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Head-Up; an interdisciplinary, participatory and co-design process informing the development of a novel head and neck support for people living with progressive neck muscle weakness

Heath Reed[1], Joe Langley PhD[1], Andy Stanton[1], Nicola Heron PhD[2,3], Zoe Clarke[2,4], Simon Judge[2,4], Avril McCarthy PhD[2,3,8] Gill Squire[5], Ann Quinn[6], Oliver Wells[7], Wendy Tindale PhD[2,3], Susan Baxter PhD[8], Pamela J Shaw[5] , Christopher J McDermott PhD[5]

[1]Lab4Living, Sheffield Hallam University, Sheffield, UK
[2]National Institute for Health Research Devices for Dignity Healthcare Technology Cooperative
[3]Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, UK
Sheffield, UK
[4]Barnsley NHS Foundation Trust, Barnsley, UK
[5]Sheffield Institute for Translational Neuroscience, University of Sheffield, UK
[6]South Yorkshire Motor Neurone Disease Association, Sheffield, UK
[7]Devices for Dignity Ltd
[8]School of Health and Related Research, University of Sheffield, Sheffield, UK

	Name	Affiliation	Postal address	Tel / fax	e-mail
1	Heath Reed1	Sheffield Hallam University	Cantor Building, 153 Arundel Street, Sheffield, S1 2NU, UK	0114 225 6759 / 6702	heath.reed@dfgroup.co.uk
	Joe Langley PhD1				acesjl1@exchange.shu.ac.uk
	Andy Stanton1				acesas6@exchange.shu.ac.uk
2	Nicola Heron PhD2,3	National Institute for Health Research Devices for Dignity Healthcare Technology Cooperative	I Floor, Suite 100 Sheffield Teaching Hospitals Foundation Trust, Royal Hallamshire Hospital, Glossop Road, Sheffield. S10 2JF, UK	0114 271373 7	Nicola.Heron@sth.nhs.uk
	Zoe Clarke2,4				z.clarke@nhs.net
	Simon Judge2,4				simon.judge@nhs.net
	Avril McCarthy PhD2,3,8				Avril.McCarthy@sth.nhs.uk
	Wendy Tindale PhD 2,3				Wendy.Tindale@sth.nhs.uk
5	Gill Squire5	Sheffield Institute for Translational Neuroscience (SITraN)	University of Sheffield 385A Glossop Road SHEFFIELD S10 2HQ, UK	079145 36751	gillsquire@me.com
	Pamela J Shaw5			0114 222 2230	pamela.shaw@sheffield.ac.uk
	Christopher J McDermott PhD5				c.j.mcdermott@sheffield.ac.uk
6	Ann Quinn6	South Yorkshire Motor Neurone Disease Association	PO Box 246, Northampton, NN1 2PR, UK	0114 262023 7	mndvisitor@gmail.com
7	Oliver Wells7	Devices for Dignity Ltd.	As 2.	07771 598644	Oliver.Wells@sth.nhs.uk
8	Susan Baxter PhD8	School of Health and Related Research (ScHaRR)	University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA, UK	077657 04922	s.k.baxter@sheffield.ac.uk

Abstract

This paper presents the Head-Up project that aims to provide innovative head support to help improve posture, relieve pain and aid communication for people living with progressive neck muscle weakness. The initial focus is motor neurone disease. The case study illustrates collaborative, interdisciplinary research and new product development underpinned by participatory design.

The study was initiated by a two-day stakeholder workshop followed by early proof-of-concept modeling and patient need evidence building. The work subsequently led to a successful NIHR i4i application funding a 24-month iterative design process, patenting, CE marking and clinical evaluation.

The evaluation has informed amendments to the proposed design we refer to here as the Sheffield Support Snood (SSS). The outcome positively demonstrates use and performance improvements over current neck orthoses and, the process of multidisciplinary and user engagement has created a sense of ownership by MND participants, who have since acted as advocates for the product.

