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Are patients' outcomes of function, pain, and quality of life, the same whether or not, they follow post-operative precautions after THR?" ReHip2; A pilot study.

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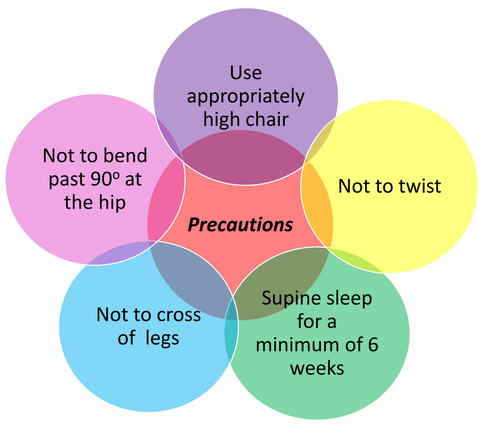
1. Background

- The purpose of the study was to explore the impact of hip precautions on function, pain and quality of life in patients following Total Hip Replacement (THR), when comparing two different rehabilitation pathways following surgery.
- Since the first THR was performed in 1969 for the treatment of osteoarthritis, it was recommended that during post-operative recovery, patients should follow 'hip precautions,' to reduce the risk of hip dislocation, thereby restricting their activities as follows.



- Precautions have remained the mainstay of rehabilitation for over 50 years, despite evidence to support their use being limited. This is surprising given the improvements in modern THR design and surgical techniques, which has increased stability of THRs.
- Current research raises questions regarding continuation of this practice, particularly if it contributes to patients' unnecessary discomfort and inconvenience by enforcing restrictions, with no known additional benefit (9)
- In addition, previous work identified that 32% of patients self-reported not fully adhering to post-operative precautions when first discharged from hospital, within days of surgery, and yet there were no dislocations amongst that cohort (12). Although this posed the question why would clinicians endorse recommendations if patients did not adhere, there remained a substantial proportion of patients reporting adherence, suggesting further work was required.
- ReHip2 therefore explored the impact of precautions on patient recovery. We were particularly interested in differences in patient function, pain, quality of life and satisfaction, when precautions were no longer endorsed. This would enable patients to dictate their own pace of recovery, with potential to increase activity levels, restore social interactions and usual function, much earlier than with routine care.

2. Objectives

- To determine if patients following an unrestricted pathway after THR, with no post-operative precautions, report a difference in function, pain, health related quality of life, sleep quality and anxiety, when compared with patients following a pathway with post-operative precautions.

3. Methods

- Patients undergoing primary THR for hip osteoarthritis were included in a multi-centre randomised controlled trial. Patients were consented to the study pre-operatively, and baseline outcomes measures completed.
- To ensure surgeons were blinded to the group assignment, patients were randomised to one of two groups post-operatively.

Group 1. Patients assigned to the routine care group were requested to continue following precautions for 6 weeks after their surgery.

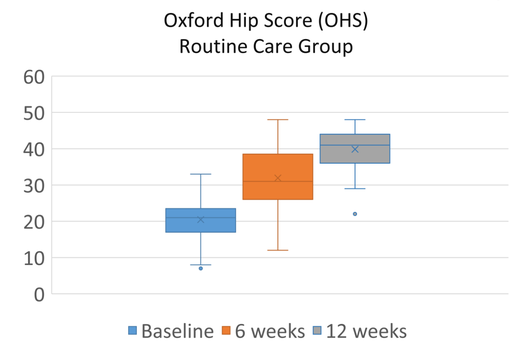
Group 2. Patients assigned to the treatment group were encouraged to continue with their recovery, limited only by their pain and physical ability.

