Fondazione Don Carlo Gnocchi Onlus

epr european platform for rehabilitation

Building capacity for excellence in service provision for people with disabilities

Study Visit to Don Gnocchi Foundation

17-18 November 2016, Milan, Italy

for EPR members involved in medical rehabilitation

Experiences with rehabilitation robotics

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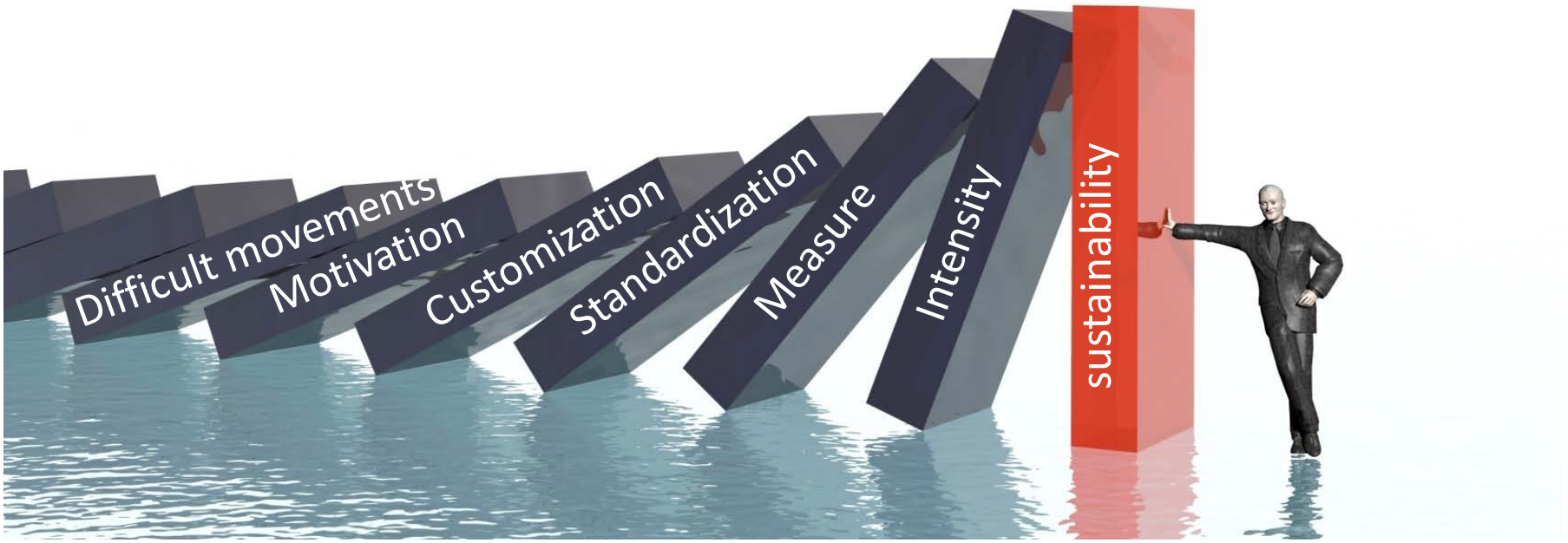
Rehabilitation using robotic devices

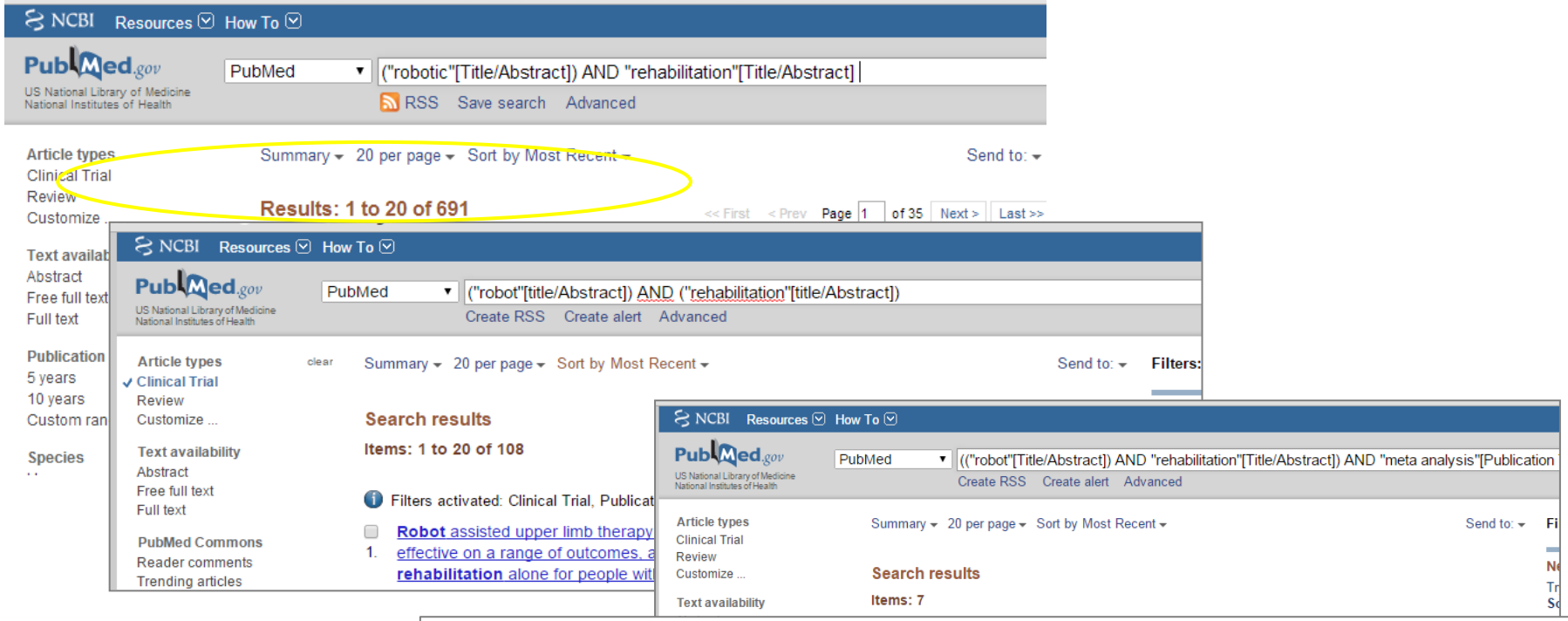
Why?



