What is the feasibility and observed effect of two implementation packages for stroke rehabilitation therapists implementing upper limb guidelines? A cluster controlled feasibility study

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ABSTRACT

Background Hand and arm activity after stroke improves with evidence-based rehabilitation. Therapists face known barriers when providing evidence-based rehabilitation and require support to implement guidelines. The aim of this study was to investigate the feasibility of two implementation packages on guideline adherence by occupational therapists and physiotherapists, and explore effect on patient upper limb outcomes.

Method This was a non-randomised clustered feasibility study of occupational and physiotherapy rehabilitation services (n=3 inpatient and n=3 outpatient services). Services were allocated to one of three groups: (group A) facilitator-mediated implementation package, (group B) self-directed implementation package or (group C) usual care (control); we recruited n=1 inpatient and n=1 outpatient service per group. Outcomes of feasibility, adherence to guidelines (medical file audits) and patient upper limb impairment (Fugl-Meyer Upper Extremity Assessment), activity (Box and Block Test) and practice (minutes/week) were collected at baseline and after 3 months of intervention.

Results 29 therapists (8 in group A, 13 in groups B and 8 in group C) and 55 patients participated. Both the facilitator-mediated and the self-directed implementation packages were feasible to deliver in the rehabilitation setting. Therapists in group A improved with respect to guideline adherence (medical file audits; median within-group proportion difference of 0.29 (95% CI 0.22 to 0.36, p<0.0001) preintervention to postintervention). No significant within-group differences from baseline to postintervention were found in group B or group C, and no between-group differences were found for upper limb outcomes.

Conclusion A facilitator-mediated package was acceptable to therapists working in stroke rehabilitation, and feasibility data suggest increased guideline uptake following implementation. An adequately powered study is planned to understand how to support therapists to provide evidence-based upper limb rehabilitation after stroke.

Trial registration number Australian New Zealand Clinical Trials Registry (ACTRN12619000596101).

BACKGROUND

In stroke rehabilitation, implementable evidence exists for arm and hand interventions, synthesised in clinical practice guidelines. Despite this, research indicates that such guidelines in stroke rehabilitation are often not followed. This variability in adherence suggests a problematic gap between what is known (as cited in the guidelines) and therapist decision-making in stroke rehabilitation practice. To support therapists to deliver evidence-based care and thus improve adherence to guidelines in practice, an active implementation approach is often required.

Implementation science seeks to understand the science behind knowledge translation models and activity efforts, so as to improve the likelihood of successful translation of research into clinical practice. We acknowledge that no ‘gold standard’ implementation activities have been identified; however, it has been suggested that active and multifaceted activities are likely to work best. There are many theories, models and frameworks in the implementation literature to guide efforts and encourage researchers and end users to employ a structured and theoretical approach. Despite the availability of these theories, it is estimated that only 10% of guideline implementation studies describe their theoretical rationale for selecting knowledge translation activities. In an effort to understand health professionals’ behaviour, previous studies have mapped the perceived barriers and enablers of health professionals to frameworks such as the Theoretical Domains Framework, however, few subsequently develop behaviour change interventions. One can conclude from research to date that to change behaviour, understanding perceived barriers to address is important.
mapping these to a model or framework to identify implementation activities, and developing a multifaceted package of active interventions maximises likelihood of therapist adherence to guideline recommendations.

In stroke rehabilitation, there is now a good understanding of the issues faced by health professionals who seek to implement upper limb guideline recommendations.17–19 However, much work is still needed to develop and test the effectiveness of behaviour change interventions. Organisations seeking to implement clinical guidelines do not yet know what activities to fund and how they should be delivered, so as to improve therapist adherence. Active and multicomponent approaches that are grounded in theory are suggested as most likely to achieve behaviour change.20 21 In a recent systematic review that explored the benefit of implementation strategies in stroke rehabilitation, Bird et al21 included 11 randomised controlled trial. According to Grades of Recommendation Assessment, Development and Evaluation (GRADE) criteria, the quality of included studies was low, and no studies explored the difference between high-resource investment (financial and non-financial) and low-resource investment implementation package of interventions (compared with no implementation interventions) for achieving behaviour change. Understanding the feasibility and effectiveness of high-resource and low-resource investment for implementation strategies (underpinned by behaviour change intervention mapping) would inform clinical trialists, service providers, funding bodies and therapists.22 To improve adherence to upper limb rehabilitation guidelines,4 we developed implementation strategies to specifically target the knowledge, belief in consequences and skill barriers identified in Australian stroke rehabilitation therapists.19 The aim of this study was to test the feasibility and potential efficacy of two tailored implementation packages for improving adherence to upper limb stroke rehabilitation guidelines, and to understand the acceptance from the therapists’ perspective. The following research questions were therefore addressed:

