

A design-led complex intervention for the stroke rehabilitation service

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Abstract

This paper discusses findings from the introduction and integration of design-led qualitative, research methods into the overall scientific methodology for the design and evaluation of a ‘complex intervention’ through a set of pilot random control trials (RCTs). A set of visualisation tools was co-developed with stakeholders to enhance patient-therapist interaction in the context of the stroke rehabilitation setting. The participative approach recognised the importance of mobilising lay knowledge and experience to drive innovation in the tools whose use helped reduce the ‘social distance’ between therapist, patient and clinical biomechanist. The visualisations aided understanding for patients, enhanced communication between patient and therapist, and provided an objective tool for therapists to monitor progress and communicate this to patients. The implications for service improvement and redesign resulting from involving designers in pilot RCT design are discussed.

KEYWORDS: RCT, physical rehabilitation, complex intervention, design approaches, visualisation

Introduction

This case study describes how design-led qualitative approaches were introduced and integrated into the overall scientific methodology for the design and evaluation of a ‘complex intervention’ through a set of pilot random control trials (RCTs) designed to understand how the use of an innovative visualisation method (Envisage, 2013) might offer improved physical rehabilitation therapy for patients following stroke. It discusses the rationale, methods, findings and implications for future involvement of designers in healthcare and service improvement and redesign, and for research in the field.

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 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 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 (i.e. in a living body, of the forces exerted during dynamic movement by muscles and gravity) of the problem and its solution is essential. Both patients’ understanding of their treatment and the effective communication with their 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. This is due to the problematic nature of communicating complex biomechanical data and analyses to other disciplines and to lay people, essentially due to the inaccessible formats of presentation of this kind of data, i.e. in graphs and charts unusable by non-biomechanics specialists or by lay people.

RCTs and complex interventions

This paper discusses how design methods and approaches were incorporated into the design of a complex intervention evaluated within a set of pilot RCTs. 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 this 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. (Lewin et al. 2009, p. 732)

Qualitative research within an RCT is still relatively uncommon and the examples published to date have been poorly integrated into RCTs (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 the patient's muscles and gravity during movement as a means to improving the quality of treatment, and ultimately the healthcare outcome. The therapist 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. The patient is concerned with recovering, to as great an extent as possible, 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 - through objective measurement - of 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, 2014). Current means to objectively mediate and enhance the therapist-patient relationship in this setting are limited: verbal, mirrors, video recordings, charts and diagrams. These inadequate means perpetuate the 'social distance' (Greger & Hatami, 2013) between the groups (see figure 1) and also disenfranchise the often-overwhelmed patient.

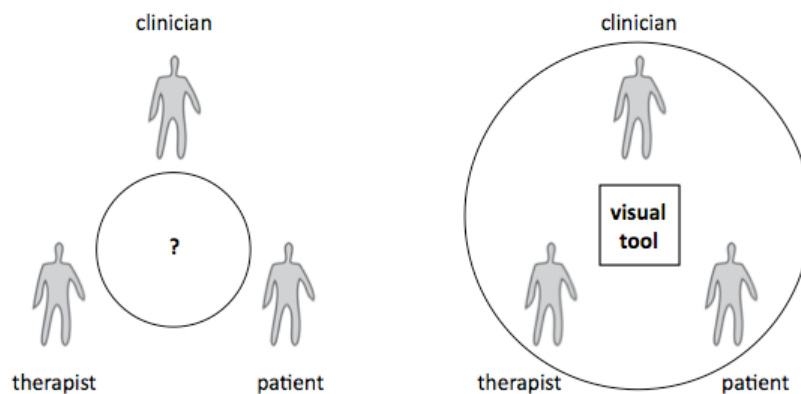


Figure 1. Clinician, therapist and patient are brought together in the stroke rehabilitation setting. However, the means to engage in meaningful discussion of vital issues through common language and points of reference are currently inadequate (left). The visual tool described here enables the 'social distance' between these three groups to be reduced to enable a shared, more equitable discourse (right).

