Author's response to reviews

Title: Development of a behaviour change intervention to increase upper limb exercise in stroke rehabilitation

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Author's response to reviews: see over
Author's response to reviews

Title: Increasing upper-limb exercise provision in stroke rehabilitation: development of a behaviour change intervention and measuring implementation fidelity

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Date: 29/01/15

Author's response to reviews: see over
21 November 2014

RE: MS: 1225190764145180

Dear Professor Michie,

Thank you for the opportunity to revise this paper, and the insightful reviewer’s comments. It was interesting to read the contrasting reviews from those with a stroke rehabilitation background compared with reviewers with a psychology background.

The paper has been substantially revised and restructured to reflect the focus on the development process. The methods and results sections are now structured by the four development phases without duplication, which we feel makes it much clearer. We have added in more detail regarding how the BCW was applied, and kept the discussion more focused towards this too. We have also added in details of future work.

We have addressed or responded to all reviewers’ concerns- please see our point-by-point response below.

Kind regards,

[Signature]

Louise Connell
Reviewer 1 comments

The target behaviours for patients listed in Table 1 are not behaviours, for example, having motivation to exercise is not behaviour. Motivation is a prerequisite for much volitional behaviour but it is not behaviour per se, it is an antecedent to behaviour.

This table has now been removed and replaced by Figure 2 to demonstrate the interdependent network of behaviours. The target behaviours have been revised to ensure they capture the therapist focus of the behaviour:

More details on how the BCW was used to guide the development of the intervention would be useful.

The methods and results have been re-structured using the four development stages and are now clearly distinct from each other. Details of how the BCW was used have been added:

In the Methods section:

Stage 2: Structured discussions to understand the problem, prioritise target behaviours and analyse target behaviours
In stage two, the intervention development group engaged in structured discussions to understand the problem (i.e. how upper limb exercise could be increased in the stroke rehabilitation unit) and identify behaviours that could be amenable to change within the limits of the project using the BCW [18] as a guide, and to prompt discussion. Information from formative research on current UK therapy practice for prescribing upper limb exercises [22], and how the GRASP has been previously implemented [13], was used as a basis for brainstorming possible target behaviours. A list of all potential target behaviours was generated by the group, which the group then prioritised according to how amenable to change they perceived them to be using guidance from the BCW.

Each target behaviour was analysed to determine how best behaviour change could be achieved using the Capability, Opportunity, and Motivation Behavioural (COM-B) model, the hub of the BCW [19]. COM-B is a simple model to understand behaviour based on Capability (psychological or physical ability to enact the behaviour), Opportunity (the physical and social environment that enables the behaviour) and Motivation (reflective and automatic mechanisms that activate or inhibit behaviour). A definition of the COM-B model and previous examples were given to the group to facilitate discussions to identify what needed to change in order for therapists to be able to perform these target behaviours.

Stage 3: Collaborative design of theoretically underpinned intervention components
The methods in stage three were less aligned with the Behaviour Change Wheel. It entailed a collaborative design exercise to identify intervention components, and was informed by the Behaviour Change Technique Taxonomy (v1) (BCTTv1) [23]. The aim of the BCTTv1 is to provide a reliable and systematic method of describing and categorising behaviour change techniques (BCTs) used in interventions. Employing
consistent terminology to describe these techniques allows developers to identify the active ingredients of interventions, test these active ingredients and comprehensively describe interventions to facilitate replication in future research [24]. During the design exercise, the BCTTv1 [23] was used by the intervention development group to facilitate discussion around potential behaviour change techniques, and delivery methods, to ensure all options were considered. A description of what intervention components could look like was then drafted. The research team produced versions of the intervention components which were presented back to the therapists for additional feedback and refining.

In the Results section:

**Stage 2: Structured discussions to understand the problem, prioritise target behaviours and analyse target behaviours**

The problem to be addressed was the intensity of upper limb task oriented training completed by stroke survivors in the stroke rehabilitation unit. Structured discussions during intervention development group meetings highlighted a range of different interdependent behaviours that need to be performed to bring about this increased intensity of exercise. These are illustrated in Figure 2.

Based on the BCW method for prioritising target behaviours it was decided by the intervention development group that therapist level behaviours would be the focus of the intervention in this study for the following reasons (i) they were viewed as the first steps in the causal chain and hence have spill-over effect, (ii) they were considered by the group to be amenable to change and (iii) following piloting demonstrated strong potential to positively increase upper limb exercise in the stroke rehabilitation unit.

The group prioritised four target behaviours at the therapist level:

1. Identifying suitable patients for exercises
2. Provision of exercises & equipment
3. Communicating exercises to family/visitors
4. Monitoring and reviewing exercises

Each target behaviour was analysed to determine what needed to change and how best behaviour change could be achieved using the Capability, Opportunity, and Motivation Behavioural (COM-B) model, the hub of the BCW. The views of the therapists discussed here were also corroborated with formative research findings and other relevant literature. The results of the behavioural analysis for the target behaviours using the COM-B model are shown in Table 1.

