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Effectiveness of sensor monitoring in a rehabilitation programme for older patients after hip fracture: a three-arm stepped wedge randomised trial

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Abstract

Objectives: to test the effects of an intervention involving sensor monitoring-informed occupational therapy on top of a cognitive behavioural treatment (CBT)-based coaching therapy on daily functioning in older patients after hip fracture.
Design, setting and patients: three-armed randomised stepped wedge trial in six skilled nursing facilities, with assessments at baseline (during admission) and after 1, 4 and 6 months (at home). Eligible participants were hip fracture patients ≥ 65 years old.
Interventions: patients received care as usual, CBT-based occupational therapy or CBT-based occupational therapy with sensor monitoring. Interventions comprised a weekly session during institutionalisation, followed by four home visits and four telephone consultations over three months.
Main outcomes and measures: the primary outcome was patient-reported daily functioning at 6 months, assessed with the Canadian Occupational Performance Measure.
Results: a total of 240 patients (mean[SD] age, 83.8[6.9] years were enrolled. At baseline, the mean Canadian Occupational Performance Measure scores (range 1–10) were 2.92 (SE 0.20) and 3.09 (SE 0.21) for the care as usual and CBT-based occupational therapy with sensor monitoring groups, respectively. At six months, these values were 6.42 (SE 0.47) and 7.59

(SE 0.50). The mean patient-reported daily functioning in the CBT-based occupational therapy with sensor monitoring group was larger than that in the care as usual group (difference 1.17 [95% CI (0.47-1.87) $P = 0.001$]. We found no significant differences in daily functioning between CBT-based occupational therapy and care as usual.

Conclusions and relevance: among older patients recovering from hip fracture, a rehabilitation programme of sensor monitoring-informed occupational therapy was more effective in improving patient-reported daily functioning at six months than to care as usual.

Trial registration: Dutch National Trial Register, NTR 5716.

Keywords

geriatric rehabilitation, patient-reported daily functioning, sensor monitoring, cognitive behavioural treatment, stepped wedge design, randomised trial, older people

Key points

- Many older adults who are returning home from a skilled nursing facility after hip fracture, do not fully recover in terms of daily functioning.
- Sensors that measure daily functioning can inform the rehabilitation of older adults after hip fracture beyond the direct observation of therapists or the self-report by patients.
- The combination of sensor monitoring and occupational therapy increases the effectiveness of rehabilitation programmes for hip fracture in older adults.
- Among vulnerable older adults recovering from hip fracture, a transitional care rehabilitation programme of sensor monitoring-informed occupational therapy was more effective in improving patient-reported daily functioning at six months than care as usual.

Introduction

Hip fracture is a common injury among older adults and associated with poor outcomes [1, 2]. Most rehabilitation programmes focus on improving mobility and activities of daily living (ADL) to help ensure independent living and are often provided during inpatient stay only [3]. However, the effectiveness of these programmes is modest [4–6]. In a systematic review which included 19 randomised trials, no particular strategy stood out as being the best. Outcome measures mostly were mobility measures, adverse events and general functioning. Intensive supervised exercise programmes and home-based functional task exercises can result in functional improvement [4–6].

Many older adults experience fear of falling after breaking their hip, and this hinders their functional recovery [7–9]. Cognitive behavioural treatment (CBT) strategies have been proven effective in fall prevention in community dwelling older adults who had fallen [10]. Therefore, the incorporation of CBT into rehabilitation programmes tackling fear of falling during skilled nursing facility stay and at home may be useful. CBT strategies include emphasising the importance of physical activity to increase strength and balance [11] and setting realistic goals for increased ADLs at home. However, since much of the rehabilitation process occurs after a patient has been discharged, often therapists lack accurate data on daily functioning at home. This lack of data hampers the setting of personalised and realistic goals. Remote activity monitoring systems using sensors that measure patients' ADLs may fill this gap. However, as far as we know, CBT- and sensor monitoring-based programmes have not yet been used in rehabilitation for older patients after hip fracture.

In this randomised trial, we tested the effects of a systematically developed intervention involving sensor-monitoring informed occupational therapy on top of a CBT-based coaching programme on patient-reported daily functioning in older patients after hip fracture [12].

