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## ■ INSTRUCTIONAL REVIEW: TRAUMA

# Developing, delivering and documenting rehabilitation in a multi-centre randomised controlled surgical trial

EXPERIENCES FROM THE PROFHER TRIAL

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## Objectives

A rigorous approach to developing, delivering and documenting rehabilitation within randomised controlled trials of surgical interventions is required to underpin the generation of reliable and usable evidence. This article describes the key processes used to ensure provision of good quality and comparable rehabilitation to all participants of a multi-centre randomised controlled trial comparing surgery with conservative treatment of proximal humeral fractures in adults.

## Methods

These processes included the development of a patient information leaflet on self-care during sling immobilisation, the development of a basic treatment physiotherapy protocol that received input and endorsement by specialist physiotherapists providing patient care, and establishing an expectation for the provision of home exercises. Specially designed forms were also developed to facilitate reliable reporting of the physiotherapy care that patients received.

## Results

All three initiatives were successfully implemented, alongside the measures to optimise the documentation of physiotherapy. Thus, all participating sites that recruited patients provided the sling immobilisation leaflet, all adhered to the physiotherapy protocol and all provided home exercises. There was exemplary completion of the physiotherapy forms that often reflected a complex patient care pathway. These data demonstrated equal and high access to and implementation of physiotherapy between groups, including the performance of home exercises.

## Conclusion

In order to increase the validity and relevance of the evidence from trials of surgical interventions and meet international reporting standards, careful attention to study design, conduct and reporting of the intrinsic rehabilitation components is required. The involvement of rehabilitation specialists is crucial to achieving this.

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## Introduction

The importance of rehabilitation, which in various forms can span and dominate much of the care pathway for people receiving surgery, can be overlooked in the design, conduct and reporting of randomised controlled trials evaluating surgery.<sup>1,2</sup> This article gives an account of the processes undertaken to ensure good practice in the rehabilitation of all participants, and the reporting thereof, within the context of a multi-centre randomised controlled trial,

the ‘PROximal Fracture of the Humerus: Evaluation by Randomisation’ (ProFHER) trial, conducted in the United Kingdom (UK).<sup>3</sup>

The ProFHER trial aimed to evaluate the effectiveness and cost effectiveness of surgical *versus* standard non-surgical treatment for adults with an acute, closed and displaced fracture of the proximal humerus involving the surgical neck. Recruitment of 250 patients took place in the orthopaedic departments of 33 UK NHS hospitals from September 2008 to

April 2011. Patient care pathways included outpatient and community-based rehabilitation.

ProFHER was a purposefully pragmatic trial by design and conduct.<sup>4</sup> It emphasised currently accepted good practice in surgery and conservative management to facilitate the general and ready applicability of its results, particularly in, but also beyond, the UK NHS. The protocol stressed standardised protocols and care pathways throughout, with comparable and sufficient expertise of care providers.<sup>3</sup> This article focuses on the measures taken to assure the quality of the non-surgical aspects of treatment and rehabilitation for both treatment groups. It reports on the success of these measures and provides insights into the complexity of achieving these aims across multiple sites and along the patient care pathway. The dependency on the contributions of physiotherapists for successful delivery is illustrated by a summary of their involvement in trial design, local management and provision of care. Finally, we discuss the results of the key initiatives and the insights gained from this trial and how these apply more generally.

## Materials and Methods

A rehabilitation specialist on upper limb conditions was brought on board early in the preparation stages of the trial, including membership of the Trial Steering Committee. This specialist also acted as the central contact for physiotherapy-related issues from participating sites.

After an appraisal of practice at the lead hospital and consultation at several other hospital sites, we focused on three key elements of the care pathway. These elements were: self-care during initial sling immobilisation, the development of a basic treatment physiotherapy protocol, and home exercises for patients. To adhere to the reporting standards for pragmatic and non-pharmacological trials,<sup>4,5</sup> we also devised data collection procedures to document the provision of rehabilitation. Such data on physiotherapy are also important regarding the use of healthcare resources, and contributed to the cost-effectiveness analysis.