1. Feasibility: What numbers of eligible therapists (ie, the occupational therapists and physiotherapists; target users of guidelines) consent to participate in the study? Is it feasible and acceptable to recruit patients (ie, recipients of guideline interventions) during their rehabilitation? How feasible is it to deliver the two packages (ie, facilitator-mediated implementation package and the self-directed implementation package)? Were both packages delivered per protocol?

2. Efficacy: What is the observed effect of the two implementation packages (facilitator-mediated or self-directed) implementation packages on (a) adherence to stroke rehabilitation guidelines for upper limb rehabilitation; and (b) patient upper limb recovery? In addition, the study will provide estimates to inform future power calculations, including estimates of variability of the proposed outcomes and CI around observed treatment effects.

3. Acceptance: What was the experience of receiving the allocated package from the perspective of the therapists?

METHOD
Design
This was a non-randomised three-arm cluster-controlled longitudinal feasibility study, with assessment at three time-points. Participating healthcare services provided neurological rehabilitation within inpatient (ie, hospital ward-based) and/or outpatient (ie, community-based) contexts in Melbourne, Australia. Given the scope and nature of this study (ie, feasibility), sample size calculations were not conducted. Power calculations for future trials will be informed by the results generated from this work. Three organisations were approached (and agreed) to take part in this study. Of the three participating organisations, six sites (three inpatient and three outpatient) took part. Sites were pragmatically allocated (ratio 1:1:1) to one of three intervention groups:

Group A: facilitator-mediated implementation package.
Group B: self-directed implementation package.
Group C: usual care.

This study recruited both therapist and patient participants. To address the feasibility research questions, we purposively recruited one inpatient and one outpatient team per group (A, B, C). Further, we sought to recruit five or more therapists per group. Together, these purposive site recruitment decisions influenced our patient participant recruitment (ie, recipients of guideline interventions), although this remained open during the 3-month intervention period such that new admissions who were being seen by an enrolled therapist would be invited to participate in the study. Figure 1 outlines the flow of participants through the study. Figure 2 outlines the inclusion criteria for the selection of therapist and patient participants.

For the purposes of this study, an acquired brain injury included stroke, traumatic brain injury, intracerebral haemorrhage and any other kind of brain injury acquired after birth. It did not include degenerative brain conditions such as Alzheimer’s type dementia, multiple sclerosis or Parkinson’s disease.23

Intervention
Using data collected from prior focus groups completed with therapists from participating organisations on the barriers and enablers for implementing the best practice arm and hand interventions,19 behaviour change intervention mapping was undertaken using the Theoretical Domains Framework.24 Behaviour Change Wheel25 and method outlined by French et al26 Online supplementary I outlines the planned knowledge translation activities that contributed towards the ‘implementation package’ for each of the intervention groups. Strategies in the self-directed group were designed to be low cost, and implementable with distance (ie, no direct intermediary contact by the research team). This was the primary
difference between group A (facilitator mediated) and group B (self-directed). Intervention content for group B, therefore, was delivered via ‘Trello’. Trello is an online, closed-group collaborative tool that allows a team of people to organise projects into ‘boards’, share files and post comments. Each topic area delivered to group B had a designated ‘board’ and participants were encouraged to use/read the uploaded files and post any comments/questions to the research team. Over the 12-week intervention period, implementation packages covering six key topics related to upper limb rehabilitation guidelines were delivered fortnightly (ie, one topic, each fortnight) to participants in groups A and B. Topics areas were selected based on the knowledge and skill gaps identified in focus groups, and included: task-specific motor training, setting up patient practice, functional electrical stimulation (FES), whole upper limb programme, modified constraint-induced movement therapy (CIMT) and behaviour monitoring. Two of the study investigators (LJ and NL) were responsible for delivering the face-to-face interventions to group A, and LJ was responsible for ensuring intervention delivery via Trello for group B.