Methods

Design, setting and patients

From 1 April 2016 to 1 December 2017, we conducted a three-arm stepped wedge cluster randomised trial in six skilled nursing facilities in the Netherlands. The study protocol was published [12] and was approved by the Medical Ethics Committee of the Academic Medical Center (protocol ID: AMC 2015_169).

Eligible participants were patients with traumatic hip fracture (> 65 years) and were admitted to a skilled nursing facility with an indication of short-term rehabilitation. Additional inclusion criteria were living alone and having a minimal-mental state examination (MMSE) score of 15 or higher. We excluded patients if they were terminally ill, were waiting for permanent placement in a nursing home, or did not give informed consent.

Randomisation

Three pairs of skilled nursing facilities were randomised to one of three fixed sequences (eTable 1). Each sequence started with providing care as usual (the control condition), followed by CBT-based occupational therapy and ending with CBT-based occupational therapy with sensor monitoring. The randomisation procedure is described in our study protocol [12].

Intervention

eTable 2 shows the details of the care as usual and the two interventions. Care as usual in the SO-HIP trial is described in eTable 3.

Briefly, patients in the CBT-based occupational therapy group received coaching aimed at the recovery in daily functioning based on principles of CBT [10, 11] as well as the care as usual. As fear of falling is common in these patients, the main aim was to reduce this fear and increase self-confidence. Five strategies were integrated to positively shift patients' attitudes and beliefs about falls and activity restriction. These strategies were based on Bandura's self-efficacy theory and were tested in a programme on fear of falling [10, 11]. Key assumptions of that programme are (i) restructuring misconceptions about falls, (ii) setting realistic goals for increasing activity and (iii) promoting daily activities that are avoided because of fear of falling. The five strategies include: (1) education about the importance of physical activity; (2) ascertainment of daily physical activity and awareness elicitation to restrictive symptoms and their cognitive and behavioural effects; (3) collaborative definition of realistic goals for ADLs; (4) joint definition of an activity plan; and (5) evaluation.

While in the skilled nursing facility, patients received weekly coaching. After discharge, the patients received four home visits followed by four telephone consultations over two and a half months [12]. The telephone consultations were similar to the occupational therapy coaching, and based on the five coaching steps (eTable 2).

Patients in CBT-based occupational therapy with sensor monitoring received the same occupational therapy programme as the first intervention group as well as sensor monitoring. The technical details of sensor monitoring are described [12] (Supplement (1 and 3). The sensor monitoring system consists of a wearable physical activity monitor (PAM AM300) (http://www.coach.com), motion sensors (Molite sensor Z wave Benext, https://www.benext.eu/) placed in the main spaces in the patients' house and a gateway (Raspberry Pi with a Z-wave shield Model B+ quad core CPU, 1024 MB RAM). The PAM measures body movement expressed by the PAM-score and communicates with the gateway via a Bluetooth adaptor(WR300-E). The motion sensors communicate wirelessly through a Z-wave protocol with the gateway. Via a web-application, users can see the visualisations. eTable 4 describes the interventions of the CBT-based occupational therapy and CBT-based occupational therapy with sensor monitoring. The occupational therapists delivered all the interventions. Therapists received a user manual and training (supplement 5) how to integrate the sensor data into the strategies. Supplement 4 shows some examples of how the sensor data were used in the coaching intervention.

Measurements and outcomes

The primary outcome was patient-reported daily functioning at 6 months after the start of the rehabilitation measured with the performance score of the Canadian Occupational Performance Measure [13–17]. The Canadian Occupational Performance Measure is a patient- centered outcome measure for the detection of change in perceived performance of activities over time. The patient prioritises up to five activities s/he deems problematic and most important and rates these activities on an ordinary 10-point scale regarding performance and satisfaction, respectively. The Canadian Occupational Performance Measure results in a *performance score* and a *satisfaction score* [12].