**Capability**

- All therapists had the physical capability to perform the four target behaviours. Therapists discussed that from assessments it was not always clear who should be prescribed upper limb exercises, in particular who should be prescribed exercises to be practiced outside of therapy time. Therapists also discussed that
entry level therapists new to stroke rehabilitation, can often find it difficult to identify exercises suitable to the stroke survivor’s level of ability. All therapists discussed the importance of family and carer involvement in rehabilitation but also highlighted the challenge of effectively engaging families/visitors in the rehabilitation process.

**Opportunity**

- The most frequently discussed issue that needed to be addressed in order for therapists to successfully perform the four target behaviours was the limited time available to them in their working day. Therapists also discussed issues around social opportunity such as the limited amount of emphasis placed on addressing upper limb impairment in inpatient stroke rehabilitation settings compared to that placed on recovery of the lower limb, transfers and mobilising. In inpatient stroke rehabilitation there is also limited physical opportunity for therapists to monitor, review and progress prescribed exercises programmes prior to discharge as a result of continually reducing length of stay and early discharge of stroke survivors.

**Motivation**

- Limited physical and social opportunity to perform the target behaviours was identified as having an effect on therapist’s motivation. All therapists discussed the importance of increasing intensity of upper limb exercises in inpatient stroke rehabilitation settings, and their desire to more actively engage in this, but the lack of external drivers hampered this motivation. For example, currently in the national stroke rehabilitation guidelines there are targets for the time taken until assessment, and amount of therapy received but no quantifiable targets relevant to upper limb rehabilitation [7].

**Stage 3: Collaborative design of theoretically underpinned intervention components**

As illustrated in the behavioural analysis (Table 1), physical opportunity and social opportunity emerged as the domains most in need of change to facilitate therapists in performing the target behaviours. To manage the scale, and the scope of the intervention, the intervention development group focused on developing intervention components, underpinned by behaviour change techniques from the Behaviour Change Technique Taxonomy (v1) that could address these domains.

The developed intervention is PRACTISE (Promoting Recovery of the Arm: Clinical Tools for Intensive Stroke Exercise). PRACTISE consists of team meetings and the PRACTISE Toolkit.

1. **Team meetings**

Although the face-to-face meetings between the clinical team and research teams at this stage in the study were initially required for the development process, they were ultimately identified as an important component of the intervention itself as they ensured commitment to implementation and provided opportunity for self-monitoring of behaviour (i.e. measuring fidelity to the developed intervention), problem solving and action planning.
2. **PRACTISE Toolkit**

Please see Additional File 1: The PRACTISE Toolkit for draft versions of each of the following components. The developed toolkit included:

2a. A screening tool and upper limb exercise plan: to enable therapists to efficiently identify patients that should be receiving upper limb exercises and document prescribed upper limb exercises in the medical notes.

2b. A PRACTISE exercise pack: to enable therapists to efficiently communicate (verbally and in written format) the rationale for the exercise programme, the individual exercises (based on GRASP exercises, with written and pictorial instructions) to be completed by the patient, and to enable the therapist and the patient to monitor repetitions of exercises using an exercise diary.

2c. An audit tool: to enable therapists to self-monitor performance around provision of upper limb exercises to suitable patients in the stroke rehabilitation unit.

Data from the screening tool and the upper limb exercise plan were used as a source of information for the audit tool to monitor the numbers of appropriate patients in the unit for which the target behaviours were being performed (see Additional File 1: The PRACTISE Toolkit). It should be noted that the components of the toolkit are intended to have some flexibility in terms of form (e.g. to fit with local systems/policies), but the intervention aim and BCTs are standardised. The intervention components, their underpinning behaviour change techniques and what they aimed to change are summarised in Table 2.

<Insert Table 2 here>

Similarly, more details of the piloting of elements of the intervention would also be of interest to readers. For example, were all elements of the intervention piloted, and if not how/why were particular elements chosen to be pilot tested and how were they pilot tested?

All elements were piloted and all components stayed, but the format was often improved. Detail added as below:

In the Results section:

**Stage 4: Piloting and refining of intervention components**

As the intervention components were drafted, they were pilot tested by the therapy team. Pilot testing allowed the group to establish whether or not the intervention impacted on the prioritised behaviours in the desired way, and also to establish in what way, if any, the intervention components could be refined and improved. Following piloting, all components stayed, but the format was often modified or refined. An example of this was the introduction of the “Front sheet” (see Additional File 1: The PRACTISE Toolkit). Originally the “Exercise Plan” was provided to
patients as part of their PRACTISE Pack. However, feedback from therapists piloting the form suggested that it contained too much information and was too complicated for this purpose. The simpler “Front sheet” was developed to include the patient’s goal, the exercises they had been prescribed, the names of individuals willing to assist with the exercises and the date for review.

Are there plans to evaluate the resulting practice framework? Currently, it appears that the framework is being used at the development site only. It would be helpful to learn of plans to evaluate formally the effectiveness of the framework both in terms of change in health professional behaviour and patient outcomes. Inclusion of this information would broaden the interest in the current paper and future reports of the evaluation of the practice framework.

A paragraph on future work has been included:

**Future Work**

Following the development and testing of PRACTISE, the intervention now needs to be tested in other stroke rehabilitation units prior to a definitive effectiveness trial, both in terms of change in health professional behaviour and patient outcomes. A feasibility case study of the PRACTISE toolkit in two stroke rehabilitation units is currently on-going.
Reviewer 5 comments

1. Is the question posed by the authors new and well defined?
Yes the purpose is relatively clear. I think this is an important question in the stroke rehabilitation field where there are relatively few papers that discuss how to approach implementation.

