Functional electrical therapy: Retraining grasping in spinal cord injury

Milos R. Popovic[1,2], T. Adam Thrasher[1,2], Marlene E. Adams[2], Veronica Takes[2], Vera Zivanovic[2] and Mark I. Tonack[2]

[1] Institute of Biomaterials and Biomedical Engineering, University of Toronto, Canada

[2] Lyndhurst Centre, Toronto Rehabilitation Institute, Canada

Corresponding Author:

Dr. T. Adam Thrasher

Rehabilitation Engineering Laboratory

Toronto Rehabilitation Institute

520 Sutherland Drive

Toronto, Ontario

M4G 3V9, Canada

Phone: +1-416-597-3422 ext. 6304

Fax: +1-416-425-9923

1 E-mail: adam.thrasher@utoronto.ca

2 Web site: www.toronto-fes.ca

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ABSTRACT

Objective: To determine the clinical efficacy of functional electrical therapy in the rehabilitation of grasping function for quadriplegics.

Study design: Randomized intervention-versus-control trial.

Setting: Rehabilitation hospital for spinal cord injury in Toronto, Canada.

Methods: 21 people with new spinal cord injuries ranging from C3 to C7 were randomly assigned to two groups: Control (N=9) and Intervention (N=12). The intervention was functional electrical therapy, which consisted of repetitive grasping exercises using a neuroprosthesis that applied surface electrical stimulation to the arm to generate and/or assist grasping movements. It was applied by registered Occupational Therapists in a clinical setting. Main outcome measures were: Functional Independence Measure (FIM), Spinal Cord Independence Measure (SCIM), and the Rehabilitation Engineering Laboratory Hand Function Test. Consumer perceptions of functional electrical therapy were assessed via qualitative interviews.

Results: Differences between the Control and Intervention groups could be observed although they are not significant due to an insufficient number of participants. Consumer perceptions were positive, including improved Activities of Daily Living and self-satisfaction.

Conclusion: Functional electrical therapy has the potential to be an effective treatment modality to restore grasping function in quadriplegia. It can be implemented by occupational therapists in a clinical setting. Further research is required to establish suitable indications for participant selection. In addition, a larger number of participants is needed to demonstrate statistical significance of the Functional Electrical Therapy.

Key Words: Neuroprosthesis, functional electrical stimulation, functional electrical therapy, spinal cord injury, quadriplegia, grasping and hand functions

INTRODUCTION

In recent decades, a number of Functional Electrical Stimulation (FES) devices have been developed to assist people with severe motor paralysis to improve grasping function[1]. Some neuroprostheses for grasping have been successfully commercialized, and are intended for everyday use[2,3]. The available neuroprostheses for grasping are able to restore two useful styles of grasping: the palmar and the lateral grasp. Palmar grasp is used to hold larger and heavier objects such as cans and bottles between the palm of the hand and the four fingers. Lateral grasp is used to hold smaller and thinner objects such as keys, paper, and compact discs between the thumb and

forefinger. Lateral grasp is generated by flexing the fingers to provide opposition followed by thumb flexion. Palmar grasp is generated by forming the opposition between the thumb and the palm, followed by simultaneous flexion of both the thumb and the fingers.

It has been reported that many patients who use FES on a regular basis experience significant carry-over in function that persists even when the device is not in use[4-7]. A neurological mechanism for such changes has been hypothesized[8]. Now, the potential role of neuroprostheses as therapeutic interventions in clinical practice is beginning to be realized. Applications of FES that attempt to harness this therapeutic effect have been dubbed Functional Electrical Therapy (FET)[9]. The basic FET approach is to regularly use a neuroprosthesis to facilitate functional exercises in a clinical environment for a period of several weeks. The goal is increased function, with a concomitant increase in independence and quality of life.

Neuroprostheses for grasping have been successfully implemented in rehabilitation programs for severe hemiplegia[10] and acute quadriplegia[11]. To date, all studies on the application of FET to the Spinal Cord Injury (SCI) population have been case series conducted without a control group. The present study represents the first randomized intervention-versus-control design to be applied to FET in SCI, which is necessary to establish the efficacy of FET as an intervention compared to conventional physiotherapy and occupational therapy techniques.

METHODS

The study presented herein describes a randomized intervention-versus-control trial. The method for analyzing data was specified in the protocol before the study begun. The study received ethical approvals from the University of Toronto and the Toronto Rehabilitation Institute ethics boards. The patients were invited to participate in the study and they gave consent before the inclusion/exclusion criteria were applied. After the participants were admitted to the program and baseline assessments were made, they were randomly assigned to control and intervention groups. A flow chart indicating the order of recruitment, therapies, and assessments that were applied to all participants is shown in Figure 1**.**

So far, a total of 21 participants with SCI at most 8-months post-injury at the time of recruitment have completed the study. Demographic and neurological data for all participants are given in Table 1. Participants were recruited from the in-patient population at the SCI unit at the Toronto Rehabilitation Institute. Participants included both motor complete (ASIA A and B) and incomplete (ASIA C and D) SCI.