**Provision of written patient information on personal care during initial use of a sling.** Identification of the lack of written patient information on this aspect of personal care prompted the development of an illustrated information sheet by two physiotherapists with input and feedback from the ProFHER trial management team and two 'service users' (both former proximal humeral fracture patients). Items covered in the information sheet were: the rationale for the sling; sling use and care; advice on keeping mobile; hand and wrist exercises; washing and hygiene; getting comfortable; sleeping position; pain relief, including breathing; important 'don'ts'; warning signs and a reminder to seek further advice in case of problems. The information sheet was provided as part of the trial recruitment materials for giving to potentially eligible patients. Hospitals were advised that the ProFHER sling care information leaflet could be replaced by locally available material, if available.

Soon after recruitment had ended, we sent each participating site a brief questionnaire designed to obtain feedback on the use of the ProFHER sling care leaflet.

**Physiotherapy: production of physiotherapy protocol.** The lack of a physiotherapy protocol to promote standard care for these fractures was noted at all hospitals involved in the funding application. In the absence of evidence on which to base practice,<sup>6</sup> our aim was to develop a physiotherapy protocol that was representative of accepted good practice. This process comprised several stages.

After an initial review of current physiotherapy practice at the lead site, a draft protocol structured to reflect successive phases of rehabilitation was drawn up by four specialist physiotherapists from different centres. Upon review, the Trial Steering Committee advised of the need to seek feedback on the draft protocol and further insights on the current management of these fractures from specialist shoulder physiotherapists and other experts. Further advice related to the importance of keeping to routine practice and avoiding unusual interventions, including electrotherapy (other than transcutaneous electrical nerve stimulation (TENS)).

A short questionnaire was prepared. This asked for feedback on the protocol in terms of its acceptability as a guide to basic treatment for these fractures and on whether the specialists themselves would follow the approach given in the protocol. Additionally, it asked the specialist to list other interventions that they applied routinely for people with these fractures, as well as any interventions available in an NHS setting that they would discourage. In June 2008, the questionnaire and draft protocol were circulated for comment primarily via the hub contacts for the National Physiotherapy Research Network (NPRN)<sup>7</sup> and distributed in person to physiotherapists at the British Elbow and Shoulder Society (BESS) annual meeting. The results from the questionnaire survey were collated and assessed in terms of the acceptability of the draft protocol and any changes that were required. All comments and routinely-used interventions not appearing in the protocol were documented.

We received 29 completed questionnaires, 14 from allied health professionals attending the BESS meeting, 12 from the NPRN mailshot and three from members of a guideline development group. Respondents were predominantly specialist physiotherapists currently involved in treating these fractures and other shoulder injuries. In total, 27 (93%) respondents agreed the protocol was acceptable as a basis for treatment and were happy with the approach given in the protocol. Two main modifications to the protocol were made in response to the feedback. The first involved additional text stressing that the protocol was only a guideline and that variation in practice was anticipated and acceptable, with the proviso that any substantive difference was recorded. The second was a correction to some contradictory instructions. None of the

listed 'other' interventions were considered unexpected or inappropriate. Notably there was a strong discouragement of electrotherapy except the use of TENS for pain relief. Overall, we concluded there were sufficient responses to inform trial methods and that the overwhelmingly positive response endorsed the use of the protocol; this in turn would serve to strengthen the delivery of physiotherapy and, thus, acceptance of the trial methods.

Subsequent feedback from the Trial Management Group and colleagues from the UKUFF trial on rotator cuff repair<sup>8</sup> indicated the need for greater emphasis on the non-surgical aspects of treatment and rehabilitation, and that the protocol should make very clear that it applied to all patients, whether treated surgically or non-surgically. The final version was installed as a document provided to trial sites and its use for all trial participants mandated in the trial manual.

**Home exercises.** We promoted the need for physiotherapists to encourage patients to perform home exercises. These tend to reflect patient ability and be adapted as the patient recovers. Since this variation contradicts the development of standardised material, our protocol indicated we would check that physiotherapists either provided information leaflets illustrating exercises for home use already or would access a standard web-based facility to generate 'bespoke' exercise sheets. It was considered essential that physiotherapists documented whether patients had done their home exercises.