2. Are the methods appropriate and well described and are sufficient details provided to replicate the work?
Yes. The methods are well described. The authors have used the behavioural change wheel to design their program.

My issue is that some of the methods have “leaked” into the results section. I recognize that this paper is a methodological study and there is an iterative component to using the Behavioural change wheel approach however I think the methods should remain in methods section and I think that it would be good if the authors used a more specific graphic or more clear stepwise methods section to outline all the planned steps as well all of the adjustments that were made because of the findings emerging.

To be as clear as possible, my suggestion is that all steps that could have been reasonably foreseen by the Behaviour Change wheel should be moved back to the methods section for clarity for the reader and all outcomes that were truly an outcome of the methodology be left in the outcomes.

The methods and results have been re-structured using the four development stages and are now clearly distinct from each other. Details of how the BCW was used have been added (see above).

3. Are the data sound and well controlled?
The qualitative data appear sound and based on the outcome of the work done. I would have liked to have a column in Table 2 that articulated which of the key issues in the COM-B framework were being targeted by the behavioural change technique. In other words presumably each of the behavioural change techniques were chosen because of a perceived issue with the Capability, Opportunity and/or Motivation of the target users. Please indicate why they were chosen.

This could be achieved alternatively by more explicitly highlighting this in the column entitled “What needs to change”

This section has been revised, with more detail on the behavioural analysis using the COM-B model for the four target behaviours. Table 2 now clearly indicates what needed to change, and how this related to behaviour change techniques and the resulting intervention components.

In the Results section:
Table 2: Intervention components, underpinning behaviour change techniques and what they aimed to change

<table>
<thead>
<tr>
<th>What needed to change</th>
<th>Behaviour change techniques</th>
<th>Intervention components (see Additional File 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical Opportunity</strong></td>
<td>Due to time constraints more efficient ways of performing the target behaviours were needed</td>
<td>4.1 Instruction on how to perform the behaviour</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.2 Social support (practical)</td>
</tr>
<tr>
<td><strong>Social Opportunity</strong></td>
<td>Getting upper limb rehabilitation higher up on the agenda was needed through managerial support and team engagement</td>
<td>1.2 Problem solving</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.4 Action planning</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.9 Commitment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.3 Self-monitoring of behaviour</td>
</tr>
</tbody>
</table>

4. Do the figures appear to be genuine i.e. without evidence of manipulation?
Yes

5. Does the manuscript adhere to the relevant standards for reporting and data deposition?
Yes.

6. Are the discussion and conclusions well balanced and adequately supported by the data?
Yes. I think the Discussion highlights the key issues in the development of the PRACTISE framework and challenges in using the COM_B framework

7. Do the title and abstract accurately convey what has been found?
I actually found the abstract to be more clear on the methods and results than the manuscript content. The abstract clearly indicates:

“The group prioritised four target behaviours at the therapist level: (i) screening patients for suitability for exercises, (ii) provision of exercises,(iii) family/carer involvement in assisting with exercises and (iv) monitoring and reviewing exercises.”
But I actually found these findings were actually only in the table 2 but harder to find in the results narrative because there was a lot of methodology in the results section.

The methods and results have been re-structured using the four development stages and are now clearly distinct from each other and easier to find.

8. Is the writing acceptable?

Yes. I think this is an interesting paper that needs some reorganization but has some interesting process steps that would if clarified be helpful for others in the field.
Reviewer 2 comments

MAJOR REVISIONS

Background

1. Page 1: Is there guidance that outlines how many minutes/repetitions should be performed when treating the upper limb in therapy sessions? This would be helpful for contextualize the frequencies provided to the reader.

Added to the Background section:

A positive relationship has been found between the time scheduled for therapy and recovery, suggesting that increased doses of therapy may lead to clinically meaningful improvements [6]. However, the optimal dose of therapy in stroke rehabilitation is not yet known, with current guidance recommending that stroke survivors have as much opportunity as possible to repeatedly practise upper limb tasks [7]. Neuroplasticity literature suggests that repetitions in the order of hundreds are likely to be necessary [8] to maximise recovery after stroke. This contrasts starkly with clinical practice, where it has been reported that the average amount of time spent treating the upper limb in therapy sessions is between 0.9 and 7.9 minutes [9] resulting in, on average, just 32 repetitions per session [10].

2. Page 1: Please provide further details regarding the uptake of GRASP. In terms of uptake, who has rapidly taken up the program, clinics? therapists? patients? And who is failing to adhere to key components? It is my understanding that dose and documentation of repetitions could be recorded by either the patient or the therapist. The target population for the intervention needs to be clarified.

