The Effects of Intramuscular FES on Objective Gait Measures in Adult Patients with Chronic Stroke: A Systematic Review

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Purpose

- To determine the effectiveness of intramuscular functional electrical stimulation (IM-FES) for improving gait in adult patients with chronic cerebrovascular accident (CVA)

Introduction[1]

- Stroke can cause persistent weakness and hemiplegia with impaired coordination leading to an increased fall risk and gait deviations

- FES is the application of electrical current to excite contractile tissue to supplement or replace lost function
  - Transcutaneous FES
  - Intramuscular FES

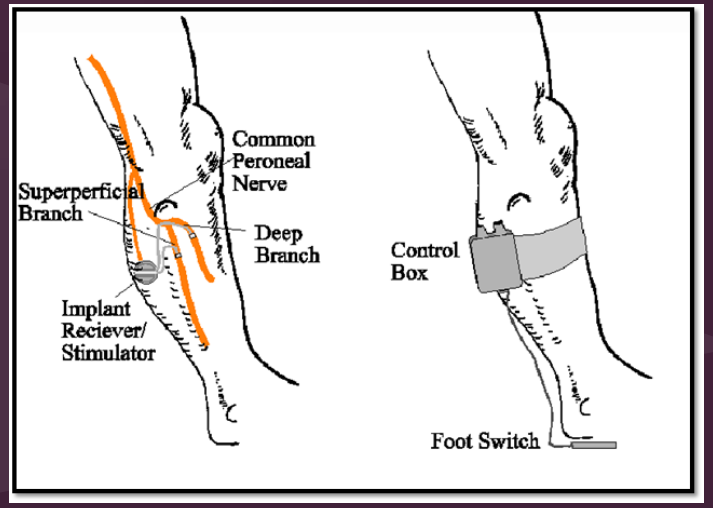


Figure 1. IM-FES

IM-FES Defined[2]

- The implantable nerve stimulator consists of:
  - External transmitter with a built-in antenna
  - Foot switch
  - Stimulator
  - Leads
  - Bipolar intraneural electrodes

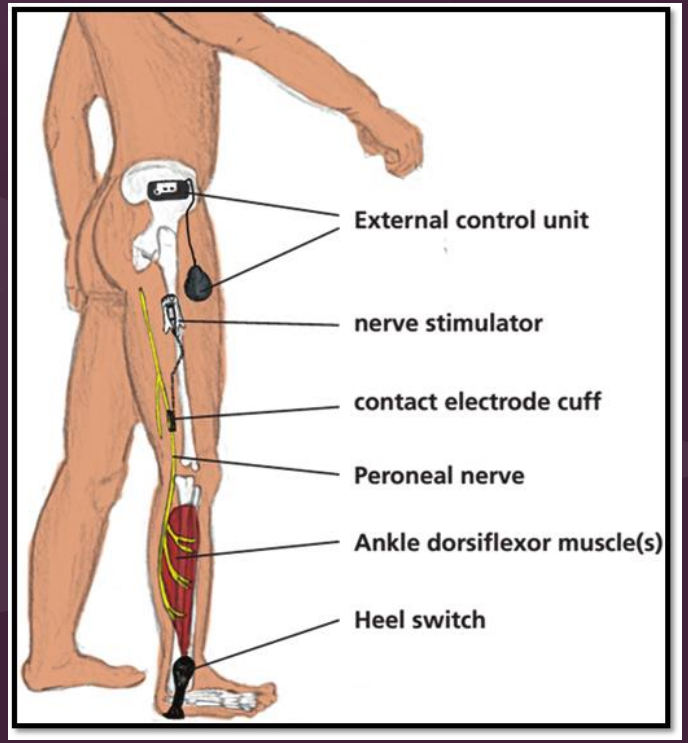


Figure 2. Actigait IM-FES

IM-FES Defined[2-3]

- A footswitch placed under the heel of the patient's foot inside the shoe activates and deactivates the stimulation.
- The implantable nerve stimulator receives information carried by radiofrequency signals and converts them into the stimulation pulses of the desired amplitude and frequency.