**Delivery.** Delivering physiotherapy to this patient population is complicated by the tendency of patients to receive physiotherapy at one or more different locations after leaving hospital. Although approval from Research and Development (R and D) often covered data collection by physiotherapists delivering care in clinics in the community, sometimes R and D approval for Primary Care Trusts was required in addition to that from acute hospital trusts. For practical purposes, only the main Primary Care Trusts were generally targeted – patients who were expected to use venues outside their catchment area were deemed ineligible for the trial. Ultimately, additional R and D approval was obtained for 16 Primary Care Trusts.

To facilitate delivery of physiotherapy and data collection, contacts for physiotherapy were identified at each trial site and named in the local site R and D approval document for the study. The contact physiotherapists usually attended the multidisciplinary team meeting at site set-up visits. The contacts were responsible for organising this aspect of care including dissemination of trial methods and materials, providing advice, distribution and collection of physiotherapy follow-up forms, and often their dispatch to the trial co-ordinating centre. All but one participating hospital had named contacts for physiotherapy.

**Data collection.** Insights from other investigators of multi-centre orthopaedic surgery trials indicated the need to design forms documenting physiotherapy treatment that could be readily completed at the end of

each session. Such forms need to capture all the key information for an assessment of the physiotherapy delivered: when, by whom, referral to other specialities and end-of-treatment data. Some limited patient outcome data were also collected. After identifying the essential data needed for collection, the focus turned to the practical aspects of collecting data over a protracted period, including optimising form design.

In designing the physiotherapy treatment log, consideration was given to physiotherapists' routine record keeping, so that completing the form would require little additional effort. It included tick boxes for registering the use of basic categories of interventions (advice and/or education, exercise, TENS, soft-tissue techniques, etc), and gave the opportunity to record other interventions, including any substantial variations from the ProFHER physiotherapy protocol. A question asked whether the patient had done his or her home exercises, and a text box was provided for any comments. Key data on a physiotherapist's grade, location and duration of session were also collected for inclusion in the cost-effectiveness analysis. Additionally, an 'end of treatment' form was designed primarily to collect reasons for discharging a patient when treatment was and was not completed. Piloting of draft data collection forms was undertaken to identify and resolve any problems. Consideration of how to maximise the completion and return of forms pointed to the need for local physiotherapy contacts to co-ordinate data collection. Hospitals were paid for the return of physiotherapy data on each participant in the trial.

## Results

**Sling care information.** All participating sites completed the post-recruitment survey on the provision of the sling care information leaflets to patients eligible for participation in ProFHER. This revealed that 28 of the 33 hospitals (85%) that had identified eligible patients routinely provided ProFHER leaflets to all eligible patients. Two sites had 'never' used the leaflet, one of which provided an alternative, which was a text-only leaflet providing general advice on sling use during conservative management of proximal humeral fractures. Three other sites 'rarely' used the leaflet. All 32 sites who had recruited patients into the trial routinely provided the ProFHER sling information leaflet.

These results confirm the delivery of a standard of care, in particular for consenting patients, thereby ensuring comparability between the two randomised groups.

**Physiotherapy.** As shown in Table I, data from physiotherapy treatment logs demonstrated equal physiotherapy access and implementation between groups. Similar numbers of patients in each group received 'other' interventions, none of which was electrotherapy (which would have been a protocol violation). A review of the 486 comments in the physiotherapy treatment logs found no record of a substantial difference from the ProFHER physiotherapy protocol. However, lack of access