Added to Background section:

GRASP has experienced unusually rapid uptake into clinical practice. For example, despite only being published in 2009, and not being explicitly recommended in the UK stroke guidelines, approximately 63% of UK therapists who responded to a survey were aware of GRASP by 2013, of whom 23% had used GRASP and 11% were regular users [12]. In order to explore the reasons for this rapid uptake, a formative evaluation of the implementation of GRASP in British Columbia, Canada was carried out [13]. Therapists working in stroke rehabilitation reported that key factors in finding out about the intervention were their own personal networks with colleagues from academia and clinical practice, and the free online availability of GRASP. A notable finding from this evaluation was that although the uptake of GRASP was good, key components of the intervention were modified when implemented by therapists in routine clinical practice. For example, GRASP was provided to non-stroke patients (e.g. spinal cord injury, brain injury patients), the exercises were often provided separately as opposed to providing the full manual, and the dose, when monitored, was less than the recommended amount.
It has also been clarified in Figure 2 that documentation of repetitions could be recorded by either the patient, family/visitors or the therapist.

The target population for the intervention is also clarified in Stage 2 of the Results section:

Based on the BCW method for prioritising target behaviours it was decided by the intervention development group that therapist level behaviours would be the focus of the intervention in this study for the following reasons: (i) they were viewed as the first steps in the causal chain and hence have spill-over effect, (ii) they were considered by the group to be amenable to change and (iii) following piloting demonstrated strong potential to positively increase upper limb exercise in the stroke rehabilitation unit.

3. Page 3: Please provide further detail of the TRACS trial.

Added in details in Background section:

Low implementation fidelity has been reported in previous trials in stroke rehabilitation, e.g. the training caregivers after stroke (TRACS) trial [14]. This was a cluster randomised controlled trial (RCT) involving 36 stroke units assigned to either an intervention to promote stroke carer training or usual care. The intervention was targeted at routine multidisciplinary stroke staff and included multiple components: carer resources (training manual and training record); taught sessions for staff; and staff resources (slides and recorded staff training sessions). It was designed to be cascaded by trained staff to those not yet trained to incorporate the intervention into usual care. However a process evaluation published in this journal demonstrated poor implementation, with no mechanisms existing for ensuring fidelity of the intervention in practice [15]. Results at six months demonstrated no clinical or statistical differences between groups on the primary outcomes of functional independence of patients or caregiver burden. The authors highlighted the need for the development of systems to monitor intervention use within practice, and for researchers to consider implementation strategies a priori, ideally in partnership with the end users of the intervention.

4. Page 3: Please use the term mechanisms of action rather than ‘active mechanisms’

Changed.

5. The Behaviour Change Wheel needs to be introduced as a method for developing interventions within the introduction. The authors should reference the BCW and accompanying guide. The authors should also outline the steps to intervention development outlined by the authors of the BCW.

Added a BCW paragraph to the Introduction:

One way to enhance the development of interventions targeting health professionals’ behaviour could be through applying the framework outlined in the Behaviour Change Wheel (BCW) [18]. This was first detailed in a publication in 2011, with
further information in a book which was published following the commencement of this project [19]. The BCW aims to provide a systematic process from behavioural analysis to intervention design. It was developed following a systematic review and a synthesis of 19 existing frameworks of behaviour change. It has three layers; at its core the COM-B (capability, opportunity, motivation, and behaviour) model, surrounded by 9 intervention functions and 7 policy categories. The authors tested the reliability of the framework against two existing policies for tobacco and obesity management. However, the process of using the BCW to develop new interventions and the extent to which applying the BCW will lead to more successful interventions has yet to be evaluated.

6. Building on my previous critique, stating that the actual methods of ‘how to develop interventions remain elusive’ misguides the readers as the purpose of the BCW is to address this barrier to intervention development. Please address this point by provided a description of the BCW and its application to date.

See point 5.

Methods:

1. The authors need to clarify that the Behaviour Change Wheel is a framework for developing and designing interventions. At its hub is the COM-B model which is a behaviour change theory. The behaviour change wheel itself it not a theory.

The semantics are consistent throughout that the BCW is a framework with the COM-B model at its hub.

2. Please provide further details regarding the development of the intervention development group and the expertise of the group for developing and designing behaviour change interventions.

Paragraph added in Results section to give more information about the group and the site:

Stage 1: Establish intervention development group
The intervention development group comprised a collaborative partnership between two members of the research team (LC and NM) and a local therapy team (physiotherapists, occupational therapists, rehabilitation assistants) representative of the end-users of the intervention. The site where intervention development took place was originally identified through existing contacts between LC and local therapists working in stroke rehabilitation. The site was a stroke rehabilitation unit in a conurbation in the North West of England, located separately to the acute stroke unit. LC and NM lead the intervention development group meetings. Both are female chartered physiotherapists working full time in the field of stroke rehabilitation research and implementation science. All members of the therapy team were invited to attend meetings and attendance ranged from 4 to 8 staff members at each meeting. A senior physiotherapist (NHS Band 6) with four years rotational experience of working in stroke rehabilitation took the lead on keeping the rehabilitation team informed about the development process and progress, and for ensuring that the intervention documentation was being completed. Meetings took
place at the development site at times deemed suitable by the therapy team. In total, eight meetings were held over a period of seven months.

3. The authors approach to using the COM-B model to determine factors that need to change (i.e., a behavioural analysis) in order for the behaviour to occur is not typical. In previous research studies applying the BCW to design an intervention, researchers have used interviews and questionnaires with the target group to identify factors that need to change in order for behaviour to occur. For example, please see the following resources:


While I commend the authors for establishing an intervention development group, I question their rationale for using this group to determine which factors in the COM-B model need to change. The authors need to provide strong rationale for this choice. In particular, the authors need to provide rationale as to why they did not use the target group to identify factors that need to change and then use the intervention development group to decide which behaviour change techniques, intervention functions and policy categories were feasible in this context. Furthermore, the authors need to provide the framework (interview schedule, etc.) for how the discussions were facilitated and structured according to the BCW. As is, the paper reads as inappropriate application of the BCW methods.

