Design Approaches for a RCT Complex Intervention: A Stroke Rehabilitation Case Study

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Abstract
This paper discusses findings from the introduction and integration of qualitative design research methods into the overall methodology for the design and evaluation of a 'complex intervention' through a set of pilot random control trials. A visualisation tool was co-designed and developed with stakeholders to enhance patient-therapist interaction in the context of stroke rehabilitation. The participative approach recognised the importance of mobilising lay knowledge and experience to drive innovation in the tool whose use helped reduce the 'social distance' between therapist, patient and clinical biomechanist to: i) aid understanding for patients; ii) enhance communication between patient and therapist; and iii) provide an objective tool for therapists to monitor progress and communicate it to patients. The implications for the use of design methods in rehabilitation service design innovation is also discussed.

Keywords
RCT, physical rehabilitation, complex intervention, design innovation, visualisation

Introduction
This case study describes how qualitative design approaches were integrated into the overall methodology for the design and evaluation of a 'complex intervention' through a pilot random control trial (RCT) to understand how the use of an innovative visualisation method might improve physical rehabilitation therapy for patients following a stroke. It discusses the approach, methods, findings and implications for future healthcare and service design research.

Stroke and rehabilitation
Stroke, a ‘brain attack’ caused either by a blockage (ischaemia) and/or a bleed (haemorrhage) in or around the brain, is a life-changing occurrence affecting c.152,000 people each year in the UK. The effects of a stroke vary between individuals due to the complex nature of a brain injury, but common outcomes are: weakness or paralysis on one side of the body; loss of sensation on one side; difficulties in speaking or understanding; vision problems; and cognitive problems. The effects can be temporary or permanent, depending on the severity of stroke, and a period of personalised rehabilitation is required to address the particular needs of the stroke patient. Physical rehabilitation following stroke focuses on relearning control and coordination of movements which have been affected by damage to areas of the brain, and on ways to cope with everyday activities to compensate for losses in function.

Overcoming presentation issues with biomechanical information
For many physical rehabilitation issues a biomechanical understanding of the problem and its solution (i.e. in a living body, of the forces exerted during dynamic movement by muscles and gravity) is essential. Both patients' understanding of their treatment and
Effective communication with clinicians have been identified to have a positive impact on their compliance leading to a better chance of improved treatment outcomes. However, despite more than three decades of developments in the field, the potential for biomechanics to fully influence rehabilitation practice has remained under-exploited due to the problematic nature of communicating complex biomechanical data and analyses to other disciplines and to lay people, essentially due to the inaccessible format of presentation of this kind of data, i.e. in graphs and charts not usable by non-biomechanics specialists or by lay people.

**RCTs and complex interventions**

This paper discusses how design methods were incorporated into the design of a complex intervention evaluated within a RCT. An RCT is the ‘gold standard’ for a clinical trial, often used to test the efficacy of a medical intervention within a patient population. The Medical Research Council (MRC) framework categorises an intervention as complex if it involves: i) an intervention in individual patient care; ii) modifications to the service for the patient; and iii) will also provide an educational intervention and decision aid for health professionals (MRC, 2000; Craig et al, 2008). Clinical metrics for RCTs are usually quantitative, however Lewin et al (2009) discuss the limitations of these methods: “Complex healthcare interventions involve social processes that can be difficult to explore using quantitative methods alone." “Qualitative research can support the design of interventions and improve understanding of the mechanisms and effects of complex healthcare interventions”. “Most of the qualitative studies were carried out before or during the trials with few studies used to explain trial results.”

Qualitative research within a RCT is still relatively uncommon and the examples published to date have largely been poorly integrated (Lewin et al, 2009).