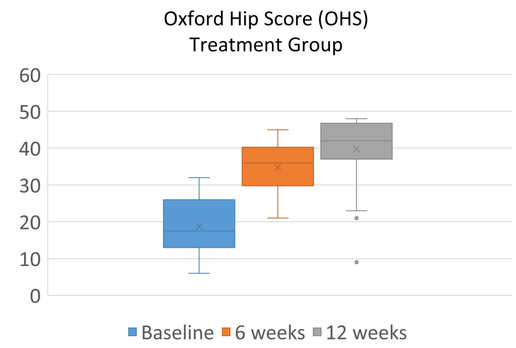
- All patients were given contact details for the study group for notification of hip dislocation, and also for support and advice during their recovery.
- Outcome measures were repeated 6 and 12 weeks after surgery, with comparisons made between the groups.
- Ethical approval was granted by the Northwest ethics review board (HRA 19/NW/0250), and the University of Manchester ref NHS001514. This study was registered with clinicaltrials.gov (study identifier: NCT03833258).

4. Results

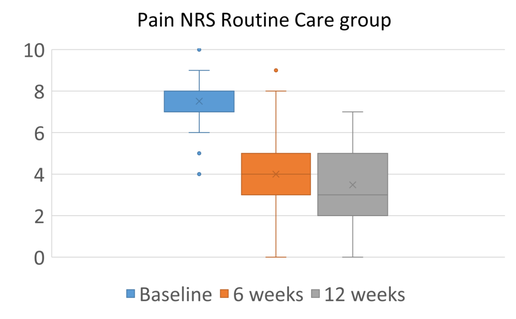
Demographics		
	6 weeks (n=91)	12 weeks (n=70)
Mean age in years	63 (SD 10.42)	64.3 (SD 10.3)
Age range (years)	35-87	39-87
Female n (%)	46 (51%)	39 (56%)
Male n (%)	45 (49%)	31 (44%)

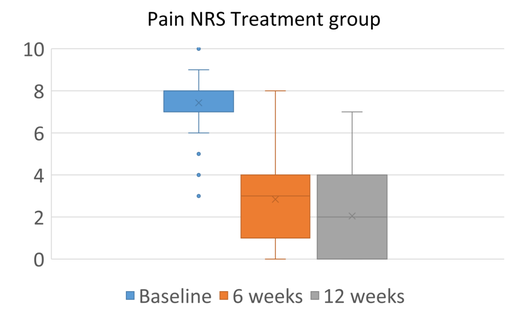
Median Oxford Hip Scores (OHS) by group



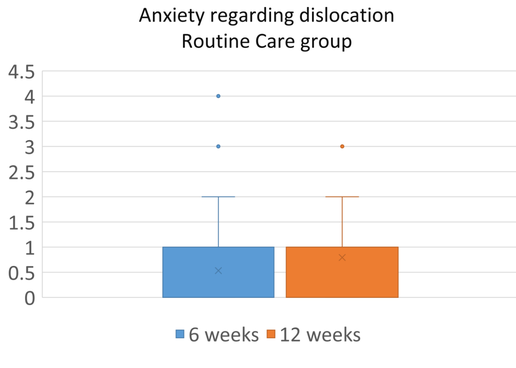


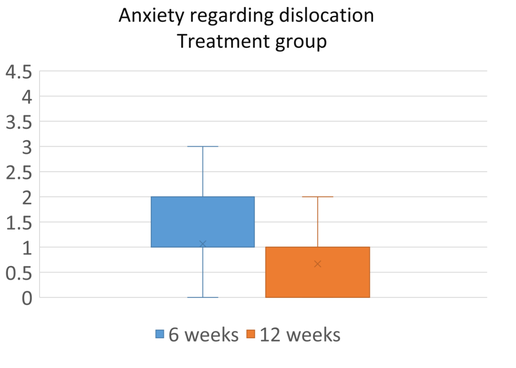
Median Pain (NRS) by group





Median patient anxiety by group





Significance testing using Wilcoxon rank sum test				
Outcome measure	6 weeks		12 weeks	
	Between group differences		Between group differences	
	z	p	z	p
Oxford Hip Score	-2.09	0.03	-0.62	0.53
Pain Numerical Rating Scale	2.09	0.04	2.48	0.01
Anxiety regarding dislocation	-6.27	0.001	0.28	0.78

Minimum clinical important difference (MCID)		
Outcome measure / group	6 weeks	12 weeks
	Between group difference	Between group difference
Oxford Hip Score Threshold for MCID = 5 (1)	8	4.5
EQ-5DL index Threshold for MCID = 0.22 (2)	0.5	0.6