The traditional hierarchical nature in healthcare research, e.g., between a clinician, a physiotherapist and their patients, has also 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 about whose agendas are being acknowledged and whether these would be sufficient to achieve a realistically workable intervention in the real practice setting. It also leads to questions of if, and in what ways, design-led approaches and methods could help address some of the issues outlined above.

Methodology

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 & Roland, 1998) the quantitative outcome measures (i.e. the measurement of the patient's ability to improve the performance of certain movements and exercises) to be used by the clinical leads in the trials would not alone provide any explanation of which aspects of the visualisation tools 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 design-led mixed methods qualitative framework into the RCT. This would test our hypothesis that *'visualisation of biomechanical data will enhance health and rehabilitative healthcare by mediating between users, clinicians and healthcare practitioners'*. It would also help in developing a complementary understanding to that obtained through the quantitative outcome measures (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) acquired by the trials' clinical leads.

The design-led rationale

There are two principal types of contribution where design-led approaches may have some value in this particular context. The stroke rehabilitation session is not only 'technical' in nature (i.e. concerned with qualities and angles of movements of 'body segments' such as limbs, hips, shoulders etc), but it is also conducted in an intensively 'social' context (i.e. concerned with patient-therapist communication, understanding and interaction). The first opportunity is to assist the team (clinicians and therapists) in understanding the inter-dependence of these two distinct but complementary aspects of the rehabilitation session. Prior, the emphasis had almost exclusively been on the technical aspects without a regard for the real-life (i.e. non-trial) contextual setting (Hempe et al., 2010). This would require creating the conditions for, and the acquisition and presentation of, new kinds of evidence regarding the 'social' dimensions. Secondly, if visualisation tools are to be used to assist in patient-therapist engagement and interaction, and are to be understandable to and usable by patients and therapists as end-users, this demands that they would be involved, to a greater or lesser extent, in its design, requiring a participative co-development and iterative prototyping approach.

Patient and public involvement (PPI)

A prototype visual method had been developed and evaluated in previous studies (Loudon, et al., 2011; Loudon et al., 2012). This would require further development for its particular application and use in the three different stroke pilot RCTs in the 'envisage' (2013) project. Using a participative co-development process, the design of this visualisation tool for use in the intervention arm of a set of three stroke pilot RCTs was enhanced through the involvement of each of the stakeholder groups in an iterative process of design and evaluation 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. To help us consider different approaches to patient and public involvement (PPI) Savory's (2010) framework is 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 1). This framework helps contrast different approaches amongst the research team. Whereas the trials' leads (biomechanists) 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-development process.

Table 1. Four idealised strategies for patient and public involvement (PPI) adapted from Savory, C. (2010). Patient and public involvement in translative healthcare research. *Clinical Governance: An International Journal*, 15(3) pp. 195–197

PPI Strategy		
A	collecting patient data	<i>represents PPI strategies that focus on the participation of patients with the primary purpose of collecting data</i>
B	patient and public consultation research	<i>represents a broader based PPI strategy involving data collection from a wider range of stakeholders</i>
C	patient-led	<i>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</i>
D	public involvement and education	<i>concerned with widespread public-involvement in translative research</i>

Table 2: The envisage project trials structure: main phases, methods and PPI strategies (see Table 1).

Trials phase	PPI Strategy	Qualitative methods	Visualisations development
1. Design	n/a C B B, C	- <i>scoping review of literature</i> - <i>survivors' focus group</i> - <i>professionals' focus group</i> - <i>testing and feedback sessions of prototypes with user groups</i>	- <i>initial selection of visualisation options</i> - <i>initial selection of visualisation options</i> - <i>iterative bespoke visualisations development for each trial</i>
2. Pre-trial	B A A B	- <i>trials leads meetings</i> - <i>trials patients' questionnaires</i> - <i>trials patient' interviews</i> - <i>trials health professionals' interviews</i>	- <i>iterative bespoke visualisations development for each trial throughout pre-trial phase</i>
3. Trial	B	- <i>observation / video</i>	- <i>adjustments made as a result of trials</i>
4. Post-trial	A B C C	- <i>trials patients' interviews</i> - <i>trials health professionals' interviews</i> - <i>trials patients' focus group</i> - <i>trials health professionals' focus group</i>	- <i>verification of findings from design and pre-trials phases plus options for future developments posed at stage 4 focus groups</i>