**The physical rehabilitation setting: contrasting concerns**

There is a need to consider the needs of each of the three different stakeholders in the stroke rehabilitation setting (i.e. clinical biomechanist, therapist and patient, although ‘carer’ is a further category outside the scope of this immediate study). Viewed from a biomechanist’s perspective, a rehabilitation session is about gaining a detailed understanding of the dynamic forces exerted by muscles and gravity during movement as a means to improving the quality of treatment, and ultimately the healthcare outcome. The therapist, by contrast, is concerned with assisting the patient in a programme of movement exercises which help in the ‘neuroplastic’ reshaping of the brain’s functions, damaged by the stroke. Finally, the patient is concerned with recovering their ‘normal (i.e. former) self’. Consequently, this rehabilitation setting becomes a theatre for intensively social and emotional processes involving physical contact and a two-way process, between the therapist and patient, of communication and understanding (whether poor or clear), of what movements should be made (and why), and in perceiving progress (or lack of) being achieved. During this the patient experiences the full gamut of emotions, from hopes and aspirations to disappointments and frustrations. In fact, the emotional impact of stroke can be just as profound as the physical effects (Stroke Association, 2013). Previously, there have been limited means to objectively mediate and enhance the therapist–patient relationship in this setting: current means are verbal, mirrors, video recordings, charts and diagrams. These do little to diminish the ‘social distance’ (Greger and Hatami, 2013) between the groups (see figure 1) and also disenfranchise the often-overwhelmed patient. The hierarchical nature of healthcare research, e.g., between a clinician, a physiotherapist and their patients, has also traditional defined the agenda, the decision-making processes, determined priorities, ultimately influencing the model of research, and the kinds of data and evidence emerging on which a resulting therapeutic intervention would be based. This then leads to a question whether this reflects the reality of the complex rehabilitation scenario described above and would be sufficient to achieve a realistically workable intervention in the practice setting.
Figure 1. The clinician, therapist and patient are brought together in the stroke rehabilitation setting. However, the means to engage in discussion of vital issues through common language and points of reference is absent (left). The visual tool described here enables the ‘social distance’ between these three groups to be reduced providing a more accessible shared visual language (right).

Opportunities for design research methods?

There are a number of issues where design approaches might have some value in this particular context. Due not only to i) the intensively ‘social’ nature of the stroke rehabilitation session (i.e. the patient/therapist communication and interaction) but also to ii) its ‘technical’ nature (i.e. concerned with qualities of movements of ‘body segments’ such as limbs, hips, shoulders etc), the appropriateness of the design of the visual tool to be used to assist in patient/therapist engagement and interaction strongly suggests that, if these are to be understandable to and usable by patients and therapists as end-users of the visualisation tool, that they are involved, to a greater or lesser extent, in its design.

Previous work by the authors had developed and evaluated a visualisation method which appeared to overcome the difficulties of access to biomechanical data by lay and non-biomechanist professionals (Loudon, Carse and Macdonald, 2011; Loudon et al, 2012) through early engagement of potential end-users. The envisage (2014) project, described here, enabled the further design and development of this visual tool for use by patients, therapists and clinicians in the context of stroke rehabilitation. Using a participative co-development process, the design development of this visualisation tool for use in the intervention arm of a set of three pilot stroke RCTs was enhanced through the involvement of each of these stakeholder groups in an iterative process of design and feedback. This process also integrated a set of qualitative methods to address the issues raised by Lewin et al (2009) above throughout the four phases of each trial.

Research approach

The bringing together of the visuals development, the participative co-design process and qualitative methods framework into the design of the trial and their integration into the overall methodology for the ‘envisage’ project is now discussed in more detail and are summarised in Table 1.

Methodology: rationale

Although the RCT offers a rigorous research method for determining whether or not a cause-effect relationship exists between a treatment and its outcomes (Sibbald and Roland, 1998) the quantitative outcome measures to be used by the clinical leads in the
trials (i.e. the measurement of the patient's ability to improve the performance of certain movements and exercises) would not alone provide any explanation of which aspects of the visualisation software were successful and which were not. Therefore, in response to Lewin et al (2009), our approach to the RCT design methodology was to introduce an over-arching mixed methods qualitative framework into the RCT to: i) test our hypothesis that 'visualisation of biomechanical data will enhance health and rehabilitative healthcare by mediating between users, clinicians and healthcare practitioners', and ii) help in developing a complementary understanding to that obtained through the quantitative outcome measures of patients made by the trials' clinical leads (e.g., the measurement of the patient's ability to improve the performance of certain movements and exercises, such as increasing speed and symmetry of walking, or the quality of arm and hand movements and reach).

Table 1: trials structure: main phases, methods, PPI strategies (see Table 2), and visualisations development for each phase.