**Outcome measures**

**Feasibility**

1. Study recruitment of occupational therapists and physiotherapists (ie, target users of the guidelines), assessed by determining the proportion of consented/those approached.
2. Study recruitment of patient participants, assessed by calculating the total number of patients who consented.
3. Time commitment for study participation, assessed by calculating the total time reportedly spent on implementation activities per group.
4. Therapists perspectives on intervention feasibility, assessed via a survey of participating therapists at completion of study.

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Figure 1  Flow of participants through the study (therapist and patient participants).
The following inclusion criteria were applied to the selection of therapist participants:

- Registered occupational (OT) or physiotherapist (PT) working at one or two of the six recruitment sites (e.g. an OT may have a split caseload between inpatient and outpatient services; this was acceptable if they are within the same employing organisation and intervention arm); and
- Working with an acquired brain injury patient (i.e. stroke and/or trauma) caseload.

The following inclusion criteria were applied to the selection of patient participants:

- The treating therapist had consented to participating in the study;
- The patient was currently receiving therapy for the upper limb due to an acquired brain injury;
- The patient has documented upper limb goals; and
- The patient (or their proxy) was able to provide to participate in the study.

**Figure 2** Study inclusion criteria applied for the selection of therapist and patient participants.

5. Protocol adjustments, assessed by logging the numbers and description of changes.

**Efficacy**

1. Guideline adherence by therapists, assessed using medical file audits preintervention and postintervention.
2. Upper limb outcomes of participating patients, assessed preintervention and postintervention (administered by a researcher) using the Box and Block Test (BBT), Fugl-Meyer Upper Extremity Assessment, assessed by a research assistant. Self-reported minutes of weekly therapy (patient reported and therapist reported) were also collected.

**Acceptance**

1. Therapist participants’ acceptance of the intervention assessed by survey and a focus group. Therapist participants in groups A and B were invited by email to complete an anonymous online survey. A focus group with therapists in group A (allocated to receive the facilitator-mediated implementation package) was then conducted to further explore intervention acceptance (given this group had more time-intensive commitment to the study).

**Data analysis**

Descriptive statistics were used to describe participant characteristics, recruitment rates and responses to multiple choice survey items. Focus group data (tape recorded and transcribed verbatim) and free-text survey responses were thematically coded (10% double coded by second reviewer to establish coding reliability) and themes generated. Free-text survey responses with the highest frequency were reported in results. Summary statistics for patient outcome measures and medical file audits, broken down by group, were analysed for medians (IQR), within group proportion differences (medians with 95% CI) and between-group proportion differences (median and 95% CI) using Wilcoxon’s signed rank tests. Estimates of variability of the proposed outcomes and CI around treatment effects were reported to permit future sample size calculations. Given our patient recruitment method (ongoing recruitment throughout intervention period), patient participants enrolled after day 35 and allocated to groups A and B were removed from the analysis of ‘baseline’ adherence audits in an attempt to control for intervention contamination.

**RESULTS**

**Feasibility**

A total of 29 therapists participated (8 in facilitator mediated, 13 in self-directed and 8 in usual care groups). Of these, 11 (38%) therapists primarily worked in the outpatient setting and 18 (62%) within the inpatient setting. The majority of therapist participants were occupational therapists (87% across all groups).

**Feasibility: study recruitment of occupational and physiotherapists (target users of the guidelines)**

There was excellent participation by therapy teams, 50% of invited therapists consented to group A (facilitator mediated), 41% consented to group B (self-directed) and 47% consented to group C (usual care).

**Feasibility: study recruitment of patient participants**

A total of 55 patient participants were recruited (20 in group A, 17 in group B and 18 in group C). Of these, 19 (35%) were recruited from the outpatient setting, and 36...
(65%) from the inpatient setting. Table 1 shows therapist and patient characteristics.