Introducing and integrating mixed 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 used to minimise abnormal gait patterns following stroke, including prevention of 'foot drop' during walking). A mix of methods (Table 2) involving focus groups, workshops, interviews and observations was used to obtain feedback during the iterative development on the visualisation tools. How these methods corresponded to each of Savory's (2010) PPI strategies is also indicated. These would enhance understanding of how the tools 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 who

had been involved in delivering rehabilitation (therapists and clinicians). They would also help incorporate the clinical trials leads' requirements for certain types of information (e.g. walking speed, step length, gait symmetry, and shank angle at mid stance) to be shown visually to assist both the therapist and patient.

Qualitative data

There were two inter-related aspects to the qualitative data (i.e. interviews, questionnaires and observations) collected. 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 rehabilitation therapy service 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 of the service 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 the process of iterative co-development, summarised in Table 2, 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. Figure 2 shows examples of the 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 (green)/ok (orange)/bad (red) ranges.

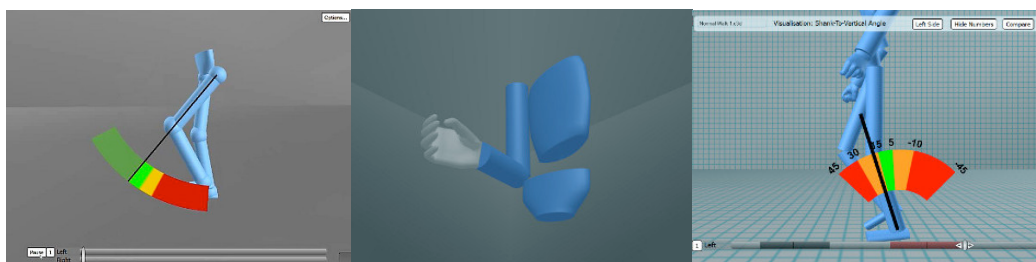


Figure 2. Examples of the visualisation tools used in the three stroke trials

Findings

The scope and intention of this paper does not provide space for a full discussion of the analysis of the data, detailed findings and the limitations of the study to be included here (these can be found at Envisage (2013)). 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

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) contribution to be much more accessible and understandable.

Discussion

This is difficult territory for designers. Including designers in the team for the design, delivery and evaluation of an RCT trial, where their competences are not generally understood, is unusual. There is a paucity of reporting, by design researchers, of their work and their contributions within mixed discipline healthcare research (as distinct from discussions of 'designing' by non-design disciplines). For example, Freire & Sangiorgi (2010) discuss innovation strategies in the healthcare context both from within and outside the NHS, discussing methodologies and service outcomes from each of four healthcare-related case studies: however, none of these describe innovation within RCT design. A number of questions arise. What were the effects and benefits of including designers in 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 introducing mixed methods into the RCTs? What value for the field of Service Design arises from this study? The implications for designers' potential contribution to healthcare service improvement and re-design are now discussed.

Infrastructuring for open innovation

The importance of mobilising lay knowledge and experience has long been recognised in design as a driver of "open innovation" through working with "multiple sources of ideas" (Cottam & Leadbeater, 2004). Using people's experiences as the basis for co-designing healthcare services has some significant exemplars, such as in the work of Bate and Robert (2007) and those mentioned by NESTA (2013). "This placing of the user of a service or a product at the very heart of the design process has become today's *grande idée* in the design industry professions" (Bate & Robert, 2007, p. 42).

The prototype visualisation tools themselves served to change the social dynamics between the key stakeholders while at one and the same time embodying and manifesting the stakeholders' separate and individual requirements through subsequent iterations of the tools' features. They also provided a prototype experience, i.e. "something real that people can interact with" (Winhall, 2011, p. 136), offering everyone a preview of potential future service provision, with the post-trial phase interviews and focus groups providing the space to reflect on their experiences of using the prototypes.