- Anecdotal reports of poor sleep after THR, steered the study group to assess sleep quality using two measures, the Pittsburgh Sleep Inventory Index (PSQI) and Sleep quality Numerical Rating Scale.
- Using the PSQI there was a difference between the two groups at 6 and 12 weeks, however in our sample these differences were not statistically significant (p=0.10 and 0.64 respectively), and the MCID threshold of 4.4 was not reached (3, 4).
- There was a difference in sleep quality with the treatment group reporting 14% greater reduction in disturbed sleep compared with the routine care group, however it must be noted the difference was not statistically significant at either 6 or 12 weeks (p=0.70, p=0.28 respectively).

5. Discussion

- The reduction of difference in OHS at 12 weeks, may have been influenced by the routine care group no longer needing to adhere to post-operative precautions beyond 6 weeks. This demonstrated that function begins to level out in both groups by week 12, however the difference in pain persists.
- Similar patterns emerged from the study by Lightfoot et al., with the treatment group without precautions, reporting significantly better function, however this difference later diminished as with ReHip2 (6).
- Peak et al., reported earlier use of a car and side sleeping in patients not following precautions after THR. 50% of such patients returned to work before 6 weeks, compared with only 19% of patients that followed precautions. Although return to work was not assessed in ReHip2, a significant difference in the OHS at 6 weeks would support the suggestion of Peak et al., that greater improvement in function of patients in the treatment group, could result in potential for ReHip2 patients with no precautions to return to work earlier (7).
- In Lightfoot et al., patients that followed post-operative precautions for 6 weeks stated that they had experienced increased pain when permitted to stop adhering, this pain was then reported to limit activities (6). The effect of post-operative precautions increasing pain, may explain the continued significant difference in pain between the groups at both 6 and 12 weeks in ReHip2. This provides further support that, with a move away from precautions, pain may be a valuable mode of patient self-regulation for future practice.
- Given the primary purpose of precautions was to reduce to incidence of dislocation, it was anticipated that such a study may increase dislocation. In this study group there were no trial related dislocations suggesting dislocation was unrelated to precautions.

6. Limitations

- Due to cancellation of all elective surgery, potential health complications of patients, and team redeployment associated with COVID-19, it was not possible to recruit the required sample for the study.
- Of the 152 patients required when using the OHS as the primary outcome, 91 was achieved at week 6, and 70 at week 12, therefore the study was underpowered. This affected the distribution of the data, and therefore subsequent testing and reporting.
- It is possible that patients lost at 12 weeks represented a group that did not perform as well as those responding, which is a recognised challenge with orthopaedic surgery, and may have introduced response bias (11). However, increased attrition from the start of the pandemic would imply that retention was heavily influenced COVID-19.
- ReHip2 evaluated patients undergoing uncomplicated primary THR and excluded those with predisposing factors to hip instability, such as previous hip surgery, neurological conditions, hypermobility, or other connective-tissue disorders and ASA grade above 4. This affects generalisability of the findings to the wider THR population.

7. Conclusion

- Despite the impact of COVID-19 resulting in the study being underpowered, the findings of ReHip2 give a clear indication there is a difference between the two groups.
- The implication is that the patients in the treatment group, no longer following precautions, demonstrate quicker improvements in pain and function, which were statistically significant. Although this also had a clinically meaningful impact on patient quality of life and function, patients reported greater levels of anxiety when advised not to follow historic, routine care advice.
- Considering that clinical practice following THR continues to include the endorsement of precautions, despite mounting evidence reporting the limited impact on dislocation and negative impact on function (6, 7, 8), further work on this topic would prove in the best interest of patient experience and outcomes (9, 10). Such work would provide robust evidence regarding ongoing care whilst also having the potential to reduce NHS and wider health and social care costs.
- The ReHip2 trial provides sound justification, and a tested protocol for a large national multi-centre study. This should include evaluation of functional outcomes, whilst also testing for the impact on dislocation.

8.References

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