Effect of an additional health-professional-led exercise programme on clinical health outcomes after hip fracture

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1 | INTRODUCTION

Hip fracture is a serious event for older individuals with negative consequences on mobility and the ability to perform activities of daily living (ADL) (Dyer et al., 2016). Hip fracture is the most serious of low-energy fractures, with a mortality rate of 5%–10% during the first month postinjury and 20%–30% at 12 months (Sogaard et al., 2016). Less than 50% of the patients regain their prefracture ADLs and walking within 3 months after hip fracture surgery (Salpakoski et al., 2014). Exercise and physical activity in the early postoperative phase is important to avoid further reduced physical function, deconditioning and to facilitate early recovery (Davenport et al., 2015). During this period, pain may significantly contribute to limited mobility (Morrison et al., 2003).

Few studies have examined the effects of exercise in the early recovery phase after hip fracture. A recent meta-analysis suggested that exercise programmes prescribed within the first 3 months posthip fracture have a positive effect on physical function (Beckmann et al., 2020). However, there remains uncertainty as to the composition of early exercise programmes and which programme confers superior outcomes (Beckmann et al., 2020).

Increasingly, older patients are discharged from the hospital ‘quicker and sicker’ than previously (Deniger, Troller, & Kennelty, 2015; Spehar et al., 2005). When patients are unable to be discharged directly home due to physical impairment, but are still aiming to get home, they may be transferred to a short-term nursing home placement within the community. However, the short-term nursing homes’ access to physiotherapy can be limited. To overcome this, one solution may be the provision of a health-professional-led functional exercise programme, with the aim to increase the patients’ physical activity and physical function. The effectiveness of this approach has yet to be determined. Prior studies have shown that interdisciplinary collaboration can aid patients’ physical recovery after hip fracture (Prestmo et al., 2015; Riemien & Hutchison, 2016), but this has not been studied in a short-term nursing home setting. Our hypothesis was that a 2-week health-professional-led exercise programme in addition to usual care containing usual caregiving and usual physiotherapy during a short-term nursing home stay, could provide better results in clinical health outcomes (physical function, pain, and quality of life) compared to usual care alone.

The primary aim of this trial was to examine the effect of a health-professional-led functional exercise programme in addition to usual care on clinical health outcomes after 2 weeks in a short-term nursing home and after 3 months.

2 | METHODS

2.1 | Study design

The study is a parallel-group, single-blinded, pseudo-randomised controlled trial. Two experienced physiotherapists, blinded for group allocation, performed the assessments. It was not possible to blind participants or the healthcare professionals who provided the study interventions.

This trial was reported in accordance to the CONSORT guidelines (Schulz, Altman, & Moher, 2010a). The trial protocol has been previously reported (Heiberg, Bruun-Olsen, & Bergland, 2017).

2.2 | Setting and participants

The study was undertaken across four nursing homes which provided short-term nursing home stays for patients after hip fracture. The patients were transferred from an acute hospital in the Oslo area, Norway. The study was approved by the Regional Committee for Ethics in Medical Research (South-East Norway) (2015/2147). Informed consent was obtained from all participants included in the study. The study was conducted according to the World Medical Association Declaration of Helsinki (2013).

2.3 | Randomisation

The nursing homes were randomised to intervention or control group and stratified by size and anticipated number of patients with hip fracture. The allocation was concealed. At hospital discharge, patients were consecutively allocated by the allocation/assignment office to the short-term nursing home, which had the first vacancy. The allocation/assignment office was unaware of which short-term nursing home delivered the experimental intervention. Neither the participants, nor their family members had any influence on the allocation.

2.4 | Participants

The participants were recruited between May 2016 and March 2019. They were eligible if they were: aged 65 years or older; had sustained a low-energy hip fracture; lived in their own homes in one particular municipality; able to walk 10 m with or without walking aid prior to the fracture; able to understand both oral and written Norwegian; able to understand instructions during exercise; and eligible for a short-term nursing home stay prior to discharge to home.

