which was higher in the trial group (Table 1). Most patients (78%) were discharged from a health centre ward to home. Half of the patients (50%) were readmitted during the follow-up period (mean 1.7) with no differences between groups. In the 3-week and 6-month follow-up periods, mortality was no different between the groups (Table 2).

Health and functional ability

At baseline, most patients perceived their health status as good or at least moderate. At 6 months the perceived health had decreased significantly (p = 0.002) in both groups. About two-thirds of patients had a 'poor' ADL at baseline with no differences between groups. At the 6-month follow-up in both groups there were no changes in ADL (Tables 2 and 4). The patients were able to manage without help in PADL-items such as eating and getting in and out of bed, but had difficulties in IADL-items (i.e. doing domestic chores).

Effects on health-related quality of life

At baseline, the patients in the trial group had significantly better EQ-5D scores than the control group. At three weeks, the EQ-5D was worse in the trial group compared to baseline (p = 0.001) and the difference between groups had disappeared. At the 6-month follow-up, there were no further changes in the EQ-5D scores and no differences between or within groups (Table 3). Summary statistics in the EQ-5D at the municipality level showed a difference at the 3-week follow-up between groups in favour of the control group (Table 4).

The NHP dimension of energy, sleep and pain improved significantly (p < 0.005) in both groups at 3-week and at 6-month follow-ups with no differences between groups. The only difference between groups was at 3-weeks in physical mobility in favour of the trial group (Table 3). Table 4 shows summary statistics for NHP at the municipality-level.

Discussion

The successful discharge of elderly patients from hospital to home care followed by adequate managing at home requires sufficient support being offered and an integration of services. We performed a cluster randomised trial (CRT) to evaluate the effects of IHCaD-practice on home care patients' FA and HRQoL. The new practice was associated with an improvement in patients' HRQoL in physical mobility at the 3-week follow-up.

The characteristics of our respondents show that the target group in home care services consists of aged and frail persons living alone [1–3]. This group demands special attention when planning and implementing hospital discharges and home care services. Our respondents already had at baseline a poor FA, which has been identified as the main risk factor in

Table 2. Changes in health and functional ability among intervention and control groups

	At baseline			Δ3-week follow-up			Δ6-month follow-up		
	Intervention (n=352–354)	Control (n=314)	p^2	Intervention (n=305–308)	Control (n=269)	p^2	Intervention (n=238–241)	Control (n=207–208)	p^2
Perceived health, %									
Good	38.2	36.0	ns	−4.2	−8.9	0.009	−17.0	−19.0	ns
Moderate	45.0	46.2	ns	−2.7	−1.1	ns	3.0	5.3	ns
Poor	16.7	17.8	ns	6.9	10.0	ns	14.0	13.8	ns
ADL[1], median (sd)	1.35 (0.49)	1.33 (0.49)	ns	<0.001 (0.53)	<0.001 (0.45)	ns	<0.001 (0.57)	<0.001 (0.53)	ns
ADL, %									
Good or moderate	35.0	33.1	ns	0	−0.4	ns	0.1	2.3	ns
Poor	65.0	66.9	ns	0	0.4	ns	−0.1	−2.3	ns
Number of deaths (f)				5	6	ns	31	33	ns
Number to institutional care (f)				1	2	ns	10	8	ns
Number to hospital care (f)				9	13	ns	16	19	ns

[1] Jylhä 1985 (ADL: 3=best, 1=worst)

[2] p=significant of change between groups using chi²-test or Mann–Whitney *U*-test

Table 3. Patients' health-related quality of life at baseline and score change after 3-weeks and 6-months follow-up

| | At baseline | | | Δ3-week follow-up[4] | | | Δ6-month follow-up[4] | | |
	Intervention (n=346)	Control (n=303)	p-value[3]	Intervention (n=287)	Control (n=252)	p-value[3]	Intervention (n=228)	Control (n=197)	p-value[3]
EQ-5D[1], median (sd)	0.53 (0.15)	0.52 (0.14)	0.014	−0.001 (0.14)	<0.001 (0.13)	ns	<0.001 (0.16)	<0.001 (0.14)	ns
(with deceased)				−0.032 (0.15)	−0.022 (0.15)	ns	−0.070 (0.23)	−0.071 (0.22)	ns
NHP[2], median (sd)	(n=329–347)	(n=294–311)		(n=252–288)	(n=238–264)		(n=197–233)	(n=186–202)	
Energy level	54.4 (24.22)	54.4 (23.65)	ns	16.05 (43.94)	20.8 (43.68)	ns	20.8 (41.63)	16.0 (45.50)	ns
Sleep	38.2 (32.18)	35.8 (31.31)	ns	<0.001 (28.97)	<0.001 (26.91)	ns	<0.001 (30.30)	<0.001 (28.13)	ns
Pain	30.8 (24.14)	33.8 (23.03)	ns	15.66 (21.95)	9.5 (25.22)	ns	6.8 (22.21)	6.8 (27.25)	ns
Physical mobility	53.6 (23.26)	52.8 (20.73)	ns	<0.001 (18.44)	<0.001 (16.54)	0.002	5.1 (21.25)	<0.01 (19.44)	ns
Emotional reactions	14.2 (25.20)	14.2 (23.75)	ns	<0.001 (22.02)	<0.001 (18.71)	ns	<0.001 (23.34)	<0.001 (18.93)	ns
Social isolation	16.4 (22.68)	16.4 (22.77)	ns	<0.001 (20.55)	<0.001 (18.04)	ns	<0.001 (18.14)	<0.001 (18.57)	ns