As stated, we have used the BCW as a guide, rather than being rigid. In addition, the BCW provides a framework but is not prescriptive about how the behavioural analysis should be undertaken. Our work builds on published formative work, consisting of surveys and interviews, together with discussions with the intervention development group. Arguably, this is an appropriate method and it is not necessary to complete further more in-depth qualitative research to collect data that is readily available from healthcare professionals. If additional in-depth qualitative work is required every time you want to apply the BCW then it loses its appeal and applicability.

Throughout the methods, we have now given more detail on how the discussions were informed by the BCW (and where it differed). The addition of detail regarding the expertise and background of the intervention development group and how discussions built on the formative research have also helped address this point.

From Methods, Stage 2:
In stage two, the intervention development group engaged in structured discussions to understand the problem (i.e. how upper limb exercise could be increased in the stroke rehabilitation unit) and identify behaviours that could be amenable to change within the limits of the project using the BCW [18] as a guide, and to prompt discussion. Information from formative research on current UK therapy practice for prescribing upper limb exercises [22], and how the GRASP has been previously implemented [13], was used as a basis for brainstorming possible target behaviours. A list of all potential target behaviours was generated by the group, which the group then prioritised according to how amenable to change they perceived them to be using guidance from the BCW.

Each target behaviour was analysed to determine how best behaviour change could be achieved using the Capability, Opportunity, and Motivation Behavioural (COM-B) model, the hub of the BCW [19]. COM-B is a simple model to understand behaviour based on Capability (psychological or physical ability to enact the behaviour), Opportunity (the physical and social environment that enables the behaviour) and Motivation (reflective and automatic mechanisms that activate or inhibit behaviour). A definition of the COM-B model and previous examples were given to the group to facilitate discussions to identify what needed to change in order for therapists to be able to perform these target behaviours.

From Methods, Stage 3:

The methods in stage three were less aligned with the Behaviour Change Wheel. It entailed a collaborative design exercise to identify intervention components, and was informed by the Behaviour Change Technique Taxonomy (v1) (BCTTv1) [23]. The aim of the BCTTv1 is to provide a reliable and systematic method of describing and categorising behaviour change techniques (BCTs) used in interventions. Employing consistent terminology to describe these techniques allows developers to identify the active ingredients of interventions, test these active ingredients and comprehensively describe interventions to facilitate replication in future research [24]. During the design exercise, the BCTTv1 [23] was used by the intervention development group to facilitate discussion around potential behaviour change techniques, and delivery methods, to ensure all options were considered. A description of what intervention components could look like was then drafted. The research team produced versions of the intervention components which were presented back to the therapists for additional feedback and refining.

Added to Results, Stage 2:

The views of the therapists discussed here were also corroborated with formative research findings and other relevant literature.

We have also included more in the discussion regarding the use of the BCW:

Developing and describing PRACTISE was resource-intensive. The efforts required for intervention development have been noted previously [14, 25], yet securing funding and publishing this type of work is still problematic. In this study, we used the Behaviour Change Wheel, although not rigidly, to guide the development process.
In trying to document the iterative process, to maintain clarity it is presented as more linear than it actually was. Although the BCW did provide a framework, there are still many ways in which it could be applied. In previous research studies applying the BCW to design an intervention, researchers have used interviews and questionnaires with the target group to identify factors that need to change in order for behaviour to occur [26-28]. We built on formative research findings [13] and had structured discussions with the intervention development group. As the development process was over several months, therapists were able to reflect on the discussions over time and consider the behavioural analysis during their clinical practice and could still input these into the development. This method has the limitations of being arguably less methodologically robust (e.g. not transcribed/less reproducible) but meant that it was insightful and comprehensive. The fact that it built on formative research which involved therapists both in the UK and Canada provides some credence that the findings will be generalizable to other stroke rehabilitation units.

The collaborative design of the intervention components (Stage 3) was less aligned with the Behaviour Change Wheel. Based on the behavioural analysis, any of the BCW intervention functions could be selected and hence any of the policy categories. In addition, the policy categories are not well defined and, as the name suggests, aimed more at a policy level (e.g. legislation, fiscal measures). Our intervention would all fit under the category ‘service provision’, which incorporates a vast array of potential intervention components. It was therefore felt the BCW was less directive and helpful at this stage. However, the behaviour change technique taxonomy (v1) was particularly useful during the intervention development process as it provided common terminology to describe the purpose of the intervention components. This aligns with previous evidence suggesting that when developing and testing complex interventions, there is a need to be clear about the function of the intervention components but to allow some flexibility with the form to allow adaptation at the local context [29]. Using specified behaviour change techniques from a published taxonomy, together with the embedded toolkit performance measures will provide components through which fidelity to the intervention can be measured in future research and clinical use. It is anticipated this will assist with the difficult process of unpicking the active mechanisms within the intervention during an evaluation study, with the importance of undertaking this careful development work recognised [30].