Participants were excluded if they: had a pathological hip fracture or a multitrauma injury; had less than 3-month life expectancy; or had severe cognitive impairment.

2.5 | Intervention

Those allocated to the short-term nursing home which delivered the experimental intervention, received a health professional-led functional exercise programme in addition to usual care (containing usual caregiving and usual physiotherapy). The healthcare professionals were registered nurses and nurse assistants. The exercise
programme was previously reported in the trial protocol paper (Heiberg et al., 2017) and outlined in File S1. The exercise programme was reported in line with the Consensus on Exercise Reporting Template guidelines (Slade, Finnegan, Dionne, Underwood, & Buchbinder, 2018). A research physiotherapist (M.B.) initiated the additional exercises delivered to the intervention group. The exercise programme was expected to be delivered by the healthcare professionals as part of the daily care routine. The prescribed programme was expected to be performed up to four times daily, 7 days a week, during the 2-week short-term nursing home stay. The programme consisted of functional exercises including stepping, walking, step-ups, chair rise, squats, and heel lift. The research physiotherapist (M.B.) arranged several meetings with the health professionals delivering this programme prior to commencing the trial. She taught the health professionals how to deliver the functional exercise programme and tailor the exercise load to individuals based on their capability.

2.5.1 Control group

All participants allocated to the control group received usual care. This contained of usual caregiving and usual physiotherapy. Usual physiotherapy consisted of individual physiotherapy, three to five times per week, for 30–45 min in duration. Exercise was tailored to each participant based on their physical capability and goals. Participants were also offered group exercise sessions twice a week.

2.6 Measurements

The primary outcome was the Short Physical Performance Battery (SPPB). This is a performance-based measure of physical function (Guralnik et al., 1994) which evaluates balance, walking speed, and muscle strength in the lower limbs. Balance is measured by the individual's ability to stand in three different positions (feet placed together, semi-tandem, and tandem), walking speed is measured by time to walk 4 m, and muscle strength is measured by time to rise up from and sit down on a chair five times. The range of each subscore is from 0 to 4, and the total score is from 0 to 12 (the higher score the better) (Guralnik et al., 1994). The test has been shown to be valid and reliable when used with older adults (Freire, Guerra, Alvarado, Guralnik, & Zunzunegui, 2012; Guralnik et al., 1994; Perera, Mody, Woodman, & Studenski, 2006).

Secondary outcome measures included: the Timed Up & Go (TUG: Podsiadlo & Richardson, 1991), New Mobility Score (NMS; Kristensen, Foss, Ekdahl, & Kehlet, 2010), The University of California, Los Angeles (UCLA) Activity Scale (Terwee, Bouwmeester, van Eslsand, de Vet, & Dekker, 2011), Fall Efficacy Scale International (FES-I; Visschedijk et al., 2015), The EuroQol five dimension-five level questionnaire (EQ-5D-5L: Bilbao et al., 2018), and the Numeric Rating Scale (NRS; Campos, Liebano, Lima, & Perracini, 2020). For further details of secondary outcomes, see the protocol paper (Heiberg et al., 2017).

Physical activity was recorded using a commercially available, small, body-worn, single-axis accelerometer-based activity monitors (activPAL, PAL Technologies Ltd.).

All outcome measures were assessed before hospital discharge (T1), after 2 weeks in a short-term nursing home (T2), and at 3 months after hip fracture surgery (T3), except for the ActivPal which registered physical activity during the two weeks in a short-term nursing home.

2.7 Sample size calculation

We calculated the sample size based on a small meaningful change in SPPB being a mean standard deviation (SD) of 0.5 (1.48) points (Perera et al., 2006). This estimate required 140 patients, 70 in each group to obtain 80 % statistical power with 5 % significance level.