Feasibility: time commitment for study participation
Therapists in groups A and B reported that intervention participation was time feasible within their work schedule. Group A dedicated 94 min/week on average (range 20–120) to intervention content. Group B dedicated 49 min/week on average (range 0–180) to intervention content. The majority (71%) of therapists reported the interventions to be time feasible, and did not perceive activities to take up too much of their time. Therapists’ preferences were to spend more time on the topic areas of CIMT and FES than other topic areas. In the free-text section of the survey, one therapist commented on their selection of CIMT and FES, saying “[these] were areas that I could improve upon in terms of knowledge and practical application”.

Feasibility: therapists perspectives on intervention feasibility
Most active intervention therapist participants (groups A and B) completed the postintervention survey (completion rate 78%). The majority (responses of ‘always’ and ‘most times’) of therapists from both groups reported that interventions made available to them were used (54%), helpful (80%), relevant (86%) and assisted them to provide evidence-based practice (EBP; 72%). Group B participants reported the use of ‘Trello Boards’ (share point for intervention content) was easy to access and navigate. Online supplementary 2 shows additional survey results and free-text responses.

Feasibility: protocol adjustments, assessed by logging the numbers and description of changes
Group B (self-directed) and group C (control) had no protocol adjustments. Group A required more time from the facilitator than expected and/or planned for in the protocol. The protocol adjustments were all related to requests for tailored resources (ie, development of five additional/unplanned patient handouts) and/or additional modelling/demonstration sessions with patient participants (six in total, each of 60 min duration). No harm or unintended effect was evident in any group throughout the study.

Efficacy
Efficacy: guideline adherence by therapist participants
Significant behaviour change was observed between preintervention and postintervention audits in group A (facilitator mediated), with a median within-group proportion increase to guideline adherence of 0.29 (95% CI 0.22 to 0.26, p<0.0001). No observed effect for within-group differences were found in group B or group C between preintervention and postintervention audits. Group A adhered to guidelines significantly more than and group B, with a median between-group difference of 0.26 (95% CI 0.16 to 0.34, p<0.0001). Effect estimates in adherence to guidelines was also found between group A (facilitator mediated) and group C (usual care), with a median difference of 0.29 (95% CI 0.21 to 0.37, p<0.0001). No observed effect for between-group differences was found between groups B (self-directed) and C (usual care). See table 2 for full results.

Efficacy: upper limb outcomes of participating patients
An increase in minutes of practice (105, 95% CI −20 to 345) of upper limb activities for patient participants was observed from pre-to post-intervention (ie, within group changes) in group A (facilitator mediated) and group C (usual care; 87.5, 95% CI −5 to 177.5). No increase in time was observed in group B participants (self-directed). There were also no between-group observed effects. All groups improved preintervention to postintervention on the BBT; however, no observed effects were found for between-group differences. Observed effect for within-group improvements on the Fugl-Meyer Upper Extremity Assessment was found for groups A (facilitator-mediated) and C (usual care). See table 2 for full results.