Keywords

Participatory Design, Quality of Life, Co-Design, Motor Neurone Disease, Healthcare, Design Innovation

1.0 Introduction

This paper presents the Head-Up project; an innovation project developing a novel head and neck support for people with neck weakness due to neuromuscular diseases, and more specifically the needs of patients living with motor neurone disease (MND). This summary presents a successful case study and blue print for a collaborative, interdisciplinary research and design practice, underpinned by user-centred and participatory processes, supported by an NIHR Healthcare Technology Co-operative (HTC) model of collaboration. The paper will give a broad overview of the deployed process, along with a reflective summary of the key considerations to success.

2.0 Background

2.1 Motor Neurone Disease and Neck Weakness

Motor Neurone Disease (MND) is a rapidly progressive neurodegenerative disease with a relentless progression, a profile of complex disabilities and fatal consequences, to which there is currently no cure [1]. MND predominantly affects the motor neurones, the cells that control muscle activity including speaking, walking, breathing, swallowing and general movement of the body. As the disease is incurable, the efforts to support patients are heavily focused on sustaining a maximum quality of life (QoL) [1].

The adult human head weighs approximately 5kg and is supported by a complex system of relatively small muscle groups that co-ordinate to support and control head movements. In very simplistic terms, the weight of the head is supported by muscles fibres that tie into the back of the base of the skull at one end and attach to the back and sides of the lower neck. Contraction of these muscles lift the head backwards and allow more complex side to side movements. For people with MND, as these muscles begin to weaken, the head drops or flops, usually forwards and/or sideways (figure 1).

Figure 1: The patient is being asked to look at the photographer.

Head drop exacerbates problems with swallowing, breathing, eating, communication and drinking. Ideally a neck collar should help alleviate these problems. However, during workshops conducted with MND patients and carers in the pre-proposal stages of this project, participants confirmed that currently available collars are of limited use for people with MND and are often rejected.

Previously reported assessments of existing neck support collars have been undertaken in *healthy* volunteers and focused on the effect of the collars on restricting range of motion [2,3,4]. Although comfort assessments have been developed for a range of other limb prostheses [5], there appears to be little literature evaluating fitness for purpose of current neck support collars in this application area.

A review of existing neck supports by the project partners concluded that broadly speaking, current provision of neck collars falls into two categories: low level support (figure 2) and high level support (figure 3). Lower level, 'unstable' support, such as soft foam collars, provide some support whilst allowing movement. High level, 'stable' support collars are often used to immobilise trauma or post-surgical patients.

Pre-study workshop participants reported that the 'unstable' variety of collars do not provide sufficient support hence allow the head to drop leading to the problems listed above. This often leaves health professionals prescribing increasingly stiffer, 'stable' type immobilisation collars. These work by supporting the jaw from below and almost completely restrict head movement. This is an unnatural way of supporting the head, can be extremely uncomfortable, and the resulting

restricted movement was reported to negatively impact daily activities such as communication, eating, mobility and result in general user discomfort. The participants in early workshops clearly expressed the unmet need as: “a neck and head support system for MND patients, and potentially those with other neck weakness conditions that provides sufficient support whilst allowing freedom for head movements, is comfortable to wear and is non-stigmatising in its cosmetic appearance”.

Figure 2: An example of a soft foam support collar (low level, 'unstable' support).

Figure 3: Example of a rigid immobilisation collar (high level, 'stable' support).

2.3 The Head-Up Project

Head-Up was initiated by the NIHR Dementias and Neurodegenerative Diseases Research Network (DeNDRoN) in response to a clearly defined unmet patient technology need coming from a number of the patient members of the DeNDRoN network. In its earliest form the need was defined by the patients’ opinions simply as …*‘the collars we are currently given are inadequate for our needs. We need something else…*'

The need defined by members of DeNDRoN was picked up by Neuroscience researchers from the University of Sheffield (UoS) working in the Sheffield Institute for Translational Neuroscience (SITraN) who brought in National Institute for Health Research Devices for Dignity Healthcare Technology Cooperative (D4D). This catalysed a process that began with validation of the need in terms of scale, unmet need, quality of life impact and market analysis.