2.8 Statistical analysis

The descriptive data were summarised as mean and SD values for continuous data and as frequencies and percentages for categorical data. The analyses were conducted per protocol (PP) and by intention-to-treat (ITT) principles. Missing data analyses were also conducted by the use of multiple imputations (MIs). There were no differences in results between PP and MI analyses. Accordingly, only PP analyses were reported in this paper. Between-group differences were analysed with independent sample Student's t-tests for continuous variables and with $\chi^2$ test for categorical variables. Analysis of covariance was conducted to account for baseline differences in pain at rest and EQ index at T2 and T3, without any impact on the results, and therefore not reported. Within-group changes were analysed with paired sample Student's t tests. A $p$-value of less than or equal to 0.05 was considered statistically significant. All analyses were conducted with SPSS statistical software version 25 (IBM Corp.).

3 RESULTS

During the recruitment period from 2016 to 2019, approximately 1050 patients were surgically treated with hip fracture within the participating hospital. Of these, approximately 350 patients lived in another municipality and 350 patients were transferred directly to home, to a rehabilitation facility, or transferred to their permanent nursing home residence. Consequently, these patients were not eligible for participation, leaving approximately 350 patients potentially eligible. Of these, approximately 30 % were excluded due to severe cognitive impairment, short lifetime expectancy, multitrauma injury, or a pathological fracture.
One hundred and forty patients accepted to participate and were randomised into two groups, 78 participants in the intervention group and 62 in the control group (Figure 1).

There were no significant between-group differences in demographic variables (Table 1).

The included participants were considered to be more fragile and have poorer physical function than those who were transferred directly home after hip fracture (Table 2). There was a statistically significant difference in NRS pain at rest and EQ index between the groups at T1 ($p < 0.05$; Table 2).

At T1, only 42 of 78 participants (54%) in the intervention group and 26 of 62 participants (42%) in the control group completed TUG. At T2 and T3 the completion of TUG were approximately 83% in the intervention group ($n = 65$) and 80% in the control group ($n = 50$; Table 2).

### 3.1 Between-group differences immediately after the intervention (T2) and after 3 months (T3)

There were no statistically significant differences between the two groups after 2 weeks (T2) in a short-term nursing home stay, nor after 3 months (T3) in SPPB (primary outcome), TUG, UCLA, FES-I, EQ-5D-5L, or NRS pain in rest or activity ($p > 0.05$; Table 2).

### 3.2 Within group improvements

Both groups demonstrated statistically and clinically significant improvements in SPPB at T2 and at T3 ($p < 0.05$), except in SPPB balance at T3 for the intervention group ($p > 0.05$; Table 3). Statistically significant improvements in secondary outcomes in TUG, FES-
I, EQ-5D-5L index and NRS pain in activity at T2 and T3 were found in both groups \((p < 0.05)\). There were no statistically significant improvements in NRS pain at rest in the groups, neither at T2 \((p > 0.05)\) nor at T3 \((p > 0.05)\). There were no statistically significant improvements in EQ-5D-5L health score for the control group at T2 and T3 or for the intervention group at T3 \((p > 0.05; \text{Table 3})\).

### 3.3 | Activity monitoring by ActivPal

There was no statistically significant difference between the groups in activity monitoring (ActivPal) in either upright time, reported as standing and walking in mean min/day, or in upright events reported as mean number of transitions (changes in movement from lying/sitting to standing) per day during the 2 weeks in a short-term nursing home \((p > 0.05; \text{Figure 2})\).

No adverse events were registered, such as falls or increased pain related to the intervention.

### 4 | DISCUSSION

The experimental intervention, which contained functional exercises initiated by the physiotherapist and performed by the healthcare professionals during short-term nursing home stay showed no additional effects on clinical health outcomes above usual care. Both
# TABLE 2 Between group differences at baseline (T1), after 2 weeks in a nursing home (T2) and 3 months after hip fracture (T3)

