

# Summary of Presentation RAPPER II

93rd Annual Meeting of the American Congress of Rehabilitation Medicine, Chicago Illinois

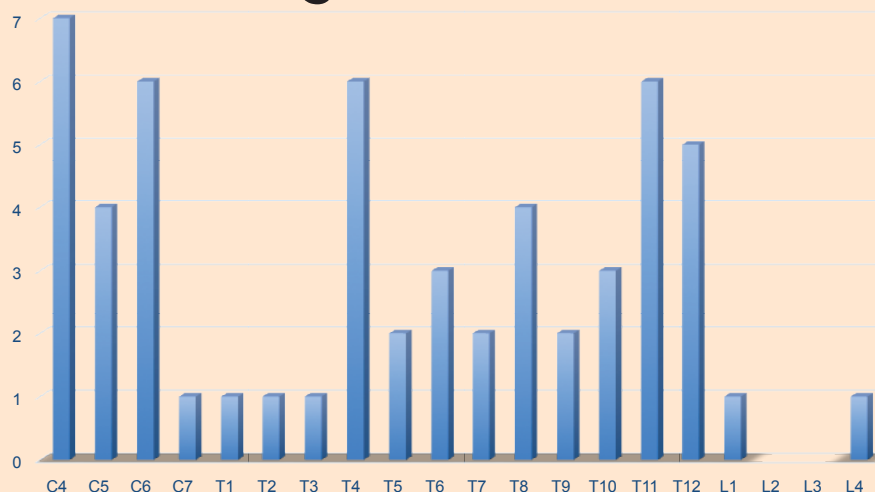
Presented by Principal Physiotherapy Investigator, Jon Graham BA, Msc, MSCP. 3rd November 2016

## RAPPER II: Introduction

- International, Multi-Center, Single-arm, Observational registry
- Safety and usability; patient-reported acceptability; and quality of life
- REX robot: Transfer, Walk, Upper Limb and Trunk Exercises
- One treatment; de novo volunteers
- Spinal Cord Injury (SCI) : C4 to L5 levels
- Principal Investigator: Nick Birch FRCS (Orth)
- ClinicalTrials.gov Reg No: NCT02417532
- Independent CRO: GDCl, Florida, USA
- Stopped by investigators at 56 patients: primary end point achieved

Trial Sites, recruiting : **PhysioFunction** Ltd and EMS Ltd, Northants, UK; **Royal National Orthopaedic Hospital**, London, UK; **East Kent Hospitals NHS Foundation Trust**, Canterbury, Kent, UK; **Victoria Spinal Cord Service**, Austin Health, Melbourne, Australia; **Auckland University of Technology**, Auckland, New Zealand

## Neurological Levels (n=56)



## Primary and Secondary End Points

### REX Safety & Usability (n=56)

- Transfer Success 56 (100%)
- Mean Transfer Time 6:51 min
- Completion of all Exercises 52 (93%)
- Minor Adverse Event 4
- Serious Adverse Events 0

### Preliminary View of Secondary End-points

One treatment only: two or seven day follow-up

- 36 participants enrolled for Quality of Life questionnaires\*
- Cohort of responders:
  - 15 (42%) reported improved sleep
  - 11 (31%) reported improved sleep + less spasticity
  - 8 (23%) reported improved sleep + less "Pain woke me up"
- Further investigation under way

\* 1 lost to follow-up

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## REX: User Experience Questionnaire Results



## REX: Results for Paraplegics and Tetraplegics

	<b>Paraplegics n=38</b>	<b>Quadriplegics n=18</b>
Mean time to transfer	6.20 minutes	7.55 minutes
Mean time to Up and Go	5.20 minutes	5.10 minutes
Pct completion of both exercises	95%	94%

## RAPPER II: Summary

- Analysis of the results of the RAPPER II trial has shown that REX is a safe and stable Powered Exercise Equipment, requiring a very limited amount of user training
- The trial has shown that it is feasible for people with SCI to carry out a functional exercise program in the REX
- There was no difference between the ability of patients with tetraplegia and paraplegia to achieve the functional goals
- The User Experience was generally positive especially across the domains of safety, comfort, stability and ease of control
- A substantial cohort of participants reported a positive effect on Quality of Life parameters
- The results of RAPPER II justify further investigation of this technology both in terms of a dose-response relationship and in people with diverse neurological conditions such as stroke and MS.