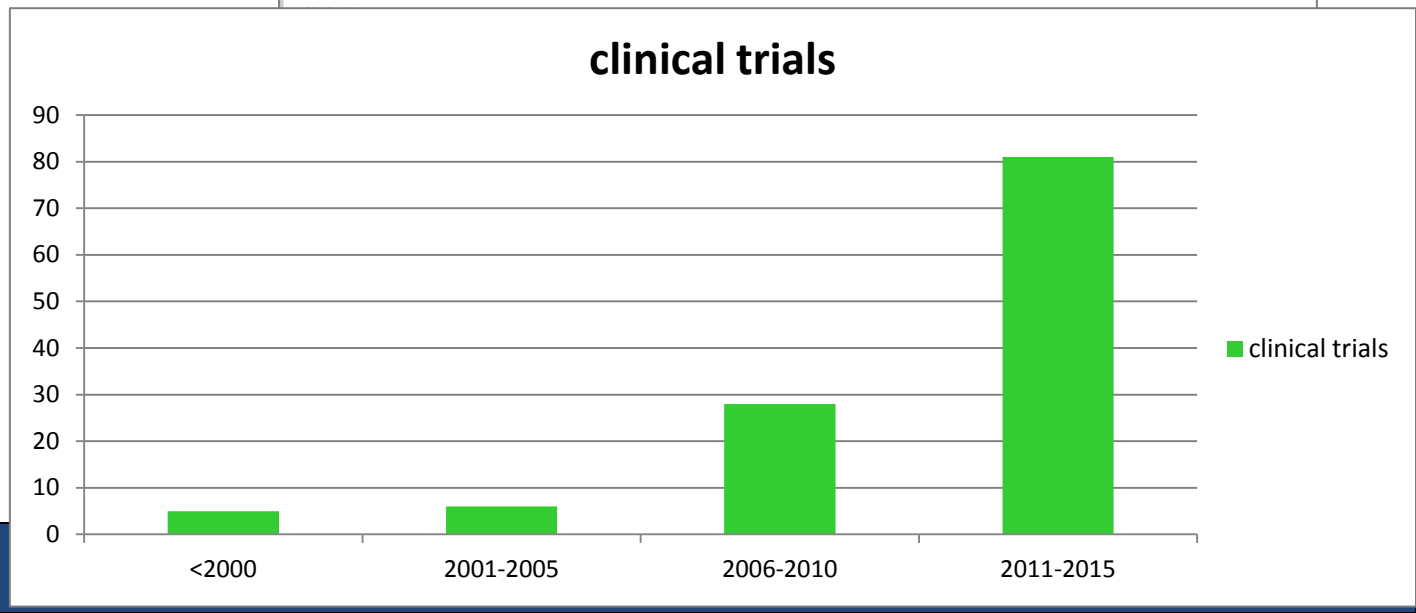
Efficacy

Cost-effective

RMT Scientific Literature



There has been growing interest on this topic but the scientific evidence is low



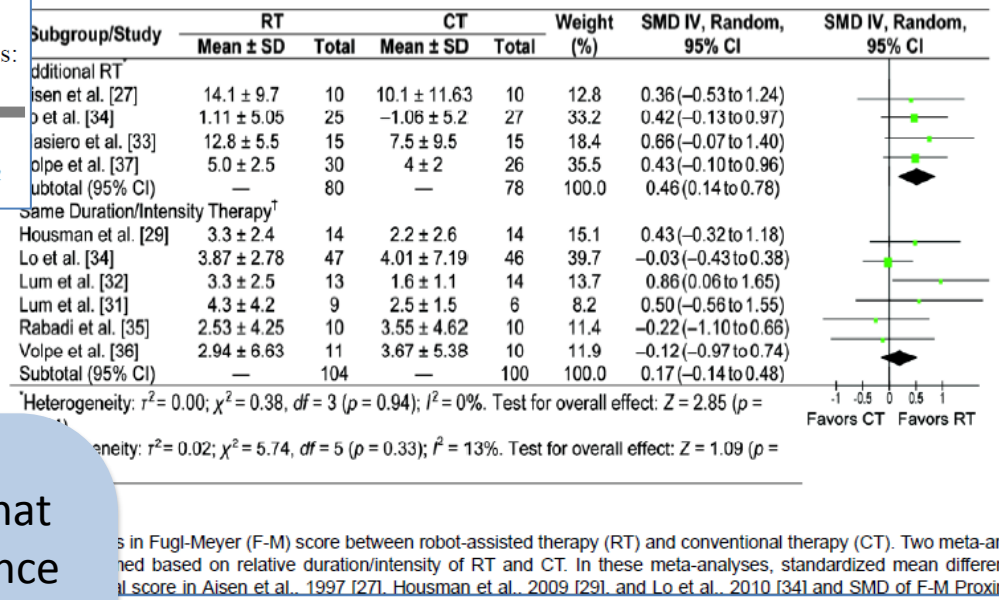
RMT Scientific Literature

2012 - 262 patients

JRRD Volume 49, Number 4, 2012 Pages 479–496

Effects of robot-assisted therapy on stroke rehabilitation in upper limbs: Systematic review and meta-analysis of the literature

Nahid Norouzi-Gheidari, MSc, OT;* Philippe S. Archambault, PhD; Joyce Fung, PhD
School of Physical and Occupational Therapy, McGill University, Montreal, Quebec, Canada; Feil/Oberfeld/CRIR Research Centre, Jewish Rehabilitation Hospital, Laval, Quebec, Canada



Subgroup/Study	RT Mean ± SD	RT Total	CT Mean ± SD	CT Total	Weight (%)	SMD IV, Random, 95% CI
dditional RT*						
isen et al. [27]	14.1 ± 9.7	10	10.1 ± 11.63	10	12.8	0.36 (–0.53 to 1.24)
o et al. [34]	1.11 ± 5.05	25	–1.06 ± 5.2	27	33.2	0.42 (–0.13 to 0.97)
asiero et al. [33]	12.8 ± 5.5	15	7.5 ± 9.5	15	18.4	0.66 (–0.07 to 1.40)
olpe et al. [37]	5.0 ± 2.5	30	4 ± 2	26	35.5	0.43 (–0.10 to 0.96)
ubtotal (95% CI)	—	80	—	78	100.0	0.46 (0.14 to 0.78)
Same Duration/Intensity Therapy†						
Housman et al. [29]	3.3 ± 2.4	14	2.2 ± 2.6	14	15.1	0.43 (–0.32 to 1.18)
Lo et al. [34]	3.87 ± 2.78	47	4.01 ± 7.19	46	39.7	–0.03 (–0.43 to 0.38)
Lum et al. [32]	3.3 ± 2.5	13	1.6 ± 1.1	14	13.7	0.86 (0.06 to 1.65)
Lum et al. [31]	4.3 ± 4.2	9	2.5 ± 1.5	6	8.2	0.50 (–0.56 to 1.55)
Rabadi et al. [35]	2.53 ± 4.25	10	3.55 ± 4.62	10	11.4	–0.22 (–1.10 to 0.66)