|                      | Intervention group |                              | Control group |                              | Mean difference between groups (95% CI) at T2 | Mean difference between groups (95% CI) at T3 |
|----------------------|--------------------|------------------------------|---------------|------------------------------|---------------------------------------------|---------------------------------------------|
|                      | N = 78             | T1                           | T2            | T3                          |                                             |                                             |
|                      |                    | T1                           | T2            | T3                          |                                             |                                             |
| **Primary outcomes** |                    |                              |               |                             |                                             |                                             |
| SPPB total 0–12, mean (SD) | 4.2 (2.6) (n = 78) | 5.7 (3.4) (n = 68)         | 2.0 (1.9) (n = 62) | 3.5 (2.6) (n = 62) | 5.3 (3.2) (n = 57) | −0.7 (−1.6, 0.3)<sup>b</sup> |
|                      |                    |                              |               |                             |                                             |                                             |
| SPPB balance 0–4     | 1.4 (1.4) (n = 78) | 2.4 (1.4) (n = 68)         | 1.2 (1.4) (n = 62) | 1.7 (1.4) (n = 62) | 2.2 (1.4) (n = 57) | −0.3 (−0.9, 0.2)<sup>b</sup> |
|                      |                    |                              |               |                             |                                             |                                             |
| SPPB walking speed 0–4 | 0.9 (0.6) (n = 78) | 2.5 (1.2) (n = 68)         | 0.7 (0.6) (n = 62) | 1.6 (1.1) (n = 62) | 2.4 (1.2) (n = 57) | −0.3 (−0.7, 0.1)<sup>b</sup> |
|                      |                    |                              |               |                             |                                             |                                             |
| SPPB strength 0–4    | 0.03 (0.2) (n = 78) | 0.8 (1.2) (n = 68)          | 0.06 (0.4) (n = 62) | 0.2 (0.7) (n = 62) | 0.7 (1.0) (n = 57) | −0.1 (−0.3, 0.2)<sup>b</sup> |
|                      |                    |                              |               |                             |                                             |                                             |
| **Secondary outcomes** |                    |                              |               |                             |                                             |                                             |
| TUG, s, mean (SD)    | 52.4 (28.7) (n = 42) | 21.7 (16.0) (n = 62) | 58.5 (25.5) (n = 26) | 41.7 (27.0) (n = 50) | 24.8 (16.8) (n = 52) | 3.1 (−7.0, 13.3)<sup>b</sup> |
|                      |                    |                              |               |                             |                                             |                                             |
| NMS 0–9, mean (SD)   | 6.7 (2.0) (n = 78) | 5.6 (2.2) (n = 66)          | 6.7 (1.9) (n = 62) | 4.8 (2.1) (n = 56) | −0.8 (−1.5, 0.02)<sup>b</sup> |
|                      |                    |                              |               |                             |                                             |                                             |
| UCLA 0–10, mean (SD) | 4.0 (1.7) (n = 78) | 3.9 (1.8) (n = 66)          | 4.0 (1.7) (n = 60) | 3.4 (1.4) (n = 56) | −0.5 (−1.0, 0.1)<sup>b</sup> |
|                      |                    |                              |               |                             |                                             |                                             |
| FES total 16–64, mean (SD) | 27.7 (10.4) (n = 77) | 29.3 (11.5) (n = 65) | 26.6 (9.4) (n = 58) | 38.6 (14.3) (n = 53) | 316.0 (132.0) (n = 54) | 0.6 (−4.2, 5.4)<sup>b</sup> |
|                      |                    |                              |               |                             |                                             |                                             |
| NRS, mean (SD)       | 46.3 (20.3) (n = 77) | 55.3 (18.9) (n = 73) | 57.7 (18.0) (n = 66) | 50.4 (20.2) (n = 57) | 54.0 (20.9) (n = 53) | 59.6 (17.9) (n = 54) |
|                      |                    |                              |               |                             |                                              |                                             |
| EQ-SD-5L, mean (SD)  | 0.3 (0.3) (n = 75)<sup>a</sup> | 0.7 (0.2) (n = 69) | 0.2 (0.3) (n = 62)<sup>a</sup> | 0.5 (0.2) (n = 55) | 0.7 (0.2) (n = 54) | −0.0 (−0.02, 0.1)<sup>b</sup> |
|                      |                    |                              |               |                             |                                              |                                             |
| Abbreviations: CI, confidence interval; EQ-SD-5L, The EuroQol five dimension-five level questionnaire; FES, Fall Efficacy Scale; NMS, New Mobility Score; NRS, Numeric Rating Scale; SPPB, Short Physical Performance Battery; TUG, Timed Up & Go; UCLA, The University of California, Los Angeles Activity Scale.  