Secondary outcomes included performance satisfaction in daily functioning at six month, (Canadian Occupational Performance Measure –*satisfaction score*) [12], physical functioning (Tinetti Performance-Oriented Mobility Assessment (POMA)) [18]; Timed up and Go (TUG)[19]; modified Katz ADL 15 index score [20]; level of sense of safety (VAS-scale); fear of falling (VAS-scale) [21]; Falls Efficacy Scale international (FES-I) [22]; and health related quality of life (EQ5D) [23]. For the process evaluation: number of sessions (inpatient and at home), duration and content of the interventions.

All patient outcomes were assessed at baseline (T0), discharge (1 month), post-intervention, 4 months and 6 months. Instruments used are described in the study protocol [12].

Power calculation

The power calculation was based on the primary outcome and described in the study protocol [12].

Statistical analysis

A detailed explanation of our statistical approach is described in supplementary file 7. Briefly, the core approaches in the statistical analysis were linear mixed models, multiple imputation using chained equations joint modelling to assess the influence of dropout (due to, e.g. death or permanent admission) [24, 25]. We present the main results based on the multiple imputed analyses.

Results

Patient inclusion

In total, 240 patients were enrolled. Figure 1 shows the flow of clusters and patients in the trial (77 care as usual, 87 CBT-based occupational therapy and 76 CBT-based