Volpe et al. [36]	2.94 ± 6.63	11	3.67 ± 5.38	10	11.9	–0.12 (–0.97 to 0.74)
Subtotal (95% CI)	—	104	—	100	100.0	0.17 (–0.14 to 0.48)

*Heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 0.38$, $df = 3$ ($p = 0.94$); $I^2 = 0\%$. Test for overall effect: $Z = 2.85$ ($p =$

eneity: $\tau^2 = 0.02$; $\chi^2 = 5.74$, $df = 5$ ($p = 0.33$); $I^2 = 13\%$. Test for overall effect: $Z = 1.09$ ($p =$

-1 -0.5 0 0.5 1
Favors CT Favors RT

s in Fugl-Meyer (F-M) score between robot-assisted therapy (RT) and conventional therapy (CT). Two meta-anal-
ned based on relative duration/intensity of RT and CT. In these meta-analyses, standardized mean difference
l score in Aisen et al., 1997 [27], Housman et al., 2009 [29], and Lo et al., 2010 [34] and SMD of F-M Proximal

When the duration/intensity of conventional therapy **is matched** with that of the robot-assisted therapy, no difference exists between the two groups in terms of motor recovery, activities of daily living, strength or motor control.

When the RT **is added** to CT, a greater effectiveness can be observed, when compared with regular CT alone

people with stroke. Rather, robots deliver highly repetitive therapeutic tasks with minimal supervision of a therapist and these additional sessions of RT improve motor recovery of the hemiparetic shoulder and elbow of patients with stroke. Developing new function-based RT protocols, building robotic devices for rehabilitation of prehension and with more degrees of freedom, and conducting new RCTs that consider the factors discussed in this review are recommended for future studies.