Our approach towards developing a response to this need was to use this as an example as part of an innovation workshop being held by D4D and Knowledge Transfer - Extending Quality of Life of older and disabled people (KT-EQUAL). Hosted by Lab4Living (a Design and Health collaboration initiative) at Sheffield Hallam University (SHU), this brought together people living with MND (plwMND), teams of designers, engineers, SITraN clinicians and researchers, to further explore the unmet patient needs.

The event resulted in a range of early design concepts, which were developed further through a series of design development and feedback loops, with MND health specialists and plwMND. This early work formed the basis of a successful NIHR Invention for Innovation (i4i) grant application to develop these concepts into a new neck-collar addressing the current unmet needs.

3.0 i4i Head-Up Project

The project took 28 months. It had management and commercialisation work-packages running concurrently throughout the duration. The research and physical design development followed a 12-month iterative and participatory design process involving repeated cycles of prototyping supported by experiential design components, a comfort assessment of existing collar designs and engineering virtual simulations. Throughout this design process a patent was applied for and the device was CE marked. It was then subjected to clinical evaluation with a sample population of 20 participants drawn from a population of plwMND discrete from those who had participated in the design process.

3.1 Research and Development

The primary design research and development took place over the first 12 months of the project. It was structured on a cycle of four design iterations buffered between five workshop sessions, held every three months. This process engaged a wide number of plwMND and health professionals; some of which were new to the project. In order to create the full sense of equal, shared ownership from this team, the design process assumed a blank starting sheet once again but accelerated the initial stages of understanding the user context, capturing user requirements and generating early concepts. The iterations cycled through:

- Introductory session, basic re-definition of the need, requirements capture and early prioritisation of requirements
- 2D visualization and ideation
- 3D 'mock-ups' where specific priorities were physically made and tested with users to understand which features or functionality were more or less important
- 3D prototypes with higher fidelity, exploring material options and introducing production considerations
- Finally, packaging, marketing and wider potential applications were addressed

Design and development iterations were 'hung' on a series of five workshops that were split into two groups; an 'expert user' group and a 'technical expert' group. The expert user group workshop would take 2-3 hours followed by the technical expert group workshop that would also take 2-3 hours on the same day. The expert user group consisted of representation from plwMND and carers of plwMND (professional and family members, both current carers and people who had previously cared for plwMND), a consultant neurologist and three designers. The total group of plwMND and carers was 17 people. However, at any one workshop there were never more than ten or fewer than five participants.

The technical expert group consisted of 15 people: the same consultant neurologist and three designers. In Addition, two assistive technology experts, two NIHR D4D commercialisation experts, an MND specialist nurse, Occupational Therapist, Physiotherapist and two Orthotists.

Approximately ten of these attended each workshop along with representatives from the MNDA.

Workshop 1 was an introductory session designed to create a common base line informing the project team of the structure of the project and reconfirming the need. The workshop captured and prioritised the user and clinical requirements of the device which were specified as: support for the head, freedom to move the head and an improved aesthetic. The original 2D, pre i4i award, concepts were re-evaluated by the two participant groups and ideas captured for alternatives. There were two categories of solutions derived from this first workshop. Solutions that supported the head in the more traditional style by wrapping around the neck and supporting the weight of the head by pushing up on the jaw and chin and solutions that replicated the natural effect of the neck muscles which enable control by pulling from the bottom of the back of the skull down the back and sides of the neck.

Workshop 2 focused on re-defining the full breadth of 2D concepts and relating them to the user requirements captured in the previous session. Some rough ‘mock-ups’, or working sketch models were created using ‘everyday’ objects to help describe and communicate specific features and ideas. For example, bendable hair curlers were used to describe a concept for modular support system. Figure 4 below is a collage of some of the drawings and ‘mock-ups’ created with the participants at workshop 2.