Acceptance
Acceptance of implementation packages (groups A and B)
Both groups reported the implementation packages to be helpful and useful; however, free-text comments in survey responses suggest that therapists allocated to group B (self-directed) would have found the intervention more beneficial if additional structure in the form of face-to-face sessions with hands on demonstration was provided. The
<table>
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<th>Outcome</th>
<th>Groups (median and IQR)</th>
<th>Within-group change (median differences and 95% CI)</th>
<th>Difference between change scores (median differences, 95% CI and p value)</th>
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<td></td>
<td>Baseline</td>
<td>End of intervention</td>
<td>End of intervention minus baseline</td>
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<tr>
<td></td>
<td>A (n=18)</td>
<td>B (n=17)</td>
<td>C (n=18)</td>
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<td>Adherence to guideline recommendation, % (IQR)</td>
<td>40 (13)</td>
<td>59 (42)</td>
<td>47 (19)</td>
</tr>
<tr>
<td>Minutes of practice per week n, (SD)</td>
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<td>360 (560)</td>
<td>180 (198.8)</td>
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<tr>
<td>Box and Block Assessment blocks per s, (SD)</td>
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<td>0.05 (0.52)</td>
<td>0.00 (0.40)</td>
</tr>
<tr>
<td>Fugl-Meyer Assessment Score (0–66), n, (SD)</td>
<td>16 (45.5)</td>
<td>37 (50)</td>
<td>10.5 (42.75)</td>
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</tbody>
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*Two outliers removed. A, Facilitator-mediated implementation package group; B, self-directed implementation package group; C, usual care group.
free-text comments from participants in group A (facilitator mediated) positively reflected on the benefit of face-to-face sessions and audit and feedback, and expressed gratitude for their involvement. There was a high attendance to group A’s (facilitator mediated) postintervention focus group (75%). Five themes emerged from the focus group: provision of tailored and accessible resources was valuable; equipment and resource availability allowed timely intervention provision; skilled behaviour monitoring incentivised EBP; direct modelling prioritised and facilitated optimal learning and study participation increased skill, knowledge and confidence. Therapists spoke positively about the usefulness of tailored resources (such as patient handouts and/or therapist workbooks) which they felt saved them time in the longer term. Audit and feedback sessions were reported to be motivating, with therapists commenting that “The [facilitator] broke it down really well” and feedback described as “very encouraging...I think that’s what helped that motivation”. Therapists reported that modelling of interventions by the facilitator promoted learning and confidence; “It means you can have a go, like hands-on, someone there to support you. Rather than just watching [a video]. Because sometimes with patients, there are those slight [differences], so you can problem solve with the [facilitator]”. Overall, therapists felt their involvement in the study had changed their practice; “It’s 100 per cent changed my practice, and the study is still very much at the forefront of my mind when I’m doing [upper limb rehabilitation]. It’s absolutely had a flow-on effect and a really positive one” and “I have changed what I do with a patient’s upper limb. I think I am more efficient in time as well”. Figure 3 outlines themes and subcategory themes.

**DISCUSSION**

This study’s main finding is that providing a facilitator-mediated implementation package to occupational and physiotherapists was feasible and acceptable. Observed improvements in guideline adherence by therapists who received the facilitator-mediated package, inclusive of multiple implementation strategies, suggest that it may also lead to therapist behaviour change in provision of upper limb rehabilitation after stroke. No changes in therapist behaviour were found in either the self-directed implementation package or usual care groups, suggesting that providing a low-resource implementation package may be no more effective than usual care in terms of delivering guideline-based upper limb rehabilitation after stroke. While significant improvements in patient upper limb rehabilitation were found in the facilitator-mediated group, no such changes were seen in the self-directed or usual care groups.

**Figure 3** Feasibility focus group themes and subcategories from facilitator-mediated implementation group therapist participants (n=6). EBP, evidence-based practice.
limb outcomes were found within groups, there were no between-group differences on any measure.

Our study was able to recruit well within each site, with around half of eligible therapists individually consenting to be active participants in the study (and 100% of eligible occupational therapists taking part at three of the six sites). This high recruitment rate may indicate therapists’ self-identified need to improve their knowledge and skills in upper limb therapy provision after stroke. The large representation of occupational therapists in our study is not surprising given that the role of upper limb rehabilitation is an occupational therapy domain of practice. We do, however, acknowledge that this may be contextually different in countries outside of Australia.

Findings also provide guidance for the development of other rehabilitation implementation interventions beyond upper limb therapy. Discussions and themes generated from the focus group held with participants of the facilitator-mediated group suggest that: (1) use of a facilitator; (2) interactive and regular education sessions; (3) targeted resources; (4) role modelling and (5) behaviour monitoring (fortnightly audit and feedback) were activities perceived by participants to contribute to their own changes in behaviour. While the self-directed group also received targeted resources and regular written education packs, the key differences were regular interactions with a facilitator and behaviour monitoring. Our study interventions (ie, implementation packages) have contributed towards our successful study findings. As indicated by Davis et al,22 greater use of explicit theories in systematic reviews were incorporated into our intervention designs. For example, learnings from successful behaviour change trials such as Bekkering et al34 and Martin et al35 suggested the use of interactive education sessions, role modelling, rehearsal and performance feedback activities. Novel approaches were also employed such as the use of a facilitator (or ‘knowledge broker’ as described by Dobbins et al26) to establish a relationship between research producers and end users via interactive and face-to-face contact.