RMT Scientific Literature

Electromechanical and robot-assisted arm training for improving generic activities of daily living, arm function, and arm muscle strength after stroke (Review)

Mehrholz J, Hädrich A, Platz T, Kugler J, Pohl M

THE COCHRANE COLLABORATION®

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2012, Issue 6

http://www.thecochranelibrary.com

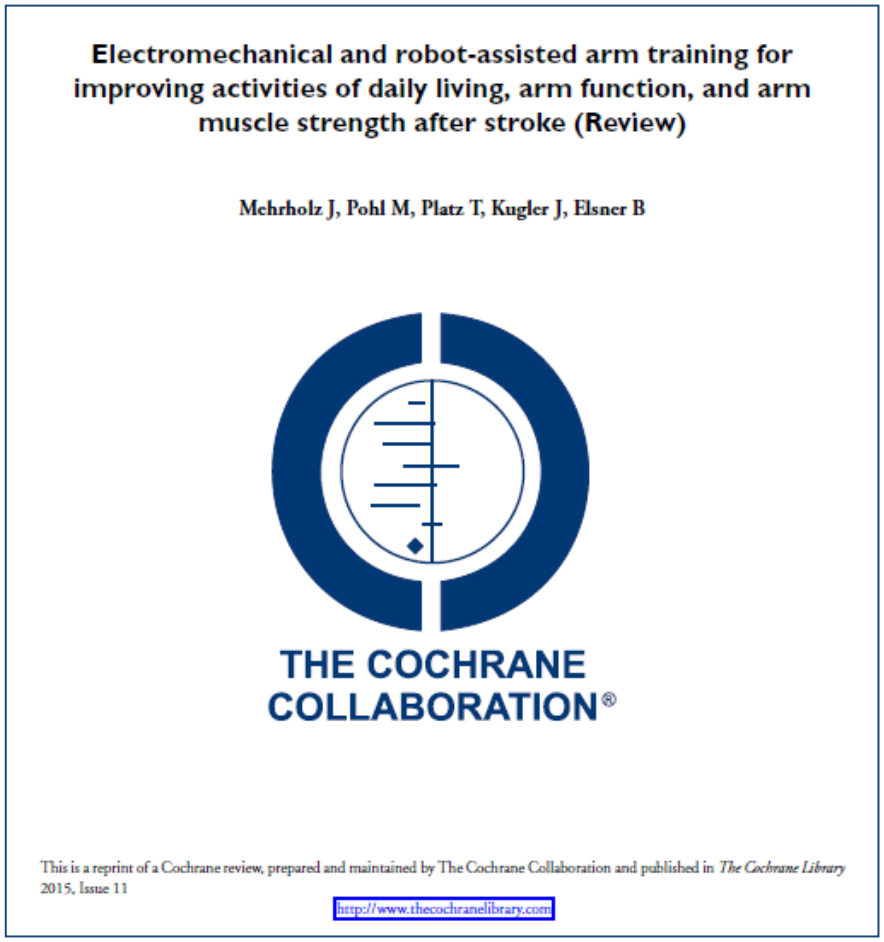
2012

19 trial (666 partecipanti)

Robotic therapy was more effective in improving upper extremity function and ADL, but not muscular strength.

But the studies reviewed were heterogeneous, then the results should be interpreted with caution.

RMT Scientific Literature



Robotic therapy VERSUS conventional therapy, placebo or no treatment.

2015

34 RCTs: 1160 patients

RT was more effective than other therapies in improving activities of daily living, motor function and muscle strength of the upper limb.

RT was well accepted by patients, there was no marked increase in the number of drop-outs and serious adverse events were rare and unrelated to the robotic treatment

Still the studies reviewed are heterogeneous, then the results should be interpreted with caution.