IM-FES Parameters & Muscles[2,4-6]

- IM-FES Parameters (within comfort):
  - Amplitude: 4 - 20 mA
  - Pulse width: 1 - 150 μs
  - Frequency: 15 - 50 Hz
- Muscles:
  - Tibialis anterior
  - Peroneus longus & brevis
  - Gastrocnemius, lateral head
  - Biceps femoris
  - Semimembranosus
  - Semitendinosus
  - Vastus lateralis
  - Gluteus medius
- Nerves:
  - Superficial and Deep Peroneal

Methods

Materials and Methods

- The conducted literature search included:
  - CINAHL
  - PubMed
  - ProQuest Nursing and Allied Health
  - SAGE Journals
  - Cochrane Library

- Two reviewers independently assessed each study
  - PEDro Scale

Search Terms

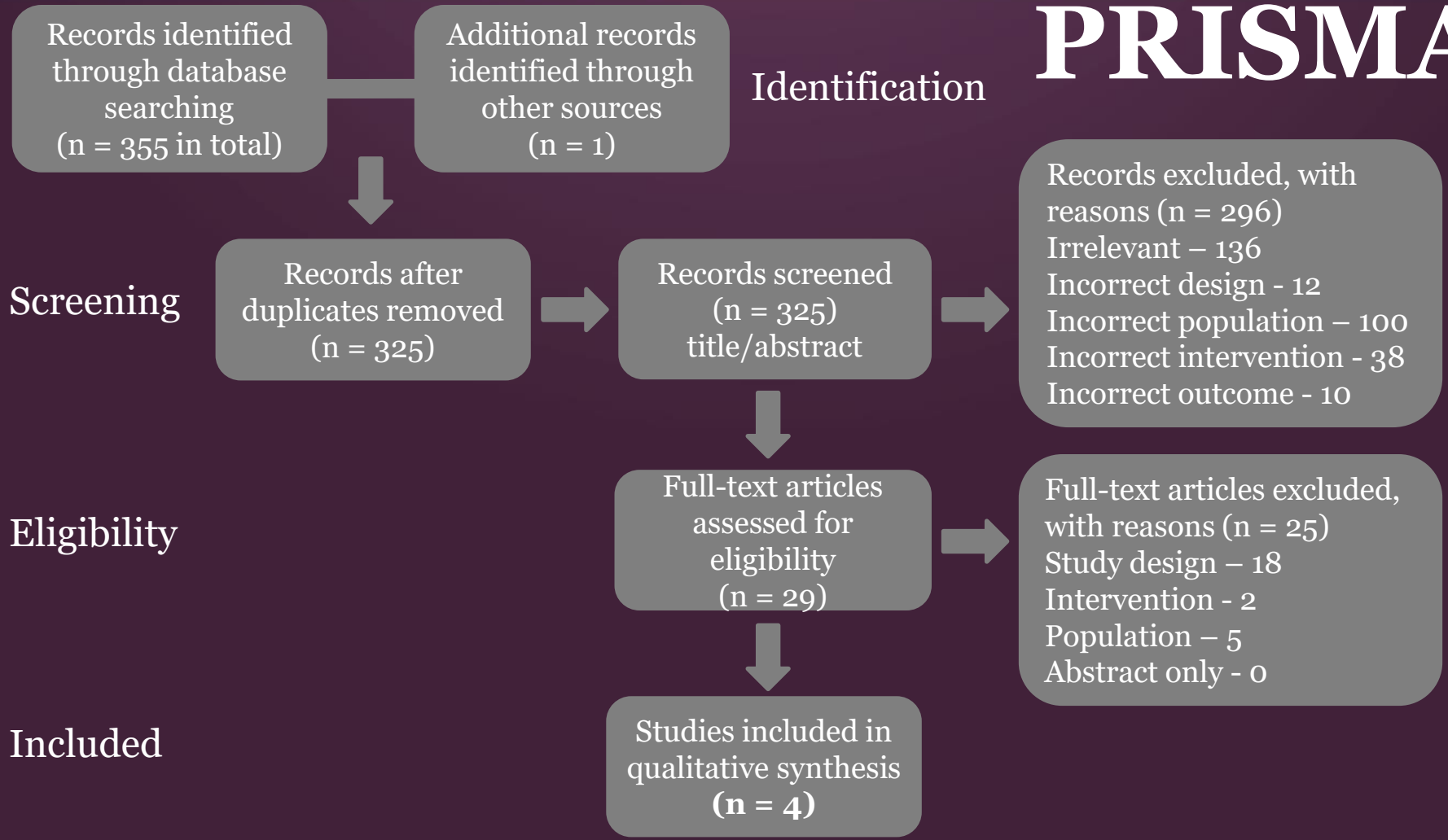
- (implant* FES **OR** neuroprosthetic **OR** neuroprosthesis **OR** implant* stimulator) **AND** (lower leg **OR** lower extremity **OR** ankle) **AND** (gait **OR** ambulat* **OR** walk*) **NOT** microprocessor