We also had the opportunity to test and refine developed intervention components with the end users. This stage is not included in the BCW but emerged as key to our development process. Involving users has been demonstrated to be the best predictor for ensuring research is translated into practice [31] and so in this study we endeavoured to maximise the acceptability of the intervention through collaborative working with users, i.e. stroke therapy teams. They reported that the developed toolkit components were inexpensive, acceptable to the therapy team, fitted well with current methods of documentation, and were practical for therapists and patients/families.

4. Building on my previous point regarding the methods used to conduct a behavioural analysis, it seems that the primary source of evidence used to develop the intervention is practitioners perceptions of 1) behaviours most amenable to change and 2) factors that would lead to behaviour change. In addition to providing
rationale for this point, the authors should also aim to provide the frequencies by which each behaviour and COM-B factor was nominated by therapists/intervention development group.

There is no consensus as to how the BCW should be applied, the authors have stated that it is new and work in progress (20). There is potentially a number of ways to integrate the use of BCW and this paper reports on one possible method of applying it. More detail has been added about these discussions and the behavioural analysis (see above). We disagree that frequencies are required, especially given the small numbers in our development group; this is the reviewer’s preference and not stipulated in the BCW.

5. One of the primary goals of the BCW is to ensure that intervention developers consider all intervention options before designing their intervention. When selecting modes of delivery, the authors state that the intervention development group brainstormed ideals relating to delivery of the techniques. This is not consistent with the BCW approach which would consider intervention developers to consider all options by using a taxonomy of delivery methods.

The fact that all methods of delivery were considered has been clarified in Methods, Stage 3:

The methods in stage three were less aligned with the Behaviour Change Wheel. It entailed a collaborative design exercise to identify intervention components, and was informed by the Behaviour Change Technique Taxonomy (v1) (BCTTv1) [23]. The aim of the BCTTv1 is to provide a reliable and systematic method of describing and categorising behaviour change techniques (BCTs) used in interventions. Employing consistent terminology to describe these techniques allows developers to identify the active ingredients of interventions, test these active ingredients and comprehensively describe interventions to facilitate replication in future research [24]. During the design exercise, the BCTTv1 [23] was used by the intervention development group to facilitate discussion around potential behaviour change techniques, and delivery methods, to ensure all options were considered. A description of what intervention components could look like was then drafted. The research team produced versions of the intervention components which were presented back to the therapists for additional feedback and refining.

6. The authors do not link their behavioural analysis (results of COM-B) to the intervention functions or policy categories within the BCW. This step should have been done before selecting BCTs or modes of delivery. The authors should take this step (even post-hoc) to determine whether the BCTs and modes of delivery are appropriate for their behavioural diagnosis, identification of intervention functions and policy categories. The paper as is does not seem to indicate the authors used this systematic approach.

The following paper and the guide provide good instruction as to how the authors should improve these steps and descriptions: Atkins, L., & Michie, S. (2013). Changing eating behaviour: What can we learn from behavioural science?
This was an iterative rather than linear process which made the reporting more difficult. We feel the re-structuring of the methods and the results, adding more detail regarding how the BCW was used and the revising of the figures and tables (as included above) should now make the links more clear.

7. The authors should provide further detail regarding the methods used to pilot the intervention and collect data from end-users. As written, the reader has no indication as to how this was completed nor what results would be expected from this step.

Some further information about the piloting methods and results have been added, which should be clearer with the re-structuring of these sections. We have clarified that this article focuses on the development methods and added information on future work.

From Methods section:

Stage 4: Piloting and refining of intervention components

Stage four represents the on-going reflexive cycle during which the developed intervention components were piloted and refined based on the experiences of the end-users. Between development meetings, the therapy team had the opportunity to test each of the intervention components designed in the real-life clinical setting for a few weeks. At each development meeting, feedback was obtained and discussed, and the reflexive cycle repeated.

Results

1. The authors state that structured discussions were used to ascertain the amount of upper limb exercise stroke survivors are doing. This is likely not a valid or reliable measure of behaviour. The authors should have a baseline measure of behaviour and should cite these results in their paper.

The challenges of capturing intensity in stroke rehabilitation are well known, and we have recently published on different methods (Connell et al, 2014). There is no valid or reliable measure of behaviour that is currently used in clinical practice, therefore structured discussions were appropriate.


2. The results section currently reads as a repetition of the methods section. I suggest the authors read previous papers that have applied the BCW to develop interventions, this will help to structure their findings. The results section should primarily focus on the results of the structured discussions (i.e. the behavioural diagnosis - key factors identified) and linking these intervention functions and policy categories. The results of the behavioural analysis (using COM-B) should be presented similar to findings qualitative interview research by identifying salient
factors and the frequency that these were mentioned or reported to be important by the group.

The Methods and Results sections have been revised and re-structured.

3. The authors need to identify how they systematically linked their behavioural diagnosis to intervention functions, policy categories, BCTs and modes of delivery that will be used in the intervention. Matrices for systematically linking each of these pieces of intervention development using the BCW are provided in the book Michie, S., Atkins, L., & West, R. (2014). The Behaviour Change Wheel: A Guide to Designing Interventions. Great Britain: Silverback Publishing. Once this long list has been produced, the authors need to outline why certain intervention functions, policy categories, BCTs and modes of delivery were seen to be inappropriate or appropriate by the intervention development team.