<table>
<thead>
<tr>
<th>Trials phase</th>
<th>PPI Strategy</th>
<th>Qualitative methods</th>
<th>Visualisations development</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Design</td>
<td>n/a C B B, C</td>
<td>- scoping review of literature (SR)</td>
<td>- initial selection of visualisation options</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- survivors' focus group (FG1)</td>
<td>- initial selection of visualisation options</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- professionals' focus group (FG2)</td>
<td>- iterative bespoke visualisations development for each trial</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- testing and feedback sessions of prototypes with user groups (TF)</td>
<td></td>
</tr>
<tr>
<td>2. Pre-trial</td>
<td>B A A B C C</td>
<td>- trials leads meetings (TL)</td>
<td>- iterative bespoke visualisations development for each trial throughout pre-trial phase</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- trials patients' questionnaires</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- trials patient' interviews (PA1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- trials health professionals' interviews (PR1)</td>
<td></td>
</tr>
<tr>
<td>3. Trial</td>
<td>B A B B C C</td>
<td>- observation / video (OV')</td>
<td>- adjustments made as a result of trials</td>
</tr>
<tr>
<td>4. Post-trial</td>
<td>A B A A C C</td>
<td>- trials patients' interviews (PA2)</td>
<td>- verification of findings from design and pre-trials phases plus options for future developments posed at FG3+FG4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- trials health professionals' interviews (PR2)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>- trials patients' focus group (FG3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- trials health professionals' focus group (FG4)</td>
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</table>

**Patient and public involvement (PPI)**

The importance of mobilising lay knowledge and experience has long been recognised in design as a driver of innovation. Although the prototype visual method had been developed and evaluated in previous studies, this would require further development for its particular application and use in the three different stroke pilot RCTs. To help us consider different approaches to patient and public involvement (PPI) Savory’s (2010) framework was helpful as it sets out a series of four ‘ideal strategies’ for ‘incorporating PPI into the wider process of translative healthcare research involving technological innovation’ (Table 2). This framework helps contrast different approaches amongst the research team. Whereas the trials' leads approached the research using predominantly strategy A to acquire quantitative data, the involvement of the design team used strategies A through C for the collection of its qualitative data and for its participative co-design process.
Table 2. Summary of Savory’s (2010) four ‘ideal strategies A to D for patient and public involvement (PPI).

<table>
<thead>
<tr>
<th>PPI Strategy</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>collecting patient data represents PPI strategies that focus on the participation of patients with the primary purpose of collecting data</td>
</tr>
<tr>
<td>B</td>
<td>patient and public consultation research represents a broader based PPI strategy involving data collection from a wider range of stakeholders</td>
</tr>
<tr>
<td>C</td>
<td>patient-led represents a strategy where the mode of patient involvement is complex with them being involved in the design, conduct and even analysis of the research</td>
</tr>
<tr>
<td>D</td>
<td>public involvement and education concerned with widespread public-involvement in translative research</td>
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</table>

**A mix of methods**

The three stroke trials to receive the visual intervention were i) upper limb; ii) lower limb; and iii) ankle foot orthosis tuning (AFO - a brace can be used to minimise abnormal gait patterns following stroke, including preventing ‘foot drop’ during walking). A mix of methods involving focus groups, workshops, interviews and observations was used to obtain feedback during the iterative development on the visualisation tools, to understand how these could be improved in terms of their function and appropriateness in the rehabilitation context, acknowledging the experiences and opinions of those who had either undergone stroke rehabilitation (survivors and current patients) or been involved in delivering rehabilitation (therapists and clinicians) and also to incorporate the clinical trials leads' requirements for certain types of information (e.g. walking speed, step length, gait symmetry, and shank angle at during the walking cycle) to be shown visually.

**Qualitative data**

There were two inter-related aspects to the qualitative data collected (i.e. interviews, questionnaires and observations). The first related to ideas and feedback useful to the forward development of the visual tools, i.e. in relation to patients’, therapists’ and trials leads' needs and expectations, and also in relationship to the context in which these were to be used, i.e. their role in the programme of rehabilitation therapy and their part in mediating and enhancing the therapist-patient relationship. The second related to understanding the potential effect of the use of the visualisations during the rehabilitation process in improving the experience and outcome for both patient and therapist.

**Development of visualisation tools and their interfaces**

Using as a basis the experience of developing the prototype in prior studies, a process of iterative development engaged survivors, therapists and trials leads. For the therapists and clinicians involved in each of the separate trials, the interfaces for the visual tools were also developed to allow them to select appropriate features, views, overlays and files for discussion with patients, to the point where these were ready for use in each of the three trials.
The Trials

**Design phase**
In the design phase 1, and following a scoping review of relevant literature, a variety of visualisation options were prepared for discussion, in FG1 (survivors, n=7) and FG2 (professionals, n=5) to: i) assist the researchers’ understanding of the appropriate avenues for further development; and ii) explore survivors’ and therapists’ issues within current rehabilitation care. Early analysis of this work is discussed in Loudon and Macdonald (2012). Analysis of responses to the phase 1 visualisations in FG1 and FG2 also provided the basis for the methodological framework to be used in the later analysis of the qualitative post-trial data.