Health Technology Assessment -Robotic group

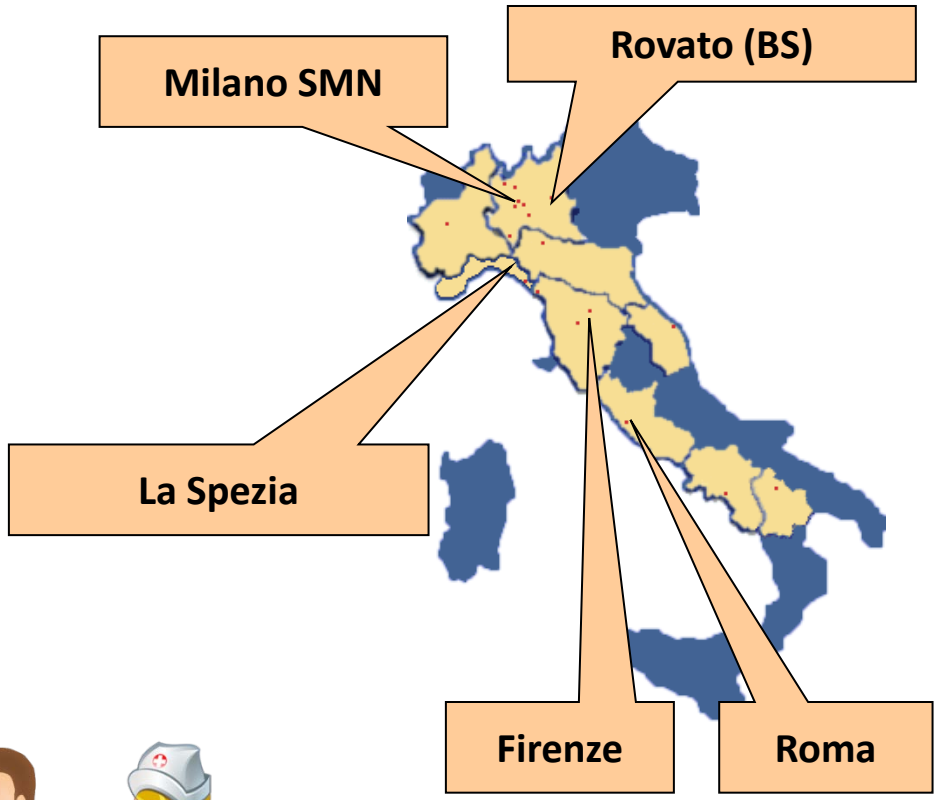
Phase 1

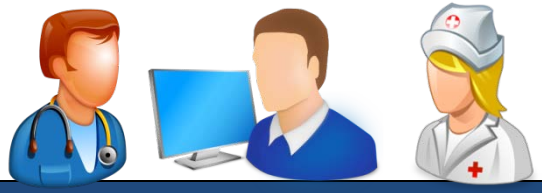
June 2015

Aim: choosing the best robotic devices for the rehabilitation

- Composition of the group:
  - Head of Health Technology Assesment
  - Medical Director
  - 3 Physiatrists, 2 Neurologists
  - 3 Physical Therapists
  - 4 Bioengineers

  …Coming from 5 centers of the FDG





Fondazione Don Carlo Gnocchi Onlus

Health Technology Assessment -Robotic group

ROBOTIC SYSTEM CHARACTERISTICS FORM

General information

Compiler	Name Profes
Date	23/06
System Name	
Manufacturer	
Company Website	
Compiler Confidence level	☐ ☐ ☐

System characteristics

Type of system	☐ ☐
Multiple versions or models (i.e.: with different HW...)	☐ ☐
Segment	☐ ☐ ☐
Pathologies indicated to treatment	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Maximum Level of impairment	
Contraindications	
Stage of development	
Portability	
Movement	
Assisted Joint Movement (example: shoulder ab-adduction, elbow flex-extension, knee flex-extension etc.)	
Type of Assistance[1] (multiple choices are possible)	
Is it possible to customize user interface/exercises?	
Main Control Inputs	
Are Outcome Measures provided?	
Normative values for the outcome variables	
Accessibility for the patient with his/her own wheelchair during therapy?	
Safety issues	

Scenario	
Special needs for installation	
Autonomy	
Group Therapy	
Number of clinicians involved in the treatment	
Preparation time (or time to wear the robot)	
Therapy administration	
Literature	
Free test period	
Maintenance Costs [if available]	
Cost (detailing cost for multiple versions)	

Demonstration	☐ Yes (When: 8/5/15; Where: Milan) ☐ No ☐ To be scheduled (When _____Where_____)
Company contact person	☐ Name: ☐ Phone_____ ☐ Email
Is the enterprise open to future collaboration?	☐ **Yes** ☐ No
Technical documentation attached	☐ **Yes** ☐ No

Compiler evaluation

Purchase priority	☐ Low – Not purchase ☐ Medium – Suggested purchase ☐ **High – Purchase with Priority**
Purchase priority choice explanation	Sistema portatile, può essere portato a letto del malato, prevede un appoggio del gomito sul tavolo che evita la caduta della spalla, può aiutare con attività assistiva e permette di eseguire un movimento "pulito e corretto da sistema", deve essere dotato di un tavolino ad altezza regolabile.
Notes	Esiste una versione molto simile su internet della che si chiama

Health Technology Assessment -Robotic group

Evaluation of 18 systems

- 8 upper limb/hand
- 8 lower limb
- 2 hand

…exoskeletons , end-effectors

…but also

•Treadmill with virtual reality

•Systems for verticalization

Set of technological/robotic systems for a global treatment of the upper limb

July 2015

The pilot study

- Pilot study (bicentric study, involving two centers in Rome)
- Aim: to compare the conventional therapeutic approach (ratio of one therapist to one patient) with a robotic approach (ratio of one therapist to every three or four patients)
- **30 patients enrolled** (October 2015 - February 2016)

Inclusion Criteria

- Age > 18 years.
- unilateral emiparetic stroke
- Time latency since stroke less than six months

Exclusion criteria

- Visual deficits
- fixed contraction deformity

Less restrictive criteria

The pilot study

Evaluation

Outcome measures

PRIMARY OUTCOME
- FUGL-MEYER

SECONDARY OUTCOME
- ARAT
- Motricity Index
- MRCS
- Modified Ashworth Scale
- Barthel Index
- Hand grip

The pilot study

FDG SM della Provvidenza:

Experimental group (16)

T0 evaluation

Robotic Treatment

- 30 sessions, lasted 45 min, 5 times per week
- 1trained therapist → 3 - 4 pts

T1 evaluation

Comparison

FDG SM della Pace:

Control group (14)