We have added detail as to how the BCW was applied (see above).

4. The description of the rationale pilot testing should be placed in the methods section. The results of the pilot testing and relate to specific methods (need to be outlined) should be placed in the results section.

Some further information about the piloting methods and results have been added, which should be clearer with the re-structuring of these sections.

From Results section:

**Stage 4: Piloting and refining of intervention components**

As the intervention components were drafted, they were pilot tested by the therapy team. Pilot testing allowed the group to establish whether or not the intervention impacted on the prioritised behaviours in the desired way, and also to establish in what way, if any, the intervention components could be refined and improved. Following piloting, all components stayed, but the format was often modified or refined. An example of this was the introduction of the “Front sheet” (see Additional File 1: The PRACTISE Toolkit). Originally the “Exercise Plan” was provided to patients as part of their PRACTISE Pack. However, feedback from therapists piloting the form suggested that it contained too much information and was too complicated for this purpose. The simpler “Front sheet” was developed to include the patient’s goal, the exercises they had been prescribed, the names of individuals willing to assist with the exercises and the date for review.

5. The authors should also avoid interpretation of the data in the results section. This information should be placed in the discussion. There seems to be several examples in the text where the authors need to carefully consider which section the information should be presented in. For example, the authors state ‘The toolkit components were inexpensive, acceptable to the therapy team, fitted well with current methods of documentation, and were practical for therapists and patients/families’. For this statement, the methods provide details as to how the
authors found this information/asked the questions. The results section should provide specific quantitative or qualitative findings that support this statement. The specific statement should likely remain in the discussion and should be discussed in further detail.

The Methods, Results and Discussion sections have been revised and re-structured.

6. The authors do not use terms consistent with the BCW to present their findings. For example, ‘intervention components’ is not an aspect of BCW and is specifically avoided by the BCW authors. The authors do not use the terms ‘behavioural analysis’ or ‘diagnosis’ even though they seek to conduct one. The authors also do not use the terms ‘intervention functions’ or ‘policy categories’. This needs to be corrected.

We have added detail as to how the BCW was applied (see above), and used terms more consistent with the BCW. We have discussed how we applied the BCW and where we found it more and less helpful.

1. The discussion needs to begin with a citable statement outlining the specific components of the intervention.

The Discussion now begins with:

This paper describes our experience of developing a complex behaviour change intervention that aims to increase upper limb repetitive task training in stroke rehabilitation units. The developed intervention is PRACTISE (Promoting Recovery of the Arm: Clinical Tools for Intensive Stroke Exercise). PRACTISE consists of team meetings and the PRACTISE Toolkit (a screening tool and upper limb exercise plan, PRACTISE exercise pack, and an audit tool).

2. The authors state that it is unclear when ‘enough is enough’ in terms of intervention development. I think the authors should review the current guide for applying the BCW. I think they will find this helpful for reporting their intervention and steps to intervention development.

Discussion revised (as above).

3. The authors should avoid discuss the limitations of the intervention (as it has yet to be tested) and rather focus on the strengths and limitations of using the BCW to develop their intervention. In particular, the challenges they faced in its application. Likewise the authors should comment on the intervention functions, policy categories, BCTs and modes of delivery that the BCW helped them to consider. In particular, how the BCW helped the intervention developers avoid creating an intervention that was not efficacious or acceptable to the target population.

Discussion revised (as above).

MINOR REVISIONS
1. Page 2: In the abstract, there is a bracket missing from the third stage of development.

Abstract revised.
Reviewer 3 comments:

I thank the author’s for writing an exceptional paper. It was a joy to read being well organized and ideas well-articulated. The topic area is of great importance in the rehabilitation science literature and particularly within stroke rehabilitation and upper limb recovery. In addition, the concepts examined in this manuscript are pioneering in this area of research and fundamental to the future development of efficacious and effective interventions for individuals with stroke.

This manuscript has a well-defined purpose and outlined the importance of it with a sound introduction. I have no concerns with the methods or interpretation of results. The discussion was link appropriately to the purpose, methods and results. It also provided pivotal points for future examination. I have no major concerns with this paper.

Minor Essential Revisions

1. There is a typo in the abstract, background section; see italics.

‘Two thirds of stroke survivors will achieve independent ambulation, but less than will half recover upper limb function.’

Should it read…..‘but less than half will recover upper limb function’?

This has been corrected.

2. The same issue is found in the Background section of the paper, page 3, paragraph 1 ‘…..but less than will half recover upper limb function at six months.’

This has been corrected.

There may have been a few other typos. Also just make sure that you have spelled out in full prior to using an acronym.
Reviewer 4 comments:

1. Is the question posed original, important and well defined?

The logic behind the development of the new BCI was not persuasive. The introduction appeared to lead to a different study from the one reported. The background to the paper indicates that there are evidence-based interventions such as GRASP that have been successful in promoting upper limb recovery and have been implemented rapidly into routine practice, but that the implementations lost key components of the BCI. The authors then argue that a new BCI should be developed which pays attention to changing the behaviour of health professionals during the process of development of the BCI. Why was the more logical approach not to investigate better methods of implementing a published successful intervention?