[1] Ohinmaa & Sintonen 1999. In EQ-5D 0 refers to dead and 1 to best state
[2] Koivukangas et al. 1995. In NHP 100 refers to worst and 0 to best state
[3] p=significance of change between groups using Mann–Whitney *U*-test
[4] =Increases in HRQoL expressed in positive and decreases in HRQoL in negative values

Table 4. Summary statistic at municipality level in ADL and HRQoL at baseline and score change after 3-weeks and 6-months follow-up

	At baseline			Δ3-week follow-up[4]			Δ6-month follow-up[4]		
	Intervention (n=11)	Control (n=11)	p[3]	Intervention (n=11)	Control (n=11)	p[3]	Intervention (n=11)	Control (n=11)	p[3]
ADL, median (sd)	1.37 (0.49)	1.33 (0.49)	ns	<0.001 (0.32)	<0.001 (0.10)	ns	<0.001 (0.14)	<0.001 (0.32)	ns
EQ-5D[1], median (sd) (with deceased)	0.57 (0.03)	0.51 (0.08)	ns	−0.03 (0.09) −0.03 (0.03)	−0.006 (0.062) −0.02 (0.07)	0.042 ns	−0.02 (0.07) −0.09 (0.06)	0.003 (0.09) −0.06 (0.08)	ns ns
NHP[2], median (sd)									
Energy level	61.43 (5.76)	63.71 (6.21)	ns	14.71 (11.84)	9.83 (14.08)	ns	18.93 (11.43)	11.48 (19.27)	ns
Sleep	45.61 (6.18)	45.10 (12.18)	ns	3.59 (4.95)	3.24 (8.10)	ns	2.87 (11.43)	6.72 (12.12)	ns
Pain	37.12 (4.69)	38.94 (6.04)	ns	9.01 (4.34)	8.66 (5.34)	ns	9.38 (6.75)	1.48 (6.95)	ns
Physical mobility	50.76 (4.48)	50.57 (4.99)	ns	2.48 (4.59)	−3.91 (6.14)	0.033	5.85 (5.99)	1.61 (10.89)	ns
Emotional reactions	21.01 (7.99)	19.78 (8.71)	ns	4.47 (4.94)	−1.26 (7.14)	ns	6.53 (5.94)	1.60 (6.01)	ns
Social isolation	18.26 (4.99)	18.25 (8.40)	ns	1.06 (4.85)	−0.87 (6.09)	ns	2.66 (3.17)	0.11 (12.36)	ns

[1] Ohinmaa & Sintonen 1999. In EQ-5D 0 refers to dead and 1 to best state
[2] Koivukangas et al. 1995. In NHP 100 refers to worst and 0 to best state
[3] p=significance of change between groups using Mann–Whitney *U*-test
[4] =Increases in HRQoL expressed in positive and decreases in HRQoL in negative values

the need for services [3]. Moreover the NHP scores in energy and physical mobility dimensions showed low HRQoL. According to previous studies [4–6], the need for health and social care are often connected and as a consequence the service package contains multiple services provided by various professionals. The care approach has changed from individual consultation to multiprofessional teamwork. The question arises as to how these services should be organised efficiently to meet patient's gradually increasing needs. An integrated health care system has proved to be one way of improving patient treatment and its efficiency [7]. According to our findings, the IHCaD-practice was associated with an improvement in patients' HRQoL in physical mobility at the 3-week follow-up. Further, the scores in other NHP dimensions were somewhat better (though not statistically significant) in the trial group. However, the FA remained almost the same during the follow-up with no differences between groups. One possible explanation could be the age and frailty of respondents, which are persistent factors in the decline of HRQoL and FA. The effects of the new practice on FA and HRQoL could be better seen in younger than in older age-groups, or in other outcomes, for example in the use of services.