T0 evaluation

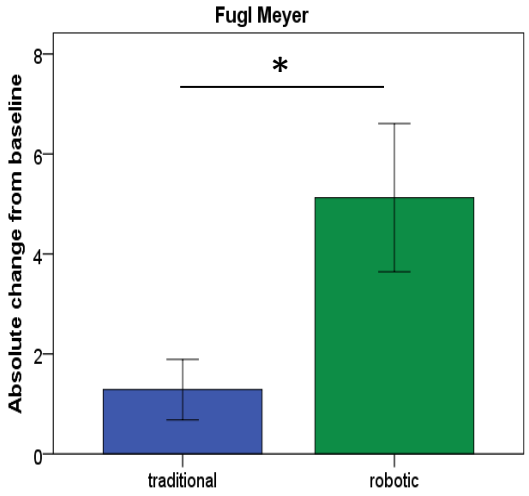
Traditional Treatment

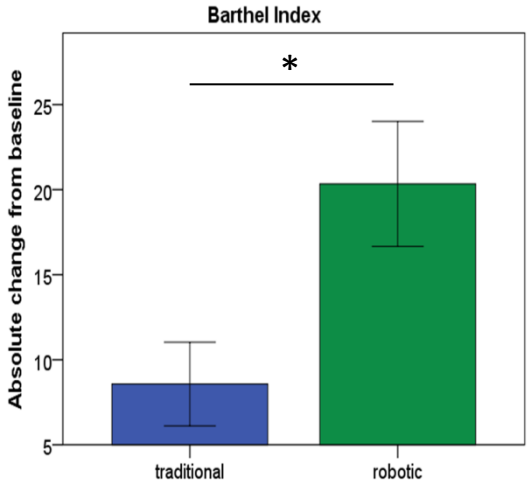
- 30 sessions, lasted 45 min, 5 times per week
- 1 therapist → 1 patient

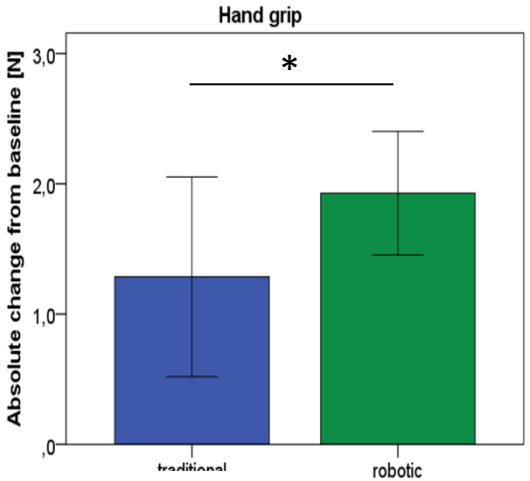
T1 evaluation

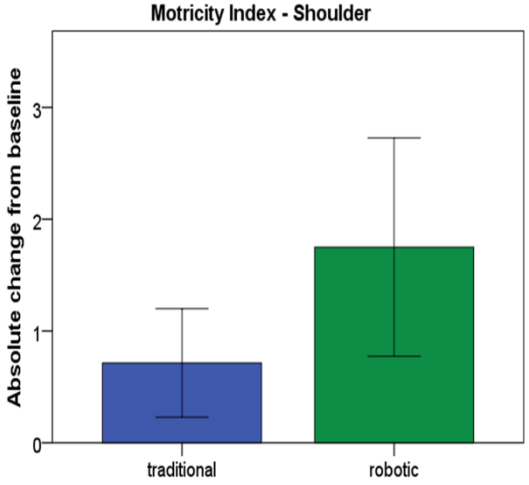
The pilot study

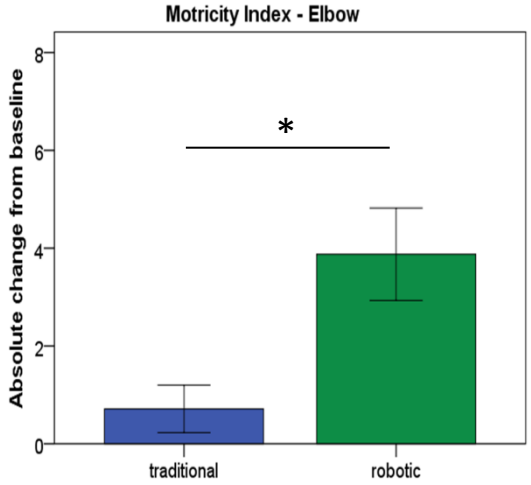
Results

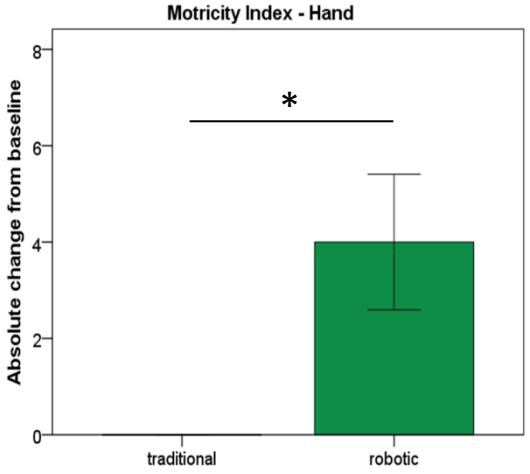












The robotic rehabilitation plan in FDG

- During 2016, 6 centres of FDG were equipped with the set of devices tested in Rome
- Currently, 7 centres are equipped with robotic devices for upper limb rehabilitation
- They are located in *Roma, Milano, Firenze, Fivizzano, La Spezia, S. Angelo dei Lombardi e Rovato*

Multicenter, randomized, controlled trial

Protocol

SAMPLE
344 patients (both inpatients, outpatients and day hospital)

Inclusion Criteria

- unilateral hemiparetic stroke
- age between 40 and 80 years
- sufficient cognitive and language abilities (SDC >2)
- Time latency since stroke ranging from two weeks to six months

Exclusion Criteria

- fixed contraction deformity;
- severe deficits in visual acuity;
- upper extremity Fugl-Meyer score >58.