AS a consequence, the various iterations of the visualisation tool prototypes together with the participative co-development process and its activities provided appropriate "infrastructuring" (Bjögvinsson et al., 2012, p. 102) to enable a "greater proportional symmetry" (Strickfaden & Devlieger, 2011, p. 208) to develop between key players,

confronting traditional hierarchies, flattening decision-making and empowering all stakeholders. Thus, they helped reduce the “social distance” (Greger & Hatami, 2013, pp. 127-129) between trial lead, therapist and patient, mediating and changing the dynamics and nature of the conversation during physical therapy sessions. For example:

Aye, cause if you didnae have visuals and they were just saying to you “well this is what you are doing blab, blab blab”, me telling you what you are doing wrong “blab, blab, blab”, 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”. So it does... 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)

RCTs are regarded as the ‘gold standard’ for research, and the evidence-base they generate often forms the basis for new treatment plans. However, creating space for the focus groups and interviews in the various phases of the RCT provided a more level playing field enabling fragments of patients’ and therapists’ narratives to begin to emerge, informing the design of the visualisation tools, and developing a sense of the patients’ (and therapists’) experiences. Without claiming this process as “directed storytelling” as defined by (Evenson, 2011, p. 69) these are narratives that can none-the-less help inform the future shape of the service through creating what Evenson (2011, p. 69) terms “empathetic connections” through the elicitation and presentation of new types of evidence not normally acquired in this type of RCT.

Conclusions

Whatever their recognised strengths, RCTs are necessarily reductionist in nature and do not mirror the real world context. 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 an awareness of, and simulation of, the pragmatics of the real world context and to understand, acknowledge and allow for the dynamics, narratives and behaviours in that setting. To achieve this, the design-led approaches facilitated the introduction and integration of mixed methods approaches into the design of the pilot RCTs. An enhanced awareness of the social dynamic between therapist and patient in the rehab setting was developed (through the qualitative data) as well as a view into the patients’ and therapists’ experiences. The innovative visual tools themselves provided a more objective means of communicating progress, and developing understanding and enhancing communication. As a consequence, new (to this type of rehabilitation RCT) kinds of evidence were presented which may assist in catalysing “culture change through influencing organisational behaviours” (Heapy, cited in Meroni & Sangiorgi, 2011, p.232).

Implications for future healthcare service research and design

Implications for the shape of the future stroke rehabilitation service model informed by the collective analysis of all the qualitative and quantitative data acquired from these RCTs are yet to be determined. At this stage the work described in this paper cannot yet be described as service design *per se*, as only one potentially improved facet of a total rehabilitation service was being explored. However, within the structure of an RCT this work has documented the collaborative development of a ‘complex intervention’ using design-led approaches to introduce social and qualitative methods and processes together with an inter-related and iterative prototyping process. This work has utilised experience-based methods (e.g. survivors’ experiences of surviving stroke, their rehabilitation journey, their preferred modes of on-screen depiction of themselves, within real therapy sessions, settings and situations). The approaches and tools also disrupted current hierarchies and behaviours providing the precursors for a service delivery rethink. The consequences of this approach led to extended design and pre-trial phases suggesting either: i) the factoring in of additional time within an RCT for people-centred participative co-development processes or ii) that the development of an intervention is completed in a prior study. The disadvantage of the latter may be the loss of the iterative reflective stages and a reversion to traditional ‘RTC mode’ thinking.

Through enabling the involvement of and engagement with all relevant stakeholders, designers can create the spaces, situations, methods and tools to help assemble and give form to these glimpses to move towards what Simon (1996) referred to as “preferred futures” allowing us to help others to begin to re-imagine the design and delivery of healthcare, and to provide the evidence to justify and support innovative approaches to healthcare service delivery. Freire & Sangiorgi’s model (2010, p.46) needs to be extended further to discuss the type of work discussed here, as neither the patient-centred nor the patient-led category is sufficient: one has also to acknowledge equally the needs and contributions of the therapist, the clinician, and the carer, i.e. a multi-stakeholder-centred philosophy based on the ‘community’ and its real-life context to enable the co-creation and innovation required to help deliver improved services.

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