Two recent and notable behaviour change studies in stroke, the out and about trial37 and implementation of the Assessment for Rehabilitation Tool38 did not lead to behaviour change of therapists. In a cluster randomised control study, Lynch et al39 delivered active, multimodal knowledge translation activities (informed by conceptual theory) over 2 weeks, followed by phone reported interventions to be time feasible and perceived it to save them time in other ways (eg, establishing patient programmes). This perceived “time tradeoff” is likely to also contribute to the positive acceptance of the study intervention, with therapists reporting personal and clinical benefits (increased skill and confidence, and clinical changes observed in their patients). Therapists in the self-directed group also reported their involvement to be time feasible (although they spent less time engaged in study interventions); however, they were not as satisfied with the time investment tradeoff for perceived increased skill and confidence.

Due to the small sample and lack of randomisation, no conclusion about patient upper limb outcomes between the three clusters can be made (no estimate of effect between-group differences was found). Patients in the facilitator-mediated inpatient group were on average 176 days post injury at the time of recruitment, compared with an average of 40 and 36 days in the self-directed and usual care groups, respectively. This may be a contributing factor to limited between-group differences of upper limb outcome measures. Few implementation studies measure patient outcomes, and future studies should incorporate this into their protocol design.
call reminders in the month following intervention. While they conducted a barrier and enabler workshop and facilitated the development of ‘action plans’, they relied on site-based opinion leaders to implement and enact the action plans. In contrast, our study developed translation activities explicitly informed by theory, and supported implementation within the workplace context using a facilitator (knowledge broker). Additionally, we conducted fortnightly audit and feedback to therapists (12 rounds in total) about their compliance to guideline recommendations, whereas Lynch et al.8 and McCluskey et al.7 completed audit and feedback on one occasion, respectively. Strategies employed by both studies, while active and multimodal in approach, were not delivered with the same frequency (ie, interaction ‘dose’) and did not contain the same type of face-to-face activities (ie, modelling and rehearsal) as our study did (in the facilitator-mediated group). This is likely to be a contributing factor to the differences in behaviour change outcomes. Activities used in our self-directed implementation package group also contained active and multimodal approaches, yet were less interactive than activities used in Lynch et al.8 and McCluskey et al.7 trials. As concluded by Bird et al.,21 the use of a facilitator appears to be a successful implementation intervention component within an implementation strategy. This finding is consistent with the findings of our study. The use of a facilitator (or knowledge broker) often removes championing tasks from busy therapists, and as identified in this study may lead to time saved in other work tasks.39 Frequency and dose of face-to-face interaction may be an important factor in successful behaviour change. While the use of opinion leaders is thought to promote EBP,48 asking therapists to champion change on top of their current workload is not ideal.

There are some limitations of this study. First, the sample size is small and caution needs to be taken when interpreting results. Grimshaw et al.41 suggest that a randomised cluster controlled trial is the ideal design for implementation allowing head-to-head comparisons of activities; however, multiple arm groups are compromised by a loss of statistical power. Second, given the scope of this study (feasibility), we were unable to randomise the clusters, which would have greatly strengthened the design. Third, our method of recruitment (ongoing patient recruitment during the 3-month intervention period) meant that some patients were enrolled mid-way through the study, so given that the treating therapist was receiving study interventions, the baseline medical file audit for that patient may not be a true reflection of the therapist ‘preintervention’ behaviour. We attempted to control for this by removing baseline audits of patient participants enrolled after day 35 in the facilitator-mediated and self-directed implementation groups. Finally, the majority of therapist participants were occupational therapists, which may reduce generalisability of the results to physiotherapists.

CONCLUSION
This study provides novel findings about high-resource and low-resource investment in implementation packages. Low-resource investment into knowledge translation activities was found to be no more effective than usual care for behaviour change with rehabilitation therapists working with stroke survivors. Given the results of this feasibility study, a randomised trial is warranted to test effectiveness of these intervention packages on therapist behaviour change and patient upper limb outcomes.

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Data availability statement The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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