Multicenter, randomized, controlled trial

Evaluation

Outcome measures

PRIMARY OUTCOME

- FUGL-MEYER

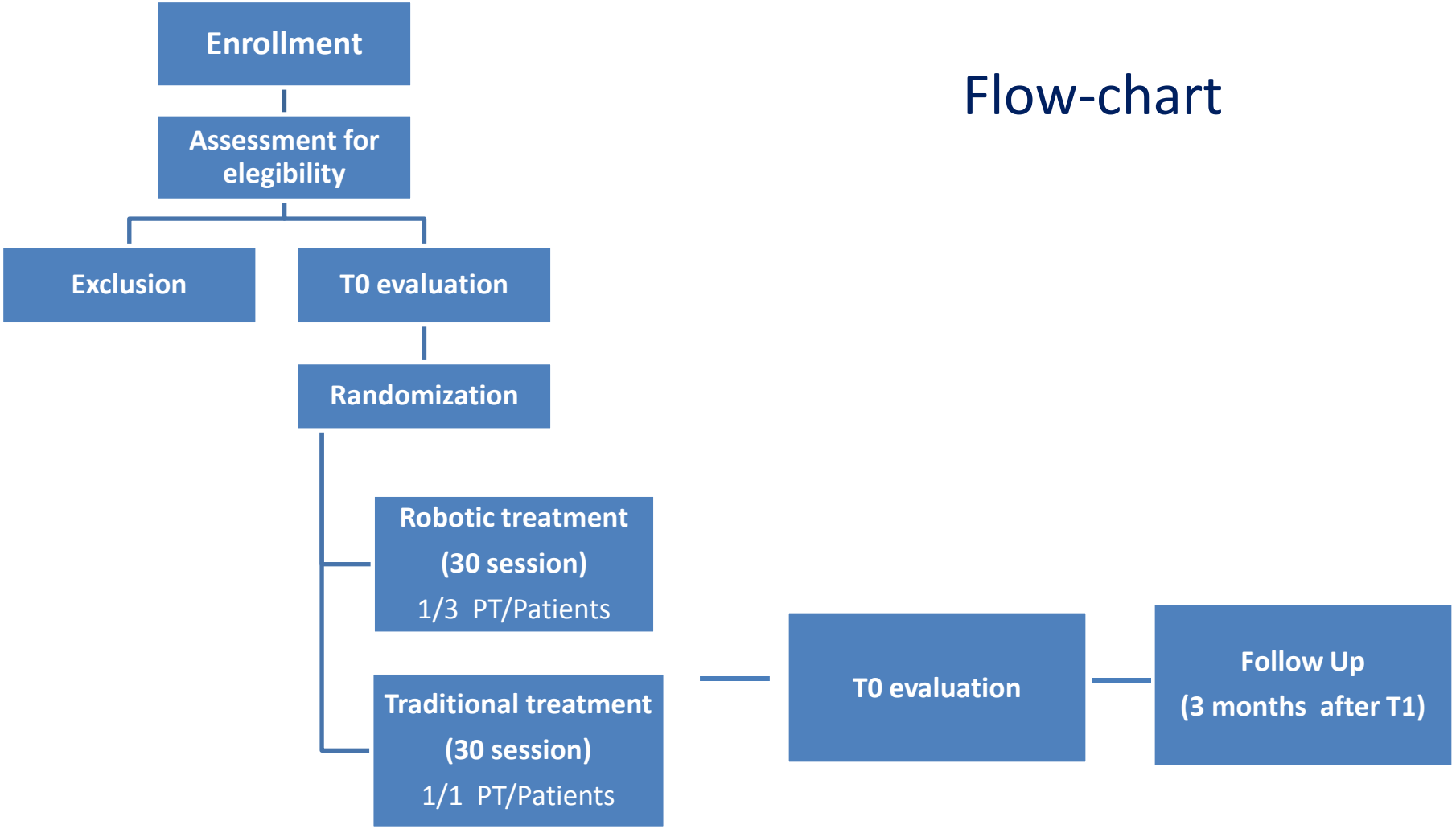
(Single Evaluator blinded to the treatment assignment)

SECONDARY OUTCOME

- ARAT
- Motricity Index
- MRCS
- Frenchay Arm Test
- Modified Ashworth Scale
- ROM
- Modified Barthel Index
- Verbal Fluency test
- Human figure testNRS
- DN4
- SF36

Multicenter, randomized, controlled trial

Flow-chart



Multicenter, randomized, controlled trial

Sample

Recruiting center	Enrolled patients	Drop out	Treated patients
Milano	14	4	10
Firenze	14	3	11
Rovato	13	2	11
Fivizzano	7	3	4
Provvidenza	13	1	12
Pace	6	1	5
Massa	11	1	10
La Spezia	3	1	2
Tricarico	5	0	5
S. Angelo dei Lombardi	5	0	5
Acerenza	5	0	5

Enrolled patients (total) : **96**

Updated to Nov 15, 2016

Multicenter, randomized, controlled trial

Don Carlo Gnocchi Onlus Foundation Centers involved in the study

- Roma (RM SM della Provvidenza)
- Milano (MI)
- Rovato (BS),
- La Spezia (SP)
- Firenze (FI)
- Massa (MS)
- Fivizzano (MS)
- Roma (RM SM della Pace)
- S. Angelo dei Lombardi (AV)
- Tricarico (MT)
- Acerenza (PZ)

... unity is strength!