**Pre-trial phase**
This phase explored patients’ pre-trial understanding of goal setting, motivation and their expectations of their rehabilitation. On the therapist side, occupational therapists (OTs) or physiotherapists (PTs) recruited to trials were interviewed (n=16) to explore their experiences of current stroke rehabilitation, the potential role and use of the visualisation intervention in the rehabilitation session and the potential use and integration of the intervention into clinical practice. Each trial lead (n=3) worked with the visualisations and software designer to develop and refine the visualisation tools and their interfaces for their specific trial.

**Trials phase**
During the trials themselves, video recorded observations (n=57 visual, 32 non-visual) were made of patients and therapists using the visualisation tools (figure 2) during real time rehabilitation sessions.

![Figure 2](image-url)

Figure 2. Examples of the three visualisation tools used in the three stroke trials (left to right): knee lift exercise visualisation in lower limb rehabilitation showing graded colour coded target; reach and grasp visualisation in upper limb rehabilitation including hand controlled by motion sensors; shank angle visualisation to evaluate tuning of an Ankle Foot Orthosis showing simple colour coded good/ok/bad ranges.

**Post-trials phase**
Patient post-trial interviews from across the three trials (n=12) and two separate post-trial focus groups of those involved in the trials, FG3 (patients, n=5) and FG4 (professionals, n=3) were used to elicit a range of views and experiences of using the visualisations and of being involved in the trials, as well as for exploring some potential future scenarios taking advantage of recent developments in the technologies involved, from both the patients’ and therapists’ perspectives.
**Findings**

The scope and intention of this paper does not provide space for a full description and discussion of the methodological framework for the analysis of the data or for detailed findings and limitations of the study to be included here (these can be found at envisage, 2014) but, in summary, the findings are:

- **Understanding**: the visualisation of the patient's own motion provided an aid to their understanding of their movement problems and the purpose of their rehabilitation tasks
- **Communication**: the visual representation of the movement and the overlay of specific measures relevant to their rehabilitation provided a medium for improved communication between the patient and the therapist
- **Progress**: the combination of quantitative measurement and clear visual representation of the measures provided an objective tool for therapists to monitor progress and communicate it to patients

**Discussion**

Including designers as part of the RCT team is unusual. A number of questions arise. What were the effects and benefits of bringing designers into the RCT research team? What kind of progress was made in addressing issues raised by Lewin et al (2009), i.e. the designers’ contribution to the approach and type of mixed methods introduced into this RCT? What value for design research arises from this case study?

**Reducing the social distance at the site of rehabilitation**

Although the design process was led by the designers in this case, the achievement in the design of the visualisations acknowledges that ‘design is a collaborative effort where the design process is spread among diverse participating stakeholders and competences’ (Björgvinsson, Ehn and Hillgren, 2012). Unlike the traditional approach to designing an RCT intervention, this participative approach ensured that everyone was ‘on the same page’, flattening traditional top-down hierarchical approaches and decision-making, allowing input from key stakeholders involved in the processes of both delivering and benefiting from rehabilitation through understanding who needs to know what at each stage, and why. By providing objective information, the visualisation tools were seen to enhance communication and understanding between the therapist and the stroke survivor in trials, while simultaneously enabling the trials leads’ (biomechanists) contributions to be much more accessible and understandable.

Due to their co-designed nature, these visualisations helped reduce the ‘social distance’ (Greger and Hatami, 2013) between trial lead, therapist and patient, mediating and changing the nature of the conversation during physical therapy sessions.