After they were admitted to the program, the participants were *randomly assigned* to two groups: *Control group*, which was administered only conventional physiotherapy and occupational therapy; and *Intervention*

group, which was administered FET in addition to conventional physiotherapy and occupational therapy.

Participants were randomized using two sets of sealed envelopes. An eligible participant first selected from an unmarked set of 40 envelopes. Each unmarked envelope contained a single sheet of paper with a printed number in the range of 1 to 40. In the second set of envelopes, which were marked with numbers from 1 to 40, single sheets of paper indicating either "control" or "intervention" were sealed. Thus, twenty randomly selected numbers in the range of 1 to 40 were assigned to the Control group, and the remaining 20 numbers were assigned to the Intervention group. Randomization of the numbers was done using the *randperm* function in Matlab (The Mathworks Inc., Natick, MA) seeded with an arbitrary clock value. After the participant selected a random number from the set of unmarked envelopes, the corresponding marked envelope was opened revealing the group to which the participant was assigned. Opened envelopes were destroyed immediately. This method ensured that the randomization process could not be contaminated.

Both Control and Intervention groups were administered their respective therapies for 12 weeks, five days per week, one session per day and 45 minutes per session.

Conventional Therapy

The control group received conventional occupational therapy pertaining to hand function. The conventional occupational therapy included: muscle facilitation exercises emphasizing the normal movement treatment approach; task-specific, repetitive functional training; strengthening and motor control training using resistance to available arm motion to increase strength; stretching exercises; electrical stimulation applied primarily for muscle strengthening (this is not FES or FET); training in activities of daily living including self-care involving compensatory upper extremity movements as appropriate; and caregiver training.

Functional Electrical Therapy

Hardware

The Compex Motion electric stimulator was used as a hardware platform for the neuroprosthesis for reaching and grasping[12].

Treatment Protocol

The intervention group received both conventional occupational therapy and FET pertaining to hand function. Ethical concerns prohibit the evaluation of FET without conventional occupational therapy.

Pre-FET Muscle Strengthening

Due to the quadriplegia, many people with SCI are unable to voluntarily contract or control some upper extremity muscles. This lack of muscle use causes significant changes in the physiology of inactive muscles. Typically with time, muscle strength decreases and the fiber ratio changes towards fast fiber predominance. This process occurs relatively quickly, resulting in a significant loss of original muscle strength only weeks after the onset of injury. The longer that these muscles remain inactive, the more severe is the muscle strength deterioration. Therefore, before the start of the functional training, and when required, the patient participated in a muscle-strengthening program.

The muscle-strengthening program is standard practice in our laboratory. It is used to stop and reverse muscle atrophy by actively exercising muscles via electrical stimulation. It consisted of five phases and was carried out with standard surface stimulation technology. Self-adhesive surface stimulation electrodes were placed on the participant's arm above the muscles/nerves that were stimulated, as shown in Figure 2. The following muscles/nerves were stimulated: *flexor digitorum superficialis m.* and the *flexor digitorum profundus m.* (finger flexion); *median nerve* or *thenar m.*, and *flexor pollicis longus m.* (thumb opposition and flexion); *extensor digitorum m.* (finger extension); *flexor carpi radialis m.* and *flexor carpi ulnaris m.* (wrist flexion); *extensor carpi radialis longus* and *brevis*

m., and *extensor carpi ulnaris m.* (wrist extension). The stimulation parameters used on these muscles/nerves were: 1) balanced, biphasic, current regulated electrical pulses; 2) pulse amplitude from 8 to 50 mA (typical values 17-26mA); 3) pulse width 250 μs; and 4) pulse frequency from 20 to 70 Hz (typical value 40 Hz).

It is important to mention that prior to the muscle-strengthening program, the participant was assessed to determine which muscles could be stimulated using surface FES technology and which combination of muscle contractions generated the palmar and/or the lateral grasp. The muscles that could generate one or both grasps were stimulated during the muscle-strengthening program. Other muscles in the forearm and hand were not trained during the muscle-strengthening program. The necessity for each of the muscle strengthening phases was determined by manual testing of the corresponding grasp or release strength. Participants were considered to have sufficient strength to advance to the next phase if they were able to grasp/release a small cylindrical object against manual resistance applied to the object by the therapist (approximately 0.5 to 1.0 Nm torque).