Figure 4: Conceptual 2D and 3D ‘mock-ups’ / sketch models

Outputs from workshop 2 included the development of further insights (captured in the form of sketches and notes) that ask and describe questions such as; 'support with movement, what does that mean?' and 'do we reduce movement by virtue of the fact we support?' Prior to the project start the term 'support with movement' had been identified, but how that would be embodied was not fully understood. Further, notions about the potential of modular systems to offer individually tailored support, for either body shape, asymmetric support requirements, and in addressing the need for more support as the disease progressed, began to emerge. These were captured and further user need and desire prioritisation undertaken.

At this stage, a target design specification prioritisation can be summarised as follows;

1. Support with movement
2. Comfort
3. Aesthetically acceptable
4. Ease of use
5. Customised support

6. Modifiable support with disease progression
7. Asymmetric support

Workshop 3 focused on a review of higher resolution prototypes that had been developed based on user and expert feedback from previous workshops and were developed to test some of the priorities identified by both the users and experts. These were specifically not put forward as potential solutions but as product feature mock-ups or 'sacrificial concepts' [6] intended to test the significance of certain forms of functionality and to explore how these might be enabled. The creation of artefacts as research tools in their own right is a methodology rapidly gaining momentum; they are used to aid communication and develop greater understanding of user's emotional and physical relationship with objects. [7]

Figure 4 shows a range of these 'sacrificial concept' prototypes and mock-ups used in workshops 2 and 3. The sacrificial concept approach is a good way to level the playing field in multi and interdisciplinary teams, they help to cut through disciplinary specific terminologies and help laypersons understand thinking to date. They are not necessarily meant to transfer into product proposals (although sometimes they do), rather they serve to manifest interpretations of issues in a physical form, and provide a focus and opportunity for all to ask 'is this what we mean?'

An example of this can be described in the context of the issue of providing 'support with movement'. As previously described, by virtue of the fact that we aim to provide support we could, implicitly, reduce ranges of movement. So, what does support with movement actually mean? The team wondered what it might be like to fully limit head movement in one plane in order to enable support and maximise movement in another. When asked which plane would be most important to them the patient group responded that they would prefer to retain head rotation, in the horizontal plane, and sacrifice up and down, vertical, ‘nodding’ movements. This workshop resulted in the selection of a number of focused conceptual solutions that were subsequently manifested as sacrificial concepts to be presented at the next workshop. Each captured an aspect of device functionality and likely enabling technology.

In workshops 3 and 4 many sacrificial concepts were tabled and discussed in more detail. The example of support with movement showing free horizontal but minimal vertical movement was demonstrated. On seeing and understanding the implications of this type of product, such as not being able to look down at ones feet for example, tangibly highlights a range of functional complexities that such a product would be required to address. In this way the team were able to select particular device functional characteristics, and ultimately evaluate which would be selected for progression into a final prototype. In this process

one of the conceptual designs, loosely formulated at the pre-award stage of the project, clearly emerged as being something that showed the potential to integrate all functional and aesthetic findings to date. The period between workshop 4 and 5 was used to bring this 'SSS' (Sheffield Support Snood) design, to a higher, physical demonstrator level.

The purpose of workshop 5 was to present a close to ‘final realisation’ of the design to the participants focused on the higher resolution design features and functionality as prescribed by the user groups. Here, potential solutions were worked up in a range of alternative material finishes that not only enabled participants to tangibly ‘visualise’ options much closer to a final realisation but also matched anticipated manufacturing routes. The product proposal also incorporated and raised the limitations and issues that might be associated with up-scaling production, and associated product costs for certain types of final finish. This enabled participants to consider the trade-offs between certain final realisations against relative price points. The event was also used to elicit insights about some final design changes. Further, the prototype was used to practically work through preliminary instructions for use for both healthcare professional doing the initial prescribing and fitting, and for patients taking the devices home.

Validation tools:

In the background to these five workshops, throughout the process, the design team was also producing a series of tools to assist them in the technical specification of the neck support. One such example of this is the development of ‘Edwood’. Edwood was a life-size wooden mannequin (figure 5) designed to simulate the human head, neck and torso. Its head could be filled with a variety of weights to bring it up to average human head weight, of between zero to six kg. Edwood’s neck had been made out of a column of flexible polymer, simulating the top of the spine, and was the only connection between the head and the torso. Edwood's structure was such that it could not independently support the weight of its head, to the extent that the head would drop forward and to the side to contact the torso; either ear to shoulder or chin to chest.