- Search limits:
  - Human subjects
  - Peer-reviewed
  - English language

Selection Criteria

- Randomized controlled trials (RCTs)
- Implantable FES
- Objective gait outcome measures
- Adults (≥18 years old)
- Chronic CVA (>6 months)

PRISMA


Records identified through database searching (n = 355 in total)
Additional records identified through other sources (n = 1)
Identification
Screening
Records after duplicates removed (n = 325)
Records screened (n = 325) title/abstract
Records excluded, with reasons (n = 296)
Irrelevant – 136
Incorrect design - 12
Incorrect population – 100
Incorrect intervention - 38
Incorrect outcome - 10
Eligibility
Full-text articles assessed for eligibility (n = 29)
Full-text articles excluded, with reasons (n = 25)
Study design – 18
Intervention - 2
Population – 5
Abstract only - 0
Included
Studies included in qualitative synthesis (n = 4)

PEDro Scale

Author	1	2	3	4	5	6	7	8	9	10	Total
Kottink et al. (2012)[2]	Y	Y	Y	N	N	N	N	N	Y	Y	5/10
Daly et. al. (2004)[6]	Y	N	Y	N	N	Y	N	Y	Y	Y	6/10
Daly et. al. (2006)[5]	Y	Y	Y	N	N	Y	N	N	Y	Y	6/10
Daly et al. (2011)[4]	Y	Y	Y	N	N	Y	Y	N	Y	Y	7/10

Results

Results

- All studies examined the effects of IM-FES to improve gait for adults with chronic CVA[2,4-6]
  - 124 subjects
- Body-weight supported treadmill training (BWSTT) and gait training were used for the control and intervention groups in 3 studies[4-6]
  - 1.5 hours
  - 4x per week
  - 12 weeks
- 1 study compared IM-FES to conventional walking devices[2]

Results

- Adverse effects of IM-FES included discomfort & erythema[4-5]
  - No infections were reported

- Outcomes were assessed pre- and post-treatment[2,4-6]
  - 6 month follow-ups were used for 2 studies[4,6]

Results

- All IM-FES groups had statistically significant improvements in gait outcomes compared to controls[2,4-6]
- Temporal distance
  - Gait Assessment and Intervention Tool (G.A.I.T.)[4]
  - Tinetti Gait (TG)[5]
  - Observational Gait Analysis (OGA)[2,4-6]
- Kinematics[2]
  - Reduced stance on paretic side
  - Reduced double support on paretic side
  - Longer first single support on non-paretic side
  - Timing/range of dorsiflexion (DF) during swing

Results

- Greater gains in self-reported functional mobility[5]
- Retention of coordinated gait components occurred 6 months post-treatment and after IM-FES removal[4]
  - Controls worsened significantly at follow-up[4]

Conclusion

Conclusion

- There is moderate evidence to support IM-FES for improving gait in patients with chronic CVA vs BWSTT or gait training alone[4-6]
- IM-FES resulted in normalized initial loading response in comparison to a conventional walking device[2]
- One study showed retention in gait kinematics 6 months post-treatment following removal of IM-FES[4]

Clinical Relevance

- Clinicians should consider using IM-FES to promote greater retention of gait improvements vs. gait training alone in adults with chronic CVA

- IM-FES is a safe and feasible intervention which may enhance carry-over and reduce falls

Limitations

- Several articles were published by the same authors
- Small sample size
- Inability to blind
- Invasive surgery
- Adverse effects
- Co-intervention
- Varied outcome measures and protocols
- Inability to generalize to other populations

Future Research

- Future research should:
  - Compare IM-FES to transcutaneous FES with gait training
  - Include larger sample sizes
  - Include other populations

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Comments or Questions?