<sup>a</sup>There is a statistical significant difference in pain in rest and EQ index between the groups at T1. 

<sup>b</sup>There were no statistical significant differences between groups.
|                          | Intervention group | Control group |
|--------------------------|--------------------|---------------|
|                          | Change within-group T1–T2 | Change within-group T2–T3 | Change within-group T1–T2 | Change within-group T2–T3 |
|                          | Mean (CI 95 %)      | Mean (CI 95 %) | Mean (CI 95 %) | Mean (CI 95 %) |
| SPPB points              |                    |                |                |                |
| - Balance 0–4            | 0.7 (0.3, 1.0)*    | 0.2 (-0.1, 0.5)** | 0.5 (0.3, 0.8)* | 0.5 (0.1, 0.8)* |
| - Walking speed 0–4      | 1.0 (0.7, 1.1)*    | 0.5 (0.3, 0.8)* | 0.9 (0.6, 1.1)* | 0.8 (0.4, 1.1)* |
| - Strength 0–4           | 0.3 (0.1, 0.5)*    | 0.5 (0.2, 0.7)* | 0.2 (0.1, 0.3)* | 0.5 (0.3, 0.7)* |
| - Total 0–12             | 1.9 (1.3, 2.4)*    | 1.2 (0.6, 1.8)* | 1.5 (1.1, 1.9)* | 1.8 (1.0, 2.5)* |
| TUG, s                   | -24.6 (-32.8, -16.5) | -15.5 (-20.6, -10.4) | -24.7 (-34.2, 15.1) | -21-1 (-28.7, -13.7) |
| NRS, mean                |                    |                |                |                |
| - Pain in rest           | 0.06 (-0.3, 0.4)** | -0.3 (-0.9, -0.1)** | 1.1 (-0.3, 0.5)** | -0.1 (-0.7, 0.5)** |
| - Pain in activity       | -1.9 (-2.5, -1.3)* | -1.4 (-2.0, -0.8)* | -2.5 (-3.2, 1.8)* | -1.6 (-2.4, -0.8)* |
| FES                      | 10.1 (7.4, 12.9)   | -8.3 (-11.1, -5.4) | 11.1 (7.2, 15.0) | -9.9 (-13.8, -6.1) |
| EQ-5D-5L                 |                    |                |                |                |
| - Index                  | 1.2 (0.1, 0.2)*    | 0.2 (0.1, 0.3)* | 1.3 (0.2, 0.4)* | 0.1 (0.1, 0.2)* |
| - Health score 0–100     | 7.6 (2.3, 12.8)*   | 3.1 (-2.0, 8.3)** | 3.4 (-3.1, 9.9)** | 5.7 (-1.8, 13.2)** |

Abbreviations: CI, confidence interval; EQ-5D-5L, The EuroQol five dimension-five level questionnaire; FES, Fall Efficacy Scale; NRS, Numeric Rating Scale; SPPB, Short Physical Performance Battery; TUG, Timed Up & Go.

*There were statistically significant improvements within group (p < 0.05)
**There were no statistically significant improvements within group (p > 0.05).

**TABLE 3** Within-group improvements from baseline (T1) to after 2 weeks in a nursing home (T2) and from T2 to 3 months after hip fracture (T3)

**FIGURE 2** Activity monitoring with ActivPal during 2 weeks in a short-term nursing home stay
groups improved equally in clinical health outcomes in the first 3 months after surgery.