The neck-column was weakened at pre-determined intervals. Hard acrylic profiles were clipped onto this polymer column at the weakened areas, terminating at their periphery as to describe surface features of the neck. As such, the Edwood mannequin exhibited ‘no’ neck strength but features describing the shape of the surface of the neck. The Edwood rig enabled the design team to offer up proposed neck support systems to it, and quickly get an idea of whether they would support the weight of a human head, without having to engage a user in such physical, mechanical testing. Concepts were developed between users, clinicians and designers, taken away and developed to appropriate levels by the

design team, resulting concepts taken back to the clinicians and users for them to try on, critique and inform further re-design iterations.

Figure 5: Edwood; a simulator used to assess the basic level of support that a design concept would be able to provide

3.2 Comfort Assessment of Existing Collars

In parallel to the design and development workshops a comfort assessment (using the Lunsford pain scale) was conducted on 34 healthy volunteers including the members of the design team and the technical expert group. The volunteers wore four different existing collars (Aspen Vista, Philadelphia, Headmaster and Stro II) for four hours each, with a week between the test of each collar.

The results of this indicate that there are significant levels of qualitatively reported discomfort, 'hotspots' for each collar, some more than others and that there is an immediate, ‘inherent design’ related discomfort experienced as soon as each collar is worn and a time dependent discomfort factor (discomfort increasing with time) that was similar for all collars. The results also showed that there was a tension between support and freedom to move, with those collars offering support being most uncomfortable and not enabling free movement whilst the collar that was least uncomfortable, enabled some free movement of the head but offered little perception of support. Although this exercise was not indicative of the actual MND use situation, as healthy participants were used, it did provide a good understanding of the range of discomfort issues, where, why and how discomfort manifests, across a broad user group. This enabled the designers to consider the specific contact points and associated pressure hotspot distribution (figure 6), consideration of which could be incorporated into the SSS collar. The greatest benefit of this study for the design team was the empathic insight this gave to the lived experience of someone required to wear a collar for long periods of time and the impact on quality of life. The full details of this study will be reported in detail in a future paper.

Figure 6: Contact point, qualitatively reported ‘hotspots’ for Philadelphia collar based on the comfort assessment data

3.3 Clinical and Functional Evaluations

Following development of a number of CE Marked but pre-production devices, an extended user evaluation phase of work was undertaken with MND Patients. The full details of this evaluation are reported in 'Evaluating a novel cervical orthosis to support neck weakness in patients with motor neurone disease ' [8]

In terms of device performance, a further, independent functional evaluation was conducted by researchers in the INSIGNEO institute at

the University of Sheffield [8]. The results indicate that the SSS was comparable to other designs in terms of ability to support the head and neck and that it did this whilst retaining the 'movement' goal that was so important to users. The full details of this evaluation will be reported in a future paper.

4.0 Discussion

This paper summarises a complex, participatory design process that followed an iterative development model with patient users, carers and clinical experts alongside the design team.

The project set out to address a specific need identified by people living with progressive neck muscle weakness resulting from MND. This need was distilled, at project outset, into a 'loose' design brief to develop a head and neck orthosis for people living with neck muscle weakness that gave support to the head whilst enabling freedom to move the head and that was aesthetically less stigmatising than current product offerings. Several validation exercises and product evaluations have been carried out that provide supporting evidence suggesting that the emerging design solution meets this brief.

In addition, the co-design process has enabled a greater understanding of the features to be integrated into the SSS device. Features such as providing customisable support as it may be tailored to body shape and size, providing asymmetric support, a device that can be used task specifically, and one that can be adapted to meet changing needs with disease progression.