‘Aye, cause if you didnae [didn’t] have visuals and they were just saying to you “well this is what you are doing blah, blah blah”, me telling you what you are doing wrong “blah, blah, blah”, but you are not taking it in. You don’t understand what they are saying until you actually see it and then the conversation changes “oh right so I’m doing that and doing this”. … the conversation does change when you’ve got the visuals.’ (female stroke patient, lower limb trial, post-trial patient focus group)

‘I took the time to, you know, play back recordings and talk through exactly what I was seeing and what we were going to work towards and talk a bit about sort of normal movement...we would play back something then I'd say... “you're not stretching your elbow out as far as it can go, and you're bending your wrist in, so what I want you to concentrate the next time we do this is trying to open this elbow up as much as you can and trying to bend your wrist back a little bit,” so I think I was explaining more to
her why I was doing what I was doing and what I wanted her to focus on, and I think that really helped.’ (occupational therapist, upper limb trial, post-trial professional interview)

**An improved evidence base for the design of healthcare tools and services**

Whereas the clinical trials leads were predominantly interested in the quantitative outcome measures within their trials design, the designers were interested in understanding the therapists’ and patients’ needs, preferences and experiences, i.e. through capturing qualitative data, throughout the four phases of the trials. These data were used in two primary ways. Firstly, they aided the design of the intervention (i.e. the visualisation tool) by helping the designers understand what would assist the communication and understanding of various physical rehabilitation movements and of patients’ progress. In doing so the visualisation tools we tried to make the tools more accessible to the three main stakeholder groups concurrently, i.e. patients, therapists and clinicians. Secondly, these data were analysed to evaluate the effectiveness of the tools in improving communication and understanding (e.g. of correct movement and progress) during the rehabilitation sessions. This qualitative data provides an enhanced evidence base not only to support the design of the intervention but also to explain, from the analysis of the post-trials interviews PA2 and PR2, some of the findings from its use, summarised above.

RCTs are regarded as the ‘gold standard’ for research, and the evidence-base they generate often forms the basis for new treatment plans. However, using people’s experiences as the basis for co-designing, improving and innovating in healthcare service delivery has some significant precedents, e.g., in the work of Bate and Robert (2007) and those mentioned by Hampson, Baeck and Langford (2013).

**The contribution of design researchers**

This is difficult territory for designers. There is a paucity of reporting, by design researchers, of their work and contribution within mixed discipline healthcare research. Designers can be involved but are usually ‘outside’ the team. In this particular case, without the inclusion of designers as part of the team, there would have been little or no acquisition of qualitative data to supplement and explain some of the findings arising from the more usual quantitative data.

Whatever their recognised strengths, RCTs are necessarily reductionist in nature and do not mirror the real world context. The designers tried to develop, as far as they could within the confines of the opportunity afforded by the RCTs, a broader understanding of the nature of the context, i.e. the rehabilitation setting’s social as well as its technical nature. As Wells et al (2012) state: ‘Instead of trying to test the efficacy of an intervention under ideal, experimental conditions, pragmatic trials are designed to find out how effective a treatment actually is in routine, everyday practice’. This may have been one of the designers’ contributions here – to shift the RCT design more towards the pragmatics of the real world context.

**Implications for future healthcare service research and design**

The consequences of this shift led to extended design and pre-trial phases suggesting that factoring in additional time for people-centred participative co-design and co-development processes for developing a complex intervention may enhance understanding within research teams of the most appropriate and productive avenues for enquiry and development in advance of the trials phase. This may provide a better quality evidence base for the subsequent design of healthcare tools and services.
Although an understanding of problematic issues arising from current therapeutic rehabilitation practice is important, rather than solely dwelling on the status quo, designers are in the business of anticipating and giving shape to the future. Our work was essentially a process of prototyping involving all the stakeholders from the outset. The findings from the experiences of the development and trialling of these prototype visualisation tools as interventions in the above RCTs has provided us with glimpses of how physical rehabilitation, for stroke survivors, might be better experienced and delivered, the professional role of therapists might be better supported in delivering this service, and the expertise of biomechanists might be better deployed in this context. Through the involvement of and engagement with all relevant stakeholders, we, as designers, can assemble and give form to these glimpses to become what Simon (1996) referred to as ‘preferred futures’ allowing us to re-imagine the design and delivery of healthcare.

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David Loudon (MEng Hons, PhD) is an information visualisation researcher with main research interests in the design of visualisations for the communication of complex data, and user-centred methods for their evaluation. He has worked on a number of RCUK projects applying visualisation within healthcare contexts, including visualising motion capture data during stroke therapy, and investigating the potential of visualising the pathogens responsible for Hospital Associated Infections.

**Anne Taylor**
Anne Taylor (RGN, BSc Hons, PhD) is an experienced qualitative health service researcher who has been involved in many projects focussing on patients’ experiences of illness, improving patients and their families’ experiences of care and improving the range of clinical services they can access. She is currently working as the qualitative researcher on a large UK Randomised Control Trial focussing on woman’s health with a process evaluation embedded within it.