**Table 1.** Physiotherapy

	<b>Surgical (n = 125)</b>	<b>Non-surgical (n = 125)</b>
Number receiving physiotherapy (%)	118 (94.4)	117 (93.6)
Days to first session		
Mean (SD)	23.1 (24.07)	25.5 (18.60)
Duration of physiotherapy (days from first to last session)		
Mean (SD)	116.7 (75.75)	113.0 (67.46)
Number of sessions		
Mean (SD)	9.6 (6.22)	9.6 (6.59)
Median (range)	8 (1 to 36)	8 (1 to 43)
Allocated time/session (mins)		
Mean (SD)	28.3 (9.57)	29.2 (10.49)
<b>Session details*</b>		
Advice and/or education (%)	115 (92.0)	113 (90.4)
Exercise (%)	118 (94.4)	114 (91.2)
TENS (%)	1 (0.8)	8 (6.4)
Soft-tissue techniques (%)	49 (39.2)	49 (39.2)
Joint mobilisations (%)	55 (44.0)	71 (56.8)
Stretching techniques (%)	83 (66.4)	84 (67.2)
Relaxation techniques (%)	31 (24.8)	31 (24.8)
Hydrotherapy (%)	5 (4.0)	10 (8.0)
Other† (%)	22 (17.6)	22 (17.6)
Home exercise*		
Recorded (Yes or No) (%)	112 (89.6)	106 (84.8)
Yes (%)	109 (87.2)	103 (82.4)
No (%)	38 (30.4)	44 (35.2)
Referral to other specialty* (%)	9 (7.2)	12 (9.6)
Occupational therapy (%)	1 (0.8)	2 (1.6)
Other(%)	8 (6.4)	10 (8.0)

\* Frequency (%) of patients if reported at least once in session logs

† These included ice, heat, mobility and stairs and acupuncture

to the physiotherapy protocol was identified from the comments by two outpatient physiotherapists for two patients in the surgical group.

**Home exercises.** When advising physiotherapists on the home exercise requirements in the protocol, the physiotherapy contact realised that some allowance was needed for home exercises that were predominantly based on daily functional tasks (such as reaching up to the top of a cupboard). For these tasks, written instructions were considered unhelpful, the emphasis being on the monitoring and reinforcement of these and related functional activities at subsequent physiotherapy. Table 1 shows the high levels of recording of home exercises, with similarly high numbers of participants in both groups recorded as performing home exercises for most sessions.

**Delivery.** The success of our processes is corroborated by data in Table 1. The underlying complexity in the provision and documentation of rehabilitation for these fractures is illustrated by the data for one centre, chosen because it served a mainly urban community (typical for ProFHER) and had sufficient patient numbers. In all, 28 physiotherapists completed the treatment log forms and provided care to the 15 patients recruited at this centre. Of the 18 physiotherapists providing outpatient care,

eight were based in one hospital outpatient department, eight in another hospital outpatient department, one from an external source provided home care and one from a health centre. While a variety of physiotherapists provide hospital ward care, patients mostly had one or two physiotherapists providing care in an outpatient department.

**Data collection.** Aside from two sites, where repeated requests for the return of physiotherapy forms were required, physiotherapy treatment logs and end of treatment forms for individual patients were returned in a timely manner throughout the trial. Ultimately, 235 of 250 (94%) physiotherapy treatment logs and 245 of 250 (98%) physiotherapy ‘end of treatment’ forms were obtained. Most of the missing logs were because patients never started physiotherapy. Overall, the data forms were well completed. The only notable yet resolvable problem found at data checking was the numbering of physiotherapy sessions, which was often recorded as starting at one again when the patient was transferred to another health-care setting.

## Discussion

The successful attainment of the recruitment target and low attrition in the return of patient questionnaires and hospital forms meant that ProFHER provides good quality evidence on a key treatment question.<sup>3,6</sup> However, the validity of trial results and their applicability also depend on other aspects of trial design, conduct and reporting.<sup>4,5</sup> In particular, it is crucial to ensure comparability in good standard care throughout the trial so that any difference in outcome can be attributed to the interventions under test.<sup>9</sup> Typically, single-centre trials are able to exert greater control over their treatment interventions and rehabilitation, but at a loss of general applicability. A recent trial on proximal humeral fractures describes the same rehabilitation protocol being rigidly prescribed to both groups, and a regular monthly visit to the physiotherapist up to 12 months.<sup>10</sup> Such control and prescription for tightly-staged physiotherapy and surveillance is neither practical nor appropriate for large multi-centre trials such as ProFHER. Here, the emphasis, especially where there is a lack of robust evidence to inform practice, has to be on taking sufficient measures to ensure comparability of accepted good practice for the intervention groups, yet allowing for acceptable variation. Thus, the focus shifts to providing a good standard of care, using familiar techniques and safeguarding for substantial deviations that might undermine this. The development of a basic physiotherapy protocol was central to achieving this aim.