<u>Phases of the muscles strengthening program:</u>

PHASE 1: 15 minutes of 10 s full muscle contraction (pulse characteristics: balanced, biphasic, current regulated electrical pulses; amplitude from 8 to 50 mA; pulse width 250 μs; and pulse frequency 40 Hz) followed by 10 s of muscle relaxation (pulse characteristics: balanced biphasic current regulated electrical pulses; amplitude ½ of the amplitude used during full muscle stimulation; pulse width 250 μs; and pulse frequency 1 Hz). This stimulation protocol was carried out until the stimulated muscle generated solid tetanic contractions against manual resistance during all "full muscle stimulation" phases.

PHASE 2: 15 minutes of 30 s full muscle contraction (same pulse parameters as in Phase 1) followed by 30 s of muscle relaxation (same pulse parameters as in Phase 1). This stimulation protocol was carried out until the stimulated muscle generated solid tetanic contractions against manual resistance during all "full muscle stimulation" phases.

PHASE 3: 15 minutes of 60 s full muscle contraction (same pulse parameters as in Phase 1) followed by 60 s of muscle relaxation (same pulse parameters as in Phase 1). This stimulation protocol was carried out until the stimulated muscle generated solid tetanic contractions against manual resistance during all "full muscle stimulation" phases.

PHASE 4: 15 minutes of 120 s full muscle contraction (same pulse parameters as in Phase 1 except for frequency, it was reduced to 20-25 Hz) followed by 60 s of muscles relaxation (same pulse parameters as in Phase

1). This stimulation protocol was carried out until the stimulated muscle generated solid tetanic contractions against manual resistance during all "full muscle stimulation" phases.

PHASE 5: 15 minutes of 180 s full muscle contraction (same pulse parameters as in Phase 4) followed by 60 s of muscle relaxation (same pulse parameters as in Phase 4). This stimulation protocol was carried out until the stimulated muscle generated solid tetanic contractions against manual resistance during all "full muscle stimulation" phases.

FET-Functional Training Intervention

FET was applied and supervised by two registered occupational therapists. Each participant in the Intervention group was asked to execute a one-handed task (e.g. reaching and grasping a pen). The participant would first try to execute the task unassisted. The components/sequences of the task that the participant was unable to carry out him/herself had to be assisted by the neuroprosthesis. Hence, the functional training for the Intervention group began by designing a stimulation protocol that could assist or generate the palmar and/or the lateral grasp on demand. In other words, the stimulation sequence (protocol) was developed for each participant individually using a Compex Motion stimulator that allowed the participant, who otherwise could not grasp, to do so with the FES system. No splinting

was used during the application of FET. The electrodes were placed with great care to produce only the desired movements. Therefore, it was not necessary to block wrist flexion or extension.

The command for activating the stimulation sequence was issued with a push button. By pressing a push button the participant commanded hand opening and closing, and also select the type of grasp to be executed[12]. Stimulation parameters that were used in these trials were: 1) balanced, biphasic, current regulated electrical pulses; 2) pulse amplitude from 8 to 50 mA (typical values 17-26 mA); 3) pulse width 250 μs; and 4) pulse frequency from 20 to 70 Hz (typical value 40 Hz). Once the individualized neuroprosthesis for grasping was developed for a participant, he/she was trained with the systems to perform grasping and releasing of everyday objects, such as a soft drink can, pencil, credit-card, etc. The participant was asked to repeat the same hand task 30 to 50 times during a 45-minute treatment session. During the intervention, the occupational therapist adjusted the placement of electrodes and guided the hand movements. The occupational therapist ensured that all movements were functional, efficient and used normal movement patterns. An independent hand strengthening and stretching program was provided as needed to facilitate normal hand function.

The first signs of functional recovery were observed four to six weeks after the onset of the FET program. As soon as the participant

showed signs of recovery of either the voluntary extension or flexion in a stimulated muscle group, he/she was encouraged to make an effort to produce the movement voluntarily, which was previously facilitated by the FET. As the participant showed improved strength and range of motion, the FET for that muscle group was phased out and moved to another muscle group that was still paralyzed and needed to be "reactivated". The order in which muscle groups were sequentially "reactivated" was patient dependent.

Outcome Measures

Functional/Independence Tests

The following tests were administered to all participants in the study before and after the intervention (both Control and Intervention groups). All tests were performed *without* stimulation.