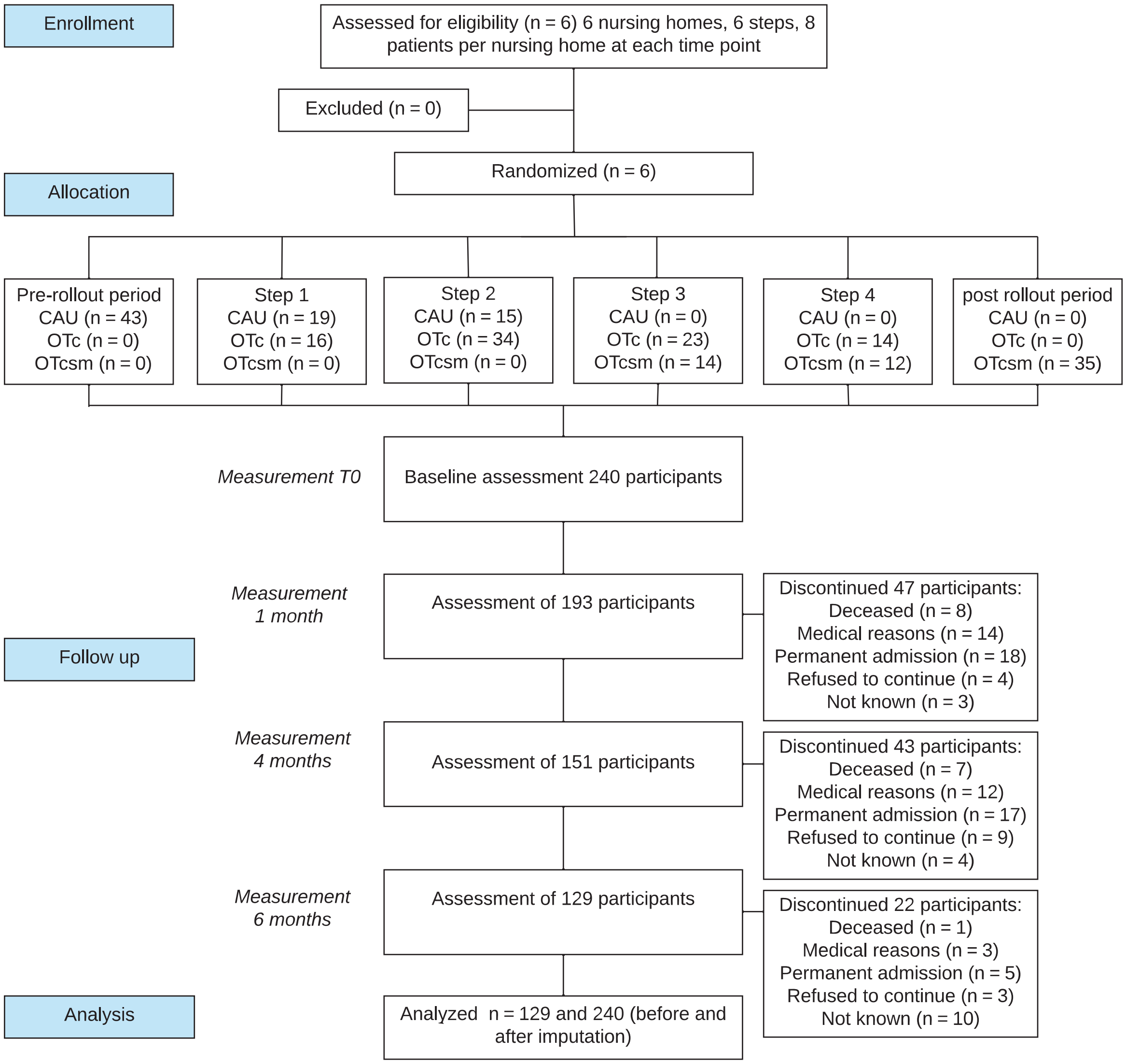

Figure 1 CONSORT diagram, Flow-chart of clusters and participants. CAU=care as usual; OTc= CBT-based occupational therapy; OTcsm=CBT-based occupational therapy with sensor monitoring

occupational therapy with sensor monitoring. The three arms were well balanced in terms of baseline characteristics (Table 1). Overall, the patients had a mean age of 84 years, 80% were female, and the median MMSE score was 24 (IQR 21 to 27). Table 1 shows patients' baseline characteristics across the three arms. During the study, 47, 43 and 22 patients had dropped out after 1, 3 and 6 months, respectively (figure 1 and eTable 6).

Adherence to the intervention protocol

During admission to the skilled nursing facility, 97.6% patients in the care as usual, 100% patients in the CBT-based occupational therapy and 95.8% patients in the group CBT-based occupational therapy with sensor monitoring received the occupational therapy sessions. The median inpatient number of sessions was 4 (IQR 2–5) for the care as usual, 4 (IQR 2–6) for the CBT-based occupational therapy and 2.5 (IQR 1–5) for the CBT-based occupational therapy with sensor monitoring.

At home, the median number of occupational therapy sessions (range 1–4) was 2 (IQR 0–4) for CBT-based occupational therapy and 4 (IQR 2–4) for CBT-based occupational therapy with sensor monitoring. The median duration of sessions at home was 41 (IQR 0–60) minutes for CBT-based occupational therapy and 45 (IQR 38.5–60) minutes for CBT-based occupational therapy with sensor monitoring. (eTable 7).

Primary outcome Canadian occupational performance measure-*performance*

A total of 47.1% of the patients (113) formulated one or more goals concerning basic ADL, while 88.3% (212) chose one or more goals concerning IADL, and 55.5% (132)