The project was interdisciplinary in the sense that a number of different disciplines worked together and across their respective disciplines, on both parallel and sequential work packages. Alongside the 'expert user' (MND patient and carer) groups, the different disciplines in this project worked alongside each other throughout the project contributing to decisions within design, development, comfort assessment, regulatory risk assessments, patenting and IP, clinical evaluation and commercialisation. This interdisciplinary and true participation has resulted in a product that:

- has a patent pending
- is CE marked as a Class 1 medical device
- has patient advocates
- has clinical evaluation data that demonstrates improved quality of life and a self-reported up-lift in the number of daily hours of collar usage

Whilst this degree of multidisciplinary and user centred co-design participation has had obvious benefits, it has also had its challenges.

5.0 Challenges

The first broad set of challenges identified concern communication across such a broad set of disciplines and with our MND patients and members of the public. Communication difficulties as a result of MND meant that we were required to be creative in enabling input from patients with limited speech. We found that the use of the design methods and approaches helped to overcome some of the product development specific barriers. A significant part of that was the use of 2D and 3D mock-ups and 'sacrificial concepts' as multidisciplinary and public communication tools because they place all parties in the same tangible 'space'.

A further challenge relates to the extent of the project scope. In this example the team aimed to cover an entire new product development cycle within a single funded program, from first concept to manufactured item. This may not be a new approach in its self but, as the Head Up project arguably functioned in new ways because it employed 'deeper' research through co and participatory design, the development program was lighter in resource in regard to implementing and detailing designs as a result of findings from the formal clinical evaluation. The authors would advise that should such programs be pursued that an additional design phase be incorporated to R&D programs to integrate new findings following clinical evaluations.

A third challenge relates to the length of time the new product development process took, at least from the commercial design team's perspective. The design team could have theoretically taken the original design brief and produced a solution without interaction with clinicians and/or patient representatives. The time taken to do this would have been considerably shorter than the adopted approach. However, the design team have commented that this would not have produced a solution as appropriate or as sensitive to the patients' needs. Whilst the approach taken could be seen as time intensive, the inclusion of the patient users and clinical experts gave considerably greater knowledge about the context of use informing both the design solution and the risk assessment and risk mitigation for the regulatory requirements. The team have not attempted to capture how much tacit knowledge, from patients, clinicians and designers has been transferred to one another, and as such is embodied within the final design solution. However, for designers to design well, they have often to get as close to the (diverse and multidisciplinary) problems as possible. It is only then that they are able to manifest that knowledge in artefacts that progress enquiry and that lead to concepts and products. Given the user and functional evaluations report good performance, the assumption may be made that the exchange has been successful.

The fourth challenge was trying to successfully commercialise the product as part of the project. In reality, the information required to be able to

develop a robust commercial package was developed only by the end of the project. The work to get the SSS device to market is still ongoing.

6.0 Conclusions

In conclusion, the process brought together a wide range of specialisms through a user focused, creative and participatory approach. This resulted in the co-research, design and co-development of a new form of orthosis. This included the gathering and use of research evidence, clinical know-how, patient-lived experiences, technical knowledge, and used creative thinking and design methods to draw out and synthesise this knowledge. Physical prototyping gave form to this new knowledge and made it tangible, further enabling joint learning. This physical language serves as a means of rapidly querying, and evolving and developing shared understandings.

User engagement in this process fundamentally changed the course of the project and ideas were ruled out as a result of patient perspectives. The benefits of this participatory process included the emancipation of the patient users and responsive action was the strongest possible affirmation that someone was being listened to.

The process can be described as an exemplar of a user involved design and innovation process with genuine user participation in the design. This has helped ensure that the novel head and neck support meets the needs of many of the target user group as well as the functional requirements identified at project outset and those that emerged during the course of the enquiry. In the context of medical device development, there were direct benefits to participation, in particular, in regard to developing deep, qualitative understandings of the context of use.. Although the neck support has only been evaluated by a relatively small sample, the results indicate a very positive response that validates the innovation model applied in this project, the user and clinician involvement and the design output.

At the time of writing the project team is in discussion with manufacturers and distributors to further explore how the SSS can move forward to full production and patient supply.

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