This article has focused on the key processes undertaken to ensure a good standard and comparable rehabilitation, and the reporting of this, within the context of this pragmatic trial. Table 2 summarises the key stages in setting up, delivering on, reviewing and reporting of rehabilitation in terms of CONSORT.<sup>4,5</sup> All measures taken were successful

**Table II.** Summary of the key stages in setting up, delivering on, reviewing and reporting of rehabilitation in ProFHER

Stage	Setting up*	Delivery	Review	Reporting (CONSORT)
Initial care	Sling care information leaflet designed	Included in trial materials	Survey	Initial care provided; standardisation
Physiotherapy	Physiotherapy protocol – development to reflect basic standard practice, included survey; PTs attend site set-up visit; assigned contact PT to co-ordinate trial processes	Protocol included in trial participant materials; emphasis on provision for all participants	Feedback to trial PT contact; physiotherapy treatment logs; end of treatment form	Participant flow diagram; attendance and extent of physiotherapy; data for cost analysis; description of rehabilitation; standardisation of basic physiotherapy; use of additional interventions, including referral to occupational therapy; notice of adverse events
Home exercises	Instruction for locally produced exercise sheets	Part of protocol; part of site set-up	Feedback to physiotherapy contact; physiotherapy treatment logs	Standardisation of treatment; additional measure of patient activity
Data collection	Design of forms; assigned contact PT to co-ordinate data collection	Physiotherapy treatment logs and end of treatment forms are part of trial materials for recruited patients; forms circulated for completion during care pathway and collated by physiotherapy contact for dispatch to trial office	Housekeeping of returned forms; consistency checks	Data within used as above

\* Common to all these was the central role, including as a source of advice, of the physiotherapy contact for the trial. PT, physiotherapist

and arguably, for some at least, their impact could have exceeded that of the trial itself. For example, the survey of the use of the sling care information leaflet by the participating sites not only provided assurance of comparability between the two treatment groups, but also revealed the correct identification of an important gap in patient management in that only one site had an alternative leaflet. The provision of the basic treatment physiotherapy protocol addressed another important gap. None of the participating sites raised objections to using the protocol, and no protocol violations were recorded or detected. Minor variation in practice, often reflecting adaptation to the needs of individual patients, was expected in the context of accepted good practice.

The return of the completed physiotherapy treatment logs and end of treatment forms was exemplary, especially given the often complex and protracted care pathway for individual patients. The data on the location and reporting of physiotherapist data for one participating centre illustrate the need for and the diligence of the great majority of the physiotherapy contacts for the trial. They vindicate also the groundwork done at the start of the study and early involvement of physiotherapists when setting up sites. Such data are essential for the full and correct reporting of the trial.<sup>4,5</sup> For example, the CONSORT participant flow diagram, where the numbers of care providers in each centre are reported; the interventions, which includes details of how these were standardised; and a discussion on the applicability of the trial findings.<sup>5</sup>

The key role played by physiotherapists in ensuring the success of this multi-centre trial is shown. The early inclusion of a physiotherapist in trial management, including importantly in the Trial Steering Committee and Trial

Management Group, was essential to ensure there was sufficient attention paid to the rehabilitation aspect of the trial. Physiotherapists also were central to local management and co-ordination of trial activities. In ten hospitals, physiotherapists were also the designated contacts and thus responsible for all trial activities including patient recruitment at a hospital site. These ten centres recruited a total of 89 patients (36% of total).

This article has shown the attention required for delivering and reporting the rehabilitation aspect of randomised controlled trials in evaluating definitive treatment options. Involvement of rehabilitation specialists (such as physiotherapists in the UK) in the trial design, setting up, conduct, reporting and interpretation of the data and results of such trials is essential to ensure their validity, applicability and implementation.

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- H. H. G. Handoll: Input into all aspects of trial methods, forms and questionnaires design; wrote the paper.
- L. Goodchild: Physiotherapy contact for trial, information leaflet and physiotherapy protocol development, advice on content, revision of manuscript.
- S. D. Brealey: Trial management, input into all aspects of trial methods, forms and questionnaires design, advice on content, revision of manuscript.
- N. C. A. Hanchard: Information leaflet and physiotherapy protocol development, advice on content, revision of manuscript.
- L. Jefferson: Trial management, input into associated trial methods, revision of manuscript.
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- None declared

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