Table 1 Baseline characteristics of the study population

Variables	Total study population (N = 240)	Care as usual (N = 77)	OT coach (N = 87)	OT coach and sensor (N = 76)
Study sites (%)				
SNF 1 (n)	23.8 (57)	11.7 (9)	20.6 (18)	39.5 (30)
SNF 2 (n)	19.6 (47)	13.0 (10)	21.8 (19)	23.7 (18)
SNF 3 (n)	14.2 (34)	18.2 (14)	13.8 (12)	10.5 (8)
SNF 4 (n)	9.2 (22)	6.5 (5)	10.3 (9)	10.5 (8)
SNF 5 (n)	17.1 (41)	24.7 (19)	17.2 (15)	9.2 (7)
SNF 6 (n)	16.3 (39)	26.0 (20)	16.0 (14)	6.5 (5)
Demographics				
Age in years, mean (SD)	83.8 (6.9)	85.0 (7.2)	83.0 (6.7)	83.5 (6.7)
Female % (n)	79.6 (191)	79.2 (61)	75.0 (66)	85.5 (65)
Education (%)				
Fewer than six years of primary school	3.4	2.6	4.7	2.7
6 years of primary school	24.6	23.4	26.7	22.7
More than six years primary school	11.0	16.9	7.0	10.7
Vocational school	26.3	20.8	26.7	32.0
Secondary professional education	25.8	26.0	26.7	24.0
High school/Gymnasium	7.2	9.1	4.7	8.0
University	1.7	1.3	3.5	0.0
Living situation prior to admission % (n)				
Independent	81.7 (196)	79.2 (61)	76.1 (67)	90.8 (69)
Independent with others	1.7 (4)	-	4.5 (4)	-
Senior residence	16.6 (40)	20.8 (16)	19.3 (17)	9.2 (7)
Widowed % (n)	75.0 (180)	71.4 (55)	75.0 (66)	78.9 (60)
Born in the Netherlands % (n)	93.3 (224)	89.6 (69)	97.7 (86)	92.1 (70)
Cognition (%)				
MMSE (0–30)[a]	24	24	24	24.5
MMSE 15–19	15.2	16.0	17.2	11.8
MMSE 20–24	35.9	37.3	33.3	38.2
MMSE > 24	48.9	46.7	49.4	50.0
≥2 morbidities (%)	89.8	89.4	95.0	82.9
Number of comorbidities (mean) (SD)	3.3 (1.5)	3.3 (1.5)	3.4 (1.4)	3.2 (1.7)
Perceived daily functioning COPM[b]				
mean COPM-p (SD)	3.0 (1.7)	2.9 (0.5)	3.2 (1.7)	3.0 (1.8)
mean COPM-s (SD)	4.3 (1.8)	4.2 (1.8)	4.5 (1.8)	4.3 (1.8)
Physical functioning				
POMA-mean (SD)[c]	14.9 (3.4)	14.2 (3.3)	15.1 (3.5)	15.4 (3.3)
TUG-mean (SD)[d]	38.5 (19.2)	43.3 (20.9)	36.4 (18.1)	36.8 (18.8)
Modified Katz ADL index[e]-mean (SD)	9.5 (2.6)	9.4 (2.7)	9.4 (2.6)	9.6 (2.4)
Level sense of safety				
SOS-VAS mean (SD)[f]	2.5 (1.8)	2.7 (2.0)	2.4 (1.7)	2.3 (1.5)
Fear of falling				
FES-I mean (SD) [g]	26.7 (10.0)	24.8 (7.8)	24.6 (9.7)	29.8 (16.0)
FOF-VAS-scale (SD)[h]	4.7 (2.7)	4.8 (2.7)	4.6 (2.6)	4.6 (2.8)
Health-related Quality of life				
EQ5D-mean (SD)	0.45 (0.26)	0.43 (0.25)	0.44 (0.26)	0.48 (0.26)
EQ5D-VAS	59.4 (19.4)	58.3 (18.9)	58.1 (19.9)	62.2 (19.4)

OTcoach=CBT-based occupational therapy; OT coach and sensor=CBT-based occupational therapy with sensor monitoring
MMSE[a] Mini Mental State Examination. score median (range of 0 to 30); a higher score indicates better cognitive functioning
COPM[b] Canadian Occupational Performance Measure. Range 1–10; 1= not able to do at all and 10 =able to do extremely well) COPM-p = performance measure COPM-s= satisfaction measure
POMA[c] Performance Oriented Mobility Assessment. ≤ 18 indicates high risk of falls; 19–23 moderate risk of falls; ≥24 low risk of falls
TUG[d] Timed Up and Go; calculated in seconds, ≤ 20 indicates normal to good mobility. A lower score indicates better functional mobility and balance
Katz-ADL index[e] Range 0–15; a higher score indicates a higher dependence in ADL and IADL
SOS[f] Sense of Safety. VAS- score 1–10; a higher score indicates feeling safe
FES-I[g] Falls Efficacy Scale international. Range 16–64; a higher score indicates a greater fear of falling
FOF-VAS[h] Fear of falling. VAS- score 1–10; a higher score indicates more fear of falling
EQ5D[i] Scale 0–1; a higher score indicates better health related quality of life.

formulated one or more goals concerning leisure activities. A total of 71.3% of the patients (171) chose one or more goals concerning spirituality, social activities or social participation.