Multicenter, randomized, controlled trial

Gantt

Competenza	Fasi del progetto	Timing
		2015: V VI VII VIII IX X XI XII | 2016: I II III IV V VI VII VIII IX X XI XII | 2017: I II III IV V VI VII
Clinica	Presentazione progetto Robotica	
HTA-Robotic group	Analisi e selez. set sistemi robotici	
Clinica	Studio pilota (centri romani)	
Direzione (gest ris)	Analisi costi	
Direzione (uff acq)	Acquisto sistemi	
Clinica	Condivisione esperienza Robotica	
Clinica	Stesura protocollo Multicentrico	
Direz. Scientifica	Valutazione protocollo	
Comitato Etico	Presentazione e approvazione CE	
Clinica	Avvio Multicentrico	
Direzione (sist inf)	Creazione di software dedicato	
Clinica	Reclutamento	
Clinica	Follow-up	
Ricerca	Analisi dati	

Multicenter, randomized, controlled trial

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
Search for studies: Search
Advanced Search | Help | Studies by Topic | Glossary

Now Available: Final Rule for FDAAA 801 and NIH Policy on Clinical Trial Reporting

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Search Results > Study Record Detail Text Size

Trial record **1 of 1** for: Multi-segmental Robotic and Technological Upper Limb Rehabilitation in Stroke
Previous Study | Return to List | Next Study

Multi-segmental Robotic and Technological Upper Limb Rehabilitation in Stroke

This study is currently recruiting participants. (see Contacts and Locations)

Verified August 2016 by Fondazione Don Carlo Gnocchi Onlus

Sponsor:
Fondazione Don Carlo Gnocchi Onlus

Information provided by (Responsible Party):
Irene Giovanna Aprile, Fondazione Don Carlo Gnocchi Onlus

ClinicalTrials.gov Identifier:
NCT02879279

First received: August 11, 2016
Last updated: August 22, 2016
Last verified: August 2016
History of Changes


LAPS
22/30

Future project: to test robot mediate treatment for walking in a wide sample (RTC)

Multicenter, randomized, controlled trial

Staff

Roma Santa Maria della Provvidenza (RM): Irene Aprile, Marco Germanotta, Arianna Cruciani, Cristiano Pecchioli, Simona Loreti, Stefania Lattanzi, Laura Cortellini, Dyonisia Papadopulous, Giuliana Liberti, Francesca Panzera, Piera Mitrione,Dario Ruzzi, Giuliana Rinaldi, Donatella Caccia, Simona Adduci, Enrica Di Sipio, Chiara Iacovelli, Chiara Simbolotti, Isabella Imbimbo, Luca Padua

Roma Santa Maria della Pace (RM): Fabio De Santis, Anna Rita Pellegrino, Pietro Spinelli, Serena Marsan, Ilaria Bastoni

Milano Santa Maria Nascente (MI): Angelo Montesano, Anna Castagna, Cristina Grosso, Paola Ammenti, Azzinnaro Luca, Barbieri Daniela, Cassani Silvia, Corrini Chiara, Meotti Matteo, Parelli Riccardo, Spedicato Albino, Zocchi Marta, Marcella Loffi, Domitilla Manenti, Laura Negri.

Rovato (BS): Silvia Galeri, Fulvia Noro, Luca Medici, Romina Garattini, Federica Bariselli, Marin Luli, Stefano Negrini

La Spezia: Manuela Diverio, Elena Giannini, Assunta Gabrielli, Barbara Deidda, Benedetta Gnetti, Paola Beatini, Giulia Giansanti, Angela Lograsso e Stefania Callegari.

Firenze (FI): Assunta Pizzi, Catiuscia Falsini, Federica Vannetti, Antonella Romanelli, Gabriella De Luca, Elisabetta Simoncini, Monica Martini, Elisa Peccini.

Fivizzano (MS): Francesca Cecchi, Lucia Avila, Manuele Barilli, Assunta Gabrielli, Giorgia Giannarelli, Elisabetta Lerda, Miriam Vasoli, Andrea Bertolini.

Massa (MS): Francesca Cecchi, Lucia Avila, Assunta Gabrielli, Elisabetta Bertocchi, Valter Marsili, Brunella Tognoni

Sant'Angelo dei Lombardi (AV): Giovanni Vastola, Gabriele Speranza, Massimo Colella, Gaetanina Competiello, Antonietta Chiusano, Antonella Della Vecchia, Soriano Pasqualina, Michela Pagliarulo, Rita Mosca.

Tricarico (MT): Nicola Lioi, Federico Marrazzo, Stefano Larocca, Roberta Calia, Sara Benevento.

Acerenza (PZ): Vito Remollino, Emanuele Langone, Marcello Magliulo, Giuseppe Araneo