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## Robot assisted training for the upper limb after stroke (RATULS): a multicentre randomised controlled trial

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### Abstract

**Background:** Loss of arm function is a common problem after stroke. Robot-assisted training might improve arm function and activities of daily living. We compared the clinical effectiveness of robot-assisted training using the MIT-Manus robotic gym with an enhanced upper limb therapy (EULT) programme based on repetitive functional task practice and with usual care.

**Methods:** RATULS was a pragmatic, multicentre, randomised controlled trial done at four UK centres. Stroke patients aged at least 18 years with moderate or severe upper limb functional limitation, between 1 week and 5 years after their first stroke, were randomly assigned (1:1:1) to receive robot-assisted training, EULT, or usual care. Robot-assisted training and EULT were provided for 45 min, three times per week for 12 weeks. Randomisation was internet-based using permuted block sequences. Treatment allocation was masked from outcome assessors but not from participants or therapists. The primary outcome was upper limb function success (defined using the Action Research Arm Test [ARAT]) at 3 months. Analyses were done on an intention-to-treat basis. This study is registered with the ISRCTN registry, number ISRCTN69371850.

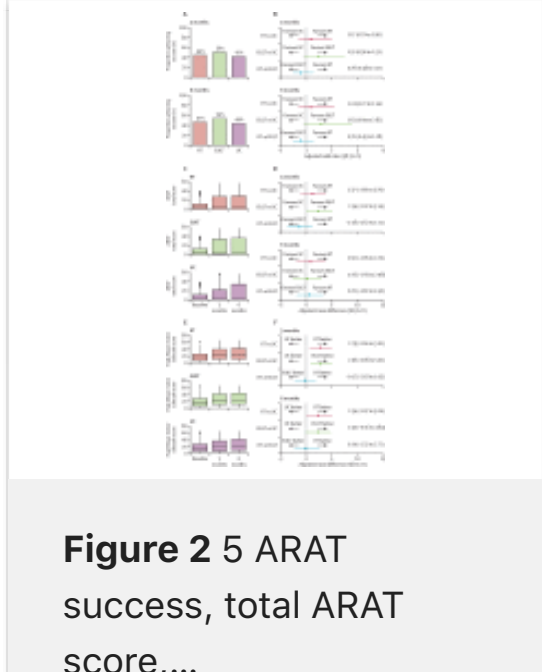
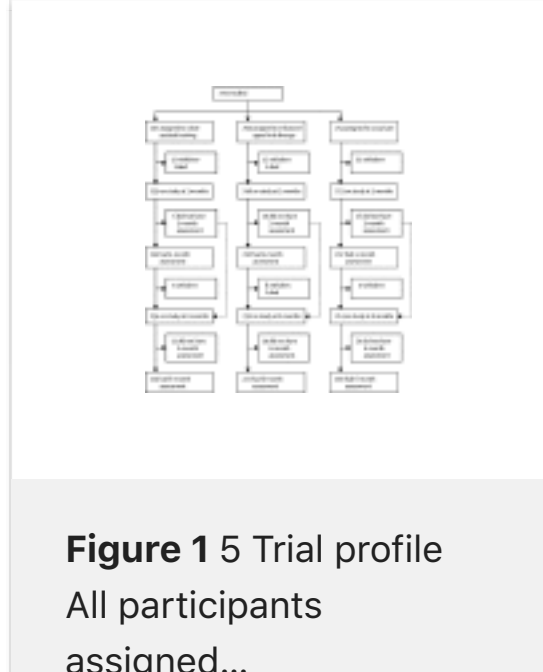
**Findings:** Between April 14, 2014, and April 30, 2018, 770 participants were enrolled and randomly assigned to either robot-assisted training (n=257), EULT (n=259), or usual care (n=254). The primary outcome of ARAT success was achieved by 103 (44%) of 232 patients in the robot-assisted training group, 118 (50%) of 234 in the EULT group, and 85 (42%) of 203 in the usual care group. Compared with usual care, robot-assisted training (adjusted odds ratio [aOR] 1.17 [98.3% CI 0.70-1.96]) and EULT (aOR 1.51 [0.90-2.51]) did not improve upper limb function; the effects of robot-assisted training did not differ from EULT (aOR 0.78 [0.48-1.27]). More participants in the robot-assisted training group (39 [15%] of 257) and EULT group (33 [13%] of 259) had serious adverse events than in the usual care group (20 [8%] of 254), but none were attributable to the intervention.

**Interpretation:** Robot-assisted training and EULT did not improve upper limb function after stroke compared with usual care for patients with moderate or severe upper limb functional limitation. These results do not support the use of robot-assisted training as provided in this trial in routine clinical practice.

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