After multiple imputation, the mean Canadian Occupational Performance Measure *-performance* in the care as usual was 2.92 (SE 0.20) at baseline and 6.42 (SE 0.47) at 6 months. The mean Canadian Occupational Performance Measure

Table 2. Treatment effects. A Treatment effects (mean difference) on COPM-p and COPM-s at six months (N = 240, primary and secondary outcome). B Treatment effect variation over time and by cognition levels at baseline (mean differences on COPM-p and COPM-s)

COPM (95% CI; *p* value)	*CAU vs OT coach*	*CAU vs OT coach and sensor*	*OT coach vs OT coach and sensor*
COPM-p	0.64 (-0.07-1.34; 0.077)	1.17 (0.47–1.87; 0.001)	0.53 (-0.11-1.17; 0.103)
COPM-s	0.55 (0.00–1.08; 0.047)	0.94 (0.37–1.52; 0.001)	0.40 (-0.11-0.92; 0.126)

COPM-performance[a]	*CAU vs OT coach*	*CAU vs OT coach and sensor*
4 months vs 1 month	1.53 (0.89–2.17; <0.001)	1.96 (1.30–2.63; 0.001)
6 months vs 1 month	1.76 (1.11–2.41; <0.001)	2.37 (1.72–3.01; 0.001)
COPM-satisfaction[b]		
4 months vs 1 month	1.42 (0.85–1.98; <0.001)	1.69 (1.12–2.26; 0.001)
6 months vs 1 month	1.50 (0.97–2.03; <0.001)	1.96 (1.40–2.52; 0.001)
In subgroup with low MMSE[c]	1.17 (0.25–2.09; 0.012)	1.66 (0.54–2.78; 0.004)
In subgroup with intermediate MMSE[d]	1.05 (0.18–1.92; 0.018)	1.29 (0.48–2.10; 0.002)

A Treatment effects are expressed as mean differences between groups, compared to the scores in the CAU group (reference group). CAU= care as usual; OTcoach=CBT-based occupational therapy; OT coach and Sensor= CBT-based occupational therapy with sens[a]COPM-p=Canadian Occupational Performance Measure-performance scale score 1–10; [b]COPM-s=Canadian Occupational Performance Measure-satisfaction range: 1–10, where higher values indicate better performance).

B Compared to the treatment effect at one month, treatment effects for the occupational therapy and coaching groups, and the sensor monitoring-informed occupational therapy and coaching group were larger after 4 and 6 months, with the largest increases between months 1 and 4. Compared to the patients at the best cognitive level at baseline, treatment effects for both intervention groups were larger for patients who entered at low and intermediate cognition levels

-performance for CBT-based occupational therapy with sensor monitoring at baseline was 3.09 (SE 0.21) and 7.59 (SE 0.50) at 6 months. The mean patient-reported daily functioning in the CBT-based occupational therapy with sensor monitoring was larger than that in the care as usual (difference 1.17 [95% CI (0.47–1.87) P = 0.001] (Table 2).

Secondary outcome Canadian occupational performance measure-*satisfaction*

The same outcome applied to the secondary outcome Canadian Occupational Performance Measure *-satisfaction* (difference 0.94 [95% CI [0.37–1.52] P = 0.001] (see Table 2). The treatment effect of CBT-based occupational therapy on Canadian Occupational Performance Measure *-satisfaction* compared to the care as usual group was 0.55 [95% CI 0.00-1.08] 0.047). The difference between CBT-based occupational therapy with sensor monitoring and CBT-based occupational therapy was 0.53 [95% CI -0.11-1.17] p = 0.103), in favour of CBT-based occupational therapy with sensor monitoring (Table 2).

The results of the sensitivity analyses (joint models) largely confirmed the results of the main analyses (eTable 9). The other secondary outcomes are described in supplementary file 8.

Subgroup analysis

For all outcomes, the treatment effects did not vary by baseline Canadian Occupational Performance measure-*performance level* (1–3 *vs.* > 3). Treatment effects differed by cognitive functioning level at baseline. We used the highest cognitive level (MMSE >24) as the reference. For Canadian Occupational Performance measure-*satisfaction*, significant differences in treatment effects were found for low (MMSE 15–19) and intermediate (MMSE 19–24) cognitive levels. The mean difference of CBT-based occupational therapy with sensor monitoring compared to the care as usual on -s for the patients with low MMSE was 1.66 (0.54–2.78; P = 0.004) and 1.29 [95% CI 0.48–2.10] P = 0.002) for patients with intermediate MMSE. For CBT-based occupational therapy, the mean difference was 1.17 [95% CI 0.25–2.09] P = 0.012) for low MMSE and 1.05 [95% CI 0.18–1.9] P = 0.018) for patients with an intermediate MMSE at baseline (Table 2).