The intervention may fail because of the poor content of the intervention or because the implementation of the intervention does not succeed. The staffs found the content to be good and were committed to developing their own municipality-specific practice. The weak effects of the intervention at the patient-level may be a consequence of the intervention being implemented for a maximum of only 1.5 years. The intervention was focused on staff practices and through the changing practices we expected to see an effect on patients. The same intervention and implementation was offered to all trial municipalities but the period of time needed to achieve the objectives varied mainly due to differences in the availability of resources across municipalities. Moreover the staff involved in the intervention had different professional cultures and styles (health and social sector, hospital and home care) so that in addition to changing work practices, efforts were made to affect the attitude of the workers to working together and to developing integrated care. New ideas take time to process and thus it takes many years to achieve permanent changes in every worker's individual practice. Typically, the effects are first seen in work practices and then later we would expect a change in patient outcomes [11, 32].

Moreover, contamination in control municipalities may have occurred, leading to an attenuation of the effect of the intervention and reduced power to detect a difference [15, 16]. To minimize contamination from one municipality to another, it was agreed at the start that the new practice would be introduced to the control municipalities after the follow-up measurements in both groups were completed. The staff's experience of the new practice was positive (the practice clarified and improved transfer of information, standardised practices and helped to integrate services) and so there was strong motivation among the staff to continue this kind of practice.

Many methodological issues must be taken into account when drawing conclusions. Sample size was based on a power calculation that predicted that 22 clusters with 35 patients in each were necessary to achieve adequate results. Twenty-two municipalities participated in the study and none of them dropped out during the follow-up. The power of the effect may have decreased because we interviewed only 87% of the target sample size of 770 [16]. Because the patients were recruited after the municipalities were randomised we could not avoid all selection bias [14]. The interviewers were aware of which group the patients belonged to. It is possible that interviewers in the trial municipalities were more eager to recruit patients and also to keep them in the study. This may explain the slightly higher number of recruited patients in the trial group at baseline and a slightly larger loss to follow-up in the control group. However, the structure of study populations in both groups remained the same during the follow-up period.

Patients who died during the follow-up period (9.5%) were excluded from the analyses, except in respect of the EQ-5D where you can code them. As the number of deceased was equal in both groups, excluding the deceased did not significantly affect the results. In the EQ-5D, the effect of the deceased may explain the small differences between groups at the municipality level. The EQ-5D score was similar in both groups at baseline, but at the 3-week follow-up the EQ-5D had decreased in the trial group. After adding the deceased to the data, this difference between groups disappeared. This may be due to the fact that in some municipalities where there were few patients, even one deceased can make a significant difference between groups.

The patients from the same municipality are more likely to have similar outcomes and as a consequence a type I error, a false positive difference, may occur [15, 16]. To avoid cluster effects, the municipalities were matched in pairs. Further, summary statistics for the outcome variables of each cluster were calculated and compared. Based on the pilot study, there were no significant differences in background characteristics or use of services between trial and control

groups. None of the clusters dropped out during the follow-up period, but in some analyses there were clusters with only a few patients. The effects, however, were the same with or without these small clusters. To eliminate the effects of possible confounding variables, we also checked whether the number of inhabitants or the administrative structure of care in the municipalities were associated with patients' FA or HRQoL. No significant associations were found.

The researchers developed a new practice that was then tailored and implemented in the trial municipalities using an action research method. The staff and the researchers were both involved in this process. The attendance of researchers in the process may weaken the objectivity of the study [27]. However, in this study, each municipality had a project group responsible for tailoring and implementing the practice. The researchers guided and supported the personnel but did not actually develop the practices in the municipalities. Neither did the researchers interview patients.

The IHCaD-practice is generic and goal-orientated, making it usable for all patient groups in different settings and organisations. Detailing the patients' care and service chain can reveal obstacles in the care chain (both what and where) and can also help to improve the practice (who, what, how). The new practice does not demand extra resources or new actors (c.f. a liaison nurse) since the working pair are appointed from within the existing home care team members.

Conclusions

Although the effects of the new practice did not improve patients' FA and HRQoL, except physical mobility at 3-week follow-up, the workers thought that the content of intervention was good and the intervention worked in practice. The practice clarified and improved the transfer of information, defined roles and responsibilities, standardised practices and helped to integrate services. The intervention was focused on staff practices and through the changing practices was thought to affect the patients. The intervention had only been implemented for a short period and the appearance of effects at the patient level is a slow process, which might first be seen in use of services. Additional evidence on the practice is required before we can draw any strong conclusions about its (clinical) effects.

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