We have added in more detail in the background regarding the GRASP and the formative research on it’s implementation to date. The GRASP in itself was not a behaviour change intervention, that it was a package intervention translated directly from research to clinical practice without consideration for how the practices of HCPs need to change to facilitate the implementation of the intervention. Hence a BCI which facilitates the implementation of the mechanisms of action of GRASP is needed.

In Background:

Rehabilitation interventions tend to be complex interventions i.e. interventions comprising several components acting either independently or inter-dependently [16]. Successful implementation of complex interventions, such as GRASP or TRACS, relies on changing the behaviours of those responsible for their implementation [16]. However, consideration of behaviour change of healthcare professionals in the development and implementation of complex interventions has traditionally been given cursory attention. Fewer still formally test the feasibility of proposed interventions prior to evaluation [17]. Developing behaviour change interventions, which by definition are complex, is a growing field of enquiry but as yet there is no gold standard method reported within the literature. Guidance, such as the MRC framework for the development and evaluation of complex interventions [16], identifies the use of theory as a fundamental component of intervention development, but how theories should be used to inform methods is less clear.

In addition to the logic of the argument, in terms of both science and practice, surely we should be seeking to improve what has already been shown to be effective either by developing it further or by improving its implementation. For example, the intensive programme that is incorporated in the BCI developed might have been evaluated as a method for ensuring and maintaining implementation of an evidence-based BCI. Instead the authors appear to have started from scratch to develop something new. There was a brief mention of GRASP materials, but no indication of how they were used in the development process.

By adding detail to the introduction, we hope it is now clear that we tried to improve on an existing intervention rather than starting from scratch.
When describing the PRACTISE pack, it has been made clear that the exercises were based on those in the GRASP manual:

2b. A PRACTISE exercise pack: to enable therapists to efficiently communicate (verbally and in written format) the rationale for the exercise programme, the individual exercises (based on GRASP exercises, with written and pictorial instructions) to be completed by the patient, and to enable the therapist and the patient to monitor repetitions of exercises using an exercise diary.

It was not clear what readers should take from this study that might be applied elsewhere. The BCI was developed and they expect it to be maintained by a group specific to the locality. The rationale was that of optimising the ‘potential fit’ with the target context which implies that a different BCI would have to be developed and maintained in every new context.

By clarifying the focus is on the development methods, and the rationale that the behaviour change techniques will be standardised but the format can be changed, we feel this point has now been addressed.

2. Are the data sound and well controlled?

n/a

3. Is the interpretation (discussion and conclusion) well balanced and supported by the data?

The authors appear to think that the developed BCI might be applied elsewhere (with further assessment of generalizability) even though they specifically say the development was designed to ensure the implementation within the same context. The only barrier to wider implementation of the BCI that is envisaged is the need for a ‘highly motivated research team’.

Perhaps there is a confusion about whether the key point of this paper is about the development process or about the BCI which has been developed.

The focus is on the development methods and the re-structuring addresses this point.

4. Are the methods appropriate and well described, and are sufficient details provided to allow others to evaluate and/or replicate the work?

In Stage 1, the collaboration involved clinicians and researchers. Given the aim of having a BCI that would be faithfully implemented, should there not have been representation from the management of the clinics? As an extreme example, if the BCI developed had required additional time or other resources, managers might have been able to rule out impossible suggestions or propose alternatives.

In Stages 2 and 3, the use of COM-B and BCTTv1 are very appropriate, well-described and explained, successfully implemented and extremely well-reported. My
only reservation at these stages is that it is unclear how evidence of previous successful BCIs was incorporated.

In Stage 4, as the authors admit, it is not possible to assess whether fidelity of delivery could be attributed to the BCI development process as the continued monitoring by the development group probably functioned as a set of BCT e.g. defining a goal, monitoring, providing feedback. So it is doubtful if the embedded toolkit for assessing fidelity could actually function as a fidelity check without being a set of BCTs.

The methods and results have been re-structured (as above).

5. What are the strengths and weaknesses of the methods?

The strengths are the clarity of description of the process and the use of good methods in identifying target behaviours and components of the BCI. The weaknesses in the methods relate to the construction of the development group, apparently not using previous evidence and seeming to have developed a BCI which requires ongoing maintenance by the full development group. It seems likely that a different BCI (including those that have published evidence of effectiveness) might be effectively implemented and maintained by the monitoring and support process that the development group continue to provide.

The methods and results have been re-structured (as above).

6. Can the writing, organization, tables and figures be improved?

Tables etc. look good. In reporting BCTs it would be useful to include the number of the BCI in the BCTTv1.

Tables revised, with the number of the BCI added into Table 2.

7. Do the title and abstract accurately convey what has been found?

Both title and abstract are caught in the dilemma about whether the paper reports an implementable BCI, that might be implemented and investigated elsewhere or whether it is about a proposed method of developing interventions.

The title implies that the main thing the paper will deal with is increasing exercise in stroke rehabilitation. If that were the case then more evidence about previous successful BCIs would be necessary.

It is misleading to include in the title ‘measuring implementation fidelity’ as this is not ‘measured’ and could not really be assessed while the process was so heavily monitored by the development group.

Title and focus amended to clarify it is regarding the development process.