Prior studies have reported the effects of exercise interventions on physical function after hip fracture (Handoll, Sherrington, & Mak, 2011). However, a recent systematic review could not identify a superior exercise intervention in the early phase after hip fracture (Beckmann et al., 2020). Of the nine clinical trials included in the meta-analysis (Beckmann et al., 2020), the trial with the largest effect on physical function involved balance task-specific training compared to general physiotherapy with open kinetic chain exercises and walking training (Monticone et al., 2018). This study showed that balance task-specific training was superior to general physiotherapy in improving physical function, pain, balance, ADL, and quality of life in elderly inpatients after hip fracture. The exercises in the study by Monticone et al. (2018) and those in the present study are comparable, except from the total time duration in each session which was higher in the study by Monticone et al. (2018). On the other hand, a study from Denmark compared progressive knee-extension strength training in addition to daily physiotherapy during hospital stay after hip fracture (Kronborg, Bandholm, Palm, Kehlet, & Kristensen, 2017). As in our study, the intervention was of a short duration, and strength training yielded no additional improvements compared to physiotherapy alone in reducing strength deficit in the lower limb and in improving mobility in patients after hip fracture (Kronborg et al., 2017). The authors questioned whether the duration of the intervention was too short to have an impact on clinical outcomes. This may have affected the results (Kronborg et al., 2017). The question of duration is also relevant in our study.

The experimental intervention was designed to increase functional activity during a short-term nursing home stay. Surprisingly, we did not find a difference between the groups in the activity monitoring (ActivPal). Both groups were equally active. Therefore, we cannot be certain whether the experimental intervention was delivered as intended, or if a more active control group caused the equal findings. Moreover, participants in both groups were more active during the 2-week intervention period compared to participants in Taraldsen et al. (2014). The difference between the activity levels can be explained by the possible postoperative pain in Taraldsen et al. (2014) as these patients were assessed in hospital and therefore in an earlier stage compared to the patients in the present study.

A large proportion of the participants demonstrated a floor-effect in TUG at baseline. This is in line with other studies, which found that mobility tests, such as TUG typically showed a floor-effect in an older acute medical population (de Morton, Keating, & Jeffs, 2007). This may indicate that TUG is an inappropriate measure for this patient group in the early phase.

4.1 Strengths and limitations

The strengths of this study include the attempt to minimise the risk of bias through assessor blinding, ITT analysis and the use of reliable outcome measures. Furthermore, protocol publication in ClinicalTrials.gov enhanced the transparency of the project, reduced publication bias, and improved reproducibility (Schulz, Altman, & Moher, 2010b). Neither the patients, assessors, the staff in the participating hospital nor the nursing homes had any influence on the allocation. However, there are important weaknesses to note. First, to avoid systematic errors, the randomisation process should secure equal possibility for each participant to be allocated to each group (Altman, 2020). There is a limitation in the randomisation process in this study as participants were allocated to the first vacancy in the short-term nursing homes. However, this was considered the most reasonable method for allocation without impeding the discharge process and thereby increased costs. The original plan was to collect information about exercise time in the intervention group. Unfortunately, the nursing homes did not record this as planned. The authors can therefore not provide information on the proportion of participants in the intervention group who received the intervention as described based on exercise time. The model of care described in this study may not be common in a vast majority of countries. Therefore, the findings may therefore be difficult to generalise to countries without community services as described in the present study.

4.2 Implications for physiotherapy practice

To our knowledge, this is the first study to examine the additional effect of a health professional-led functional exercise programme compared to usual physiotherapy on clinical health outcomes among patients after hip fracture. The additional functional exercise programme demonstrated no difference in immediate and 3-month effect on physical health outcomes compared to the control group, while both groups improved during a three-month period. The patients with hip fracture are fragile and vulnerable in this early phase, and the results show that usual physiotherapy may be sufficient to improve their physical function. A large proportion of the participants experienced a floor-effect in TUG, and this may suggest that the use of this outcome measure is inappropriate in the early phase after hip fracture.

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CONFLICT OF INTERESTS

The authors declare that there is no conflict of interests.

ETHICS STATEMENT

This trial was approved by the Reginal Committee for Ethics in Medical Research (South-East Norway) (2015/2147).
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