

# Head up: The development of a novel cervical orthosis to support neck weakness due to neurological disease.

<https://neurodegenerationresearch.eu/survey/head-up-the-development-of-a-novel-cervical-orthosis-to-support-neck-weakness-due-to-neurological-disease/>

## Principal Investigators

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University of Sheffield

## Contact information of lead PI Country

United Kingdom

## Title of project or programme

Head up: The development of a novel cervical orthosis to support neck weakness due to neurological disease.

## Source of funding information

NIHR (i4i Early-stage Call 2 Full)

## Total sum awarded (Euro)

€ 605,132

## Start date of award

01/04/2012

## Total duration of award in years

4.5

## The project/programme is most relevant to:

Motor neurone diseases

## Keywords

Research Abstract

Workpackage 0: Approvals and Project Management (-3 months, pre contract).

Milestone 0 (M0) – a favourable ethical opinion and authorisation to proceed.

**Workpackage 1: Iterative, co-design process (12 months).**

The **FlexLace** and **Pull-a-Neck** concepts will be fed into a co-design process comprising of two expert panels; a user panel and a technical panel. Views from the two panels will crossover and feed into an iterative design process consisting of 4 development cycles and a final evaluation.

Each iteration will focus on different aspects of the design concept:

- 1) Review of current concept sketches.
- 2) Review of low fidelity prototypes to focus on potential geometry of the concepts, with examples of mechanism details for fixing, closing and opening.
- 3) Review of mid level prototypes and materials samples to finalise geometric and structural considerations and introduce potential material solutions.
- 4) Review of the combined solution ideas leading to ‘finished’ prototypes to confirm structural and material solutions.

Each of the four iterations will consist of four stages:

Stage 1 – Expert user panel

Stage 2 – Expert technical panel

Stage 3 – NAT (Neck assessment tool)

Stage 4 – Design modifications and preparation of higher level prototypes for next iteration

Milestone 1: end of iteration 4, ‘finalised’ prototypes

**Workpackage 2: Manufacture and CE marking (4 months).**

In collaboration with the D4D Regulatory advisors, we will ensure we are compliant with appropriate standards for external limb prostheses and external orthoses and will work to ISO 13485 and ISO 14071 for risk management.

The prototypes will be CE marked as Class 1 medical devices to meet regulatory requirements (93/42/EEC) by an appropriate manufacturer selected on the basis of skills fit. Development of the design concepts for manufacture will form an integral part of this workpackage.

Milestone 2: 30 CE marked devices.

### **Workpackage 3: Extended user evaluation (9 months).**

20 patients with neck weakness will be recruited and will evaluate a single cervical neck orthosis for one month. At baseline and at one month patients will complete, an analogue pain scale, SF36 and a newly-developed neck support questionnaire. At the same time points, patients will participate in pre and post qualitative interviews. The topic guides for these semi-structured interviews will cover specific issues such as pain, and putting on, fixing and modifying the orthosis. Also the effects on day-to-day activities such as communication, eating drinking and travelling will be reviewed. The interviews will draw directly upon the patients experience of neck weakness, their day to day experience of current cervical orthoses and the new cervical orthosis. Data from the 40 interviews will be recorded, transcribed and undergo Framework analysis.

During the course of this workpackage, two further focus groups will be run. The aim of the first focus group will be to test the transferability of the proposed design to conditions beyond MND. The aim of the second focus group will be to explore issues of clinical prescription with relevant independent healthcare professionals.

Milestone 3: Demonstration of acceptability and benefits of a new cervical orthosis.

### **Workpackage 4: Ascertain commercial feasibility (in parallel for 23 months).**

An exploitation strategy will be developed that protects the intellectual property of the concepts, that seeks out and aligns with appropriate partners from materials producers and suppliers to global neck support manufacturers, and that generates evidence of the wider potential market.

Milestone 4: Commercial exploitation and IP implementation report.

### **Workpackage 5: Forward development (3 months).**

This work package will prepare an i4i late stage proposal or a direct to market strategy based

upon having evidenced both technical and commercial feasibility.

Milestone 5: Funding proposal written or direct to market strategy developed.

**Lay Summary**

**Further information available at:**

**Types:**

Investments > €500k

**Member States:**

United Kingdom

**Diseases:**

Motor neurone diseases

**Years:**

2016

**Database Categories:**

N/A

**Database Tags:**

N/A