Discussion

The rehabilitation programme, based on sensor-informed OT coaching, was associated with greater, clinically relevant improvements in patient-reported daily functioning at six months than those with care as usual. We found no significant difference in daily functioning between OT without sensor monitoring compared to that of care as usual. No statistically significant differences in the CBT-based occupational therapy with sensor monitoring were found for secondary outcomes except for the Canadian Occupational Performance Measure-*satisfaction.*

Our intervention was designed to target fear of falling, boosting self-confidence by exploiting sensor-based information to improve the rehabilitation process. The findings demonstrate that the use of CBT- coaching techniques supported by the use of sensor data can improve daily functioning. First, by using the sensor data, the therapist could employ objective feedback about patients' real-time activity levels (e.g. PAM-measure per day, number of minutes of regular and vigorous activity per day) to evaluate progress in daily functioning and to design and execute realistic plans for improving daily functioning. In contrast, coaching in the CBT-based occupational therapy group (without sensors) was based on patients' self-reported memories of their activities. Second, therapists reported that for older patients with cognitive restrictions, coaching without sensors was difficult. The objective information by the sensors was helpful in this group. Finally, because patients can follow their own level of activity and progress on a tablet, they may be more engaged in their rehabilitation [26].

Patient-reported daily functioning was chosen as the primary outcome because limitations in daily functioning are an immediate result that older patients experience after hip fracture. These patients have large variations in functioning, and there are differences in what activities patients want to regain. The Canadian Occupational Performance measure captures activities that are important to the patient, how those activities are performed and the patient's satisfaction with them. Moreover, the Canadian Occupational Performance measure has good measurement properties [13]. The minimal important difference is 1; therefore, the statistically significant benefits for CBT-based occupational therapy with sensor monitoring of 1.17 at six months compared with that of the care as usual represents a clinically meaningful effect [16, 27].

Our findings have important implications for those active in the support of older patients after hip fracture. The implementation of a transitional care rehabilitation programme performed both in the skilled nursing facilities and continued at home seems crucial as patients have to apply their newly learned skills at home and regain confidence to perform those activities safely as already demonstrated in other patient groups [27–30]. A successful implementation of this intervention, requires a training programme to the use of goal setting and CBT-strategies to motivate patients to increase daily activities with the goal to recover. The objective information of the sensors provides professionals with more detailed information about daily activity patterns, so they can more effectively discuss goals and coach patients to recover.

A strength of the study is the pragmatic stepped wedge randomised controlled design with multiple participating therapists and centres. Because all patients received one intervention during the study, there were no crossover effects in switching from one intervention to another. Another strength is that we included a vulnerable group of old patients and considerable comorbidity. These groups are often excluded in trials.

A limitation is some degree of unblinding. All patient outcomes were assessed by the research assistants who were blinded to treatment allocation, in particular where it involved the care as usual and CBT-based occupational therapy groups. However, research assistants could have been unblended if a participant said something about sensors. An important limitation is the high dropout rate due to different reasons mentioned before that may invalidate naïve effect estimates. Therefore we used multiple imputation and joint models to protect out effect estimates from potential bias. The joint model analyses served as a sensitivity analysis to test the robustness of our findings to patients dropping out early. The sensitivity analyses on the Canadian Occupational Performance measure-*performance* and Canadian Occupational Performance measure-*satisfaction* indicated that our results are probably robust to drop-out by deaths and several other reasons.

Conclusions

In conclusion, in this stepped wedge cluster-randomised trial among older patients after hip fracture, a rehabilitation intervention of sensor monitoring-informed OT coaching was more effective in improving patient-reported performance of daily functioning at six months than an intervention with usual care.

Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

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