1. Functional Independence Measure (FIM) – total score[13].
2. Spinal Cord Independence Measure (SCIM) – total score[14].
3. Rehabilitation Engineering Laboratory Hand Function Test (REL test) of each arm – total score[10]. This test was developed to evaluate improvements in the gross motor function of the unilateral grasp due to neuroprosthesis for grasping treatment. The REL test was the only nonstandard test applied in this study. In summary, the hand functions that were tested with the REL test are: *lateral or*

pulp pinch, and *palmar* grasps. This test consists of five components:

i. Objects – An ordinal scale representing the lifting of several ordinary objects using different hand positions (0 to 56).
ii. Blocks – An ordinal scale representing the lifting of wooden blocks with varying degrees of slipperiness and weight (0 to 18).
iii. Cylinder – A numerical measurement of the maximum torque generated by a palmar grip on a 3 cm diameter cylinder.
iv. Credit card – A numerical measurement of the maximum force resisted by a pinch grasp on a credit card.
v. Wooden bar – A numerical measurement of the eccentric load that can be held in a pronated palmar grip, measured using an axe handle of approximately 3 cm diameter and 50 cm length.

Scoring: With exception to the *instrumented cylinder*, *credit card attached to a dynamometer* and *wooden bar*, all test objects were placed on a desk 20 to 30 cm in front of the participant, one after another. The participant was requested to pick up the objects, lift them in front of his/her chest and move the objects from supination, to neutral and then to pronation position. In each position, the

participant was told to hold the object for 20 to 30 s. If the participant was unable to hold the object in any of these three positions, then he/she received 0 points for that position. The participant received 1 point if they could hold the object for a short period of time (2 to 10 s) and then eventually drop it. Finally, participants received 2 points if he/she was able to hold the object for 20 to 30 s in the intended hand position. The *instrumented cylinder*, *credit card attached to a dynamometer* and *wooden bar* were used to measure torque generated by the palmar grasp, force produced by the pinch grasp, and exocentric load that the palmar grasp can sustain, respectively.

Statistical Analysis

Changes in the outcome measures were tested for statistical significance using a Wilcoxon rank-sum test, which is non-parametric and robust to non-normal distributions of data. Participants with motor complete SCI were analyzed separately from participants with motor incomplete SCI. The allotment to these two groups was based on admission diagnosis and the physician's clinical observations.

Consumer Perceptions

All participants in the Intervention group attended a face-to-face interview session. Interviews were carried out two weeks after completing

intervention and prior to permanent discharge from in-patient rehabilitation services. The purpose of the interviews was to provide an opportunity for participants to describe their experiences and perceptions of using the neuroprosthesis. Specific attention was directed toward documenting both positive and negative attributes of the intervention as well as determining how participants perceived impact on their quality of life. Interviews lasted from 30 to 60 minutes; all discussions were recorded on audiocassettes. General, open-ended questions were supported by prompts and follow-up questions.

In a qualitative research approach the data analysis proceeds in parallel with the data collection. This analytical process is based on well-established procedures in the social sciences[15-17]. Based on the method of inductive analysis, the interview tapes were systematically scrutinized and emergent themes and sub-themes were identified. Once thematic saturation was accomplished, data analysis was terminated. A trained qualitative researcher, a staff research scientist that was not involved in any other aspect of the study, conducted this data collection and analysis.

RESULTS

Improvements between baseline and post-treatment scores were seen in all tests and groups with two exceptions: the credit card force test for participants with incomplete SCI and the blocks test for participants with complete SCI. The differences between mean scores obtained at baseline and at the end of the intervention period for the individuals with complete SCI are shown in Figure 3. Figure 4 shows the changes over the course of treatment for the participants with incomplete SCI. As indicated by the error bars, there was a great deal of variance between participants in most measures. Due to the low number of subjects, no significant differences were found between the Control and Intervention groups. Figures 5 and 6 show "Box and Whisker" plots of all quantitative outcome measures at baseline and the end of treatment separated by group and type of injury (complete and incomplete SCI). The data so far suggests that greater improvements are seen in hand function when FET is added to the therapy program.

The qualitative interviews revealed that all participants in the Intervention group decided to enter the study because they wanted to see if the treatment regime would affect their function in a positive manner. The sub-themes identified are summarized in Table 2. Some just wanted the opportunity to be involved in as much therapy as possible – regardless of the type of therapy. All participants articulated advantages or outcomes that they did not expect. All participants stated that the functional changes they

experienced were important, regardless of degree, because improvement enhanced their personal independence. Respondents reported that the success with FET motivated them to work harder in other facets of their rehabilitation. In addition, they often described feeling a sense of self-satisfaction and improved well-being. Participants did not identify any negative aspects of using the neuroprosthesis. In fact, all individuals indicated that they would prefer to continue to use the equipment because of their positive experiences. However, participants did explain that there were some negative aspects of testing for the correct location of the electrodes and that initially there was some minimal pain, which one got used to eventually. Most participants felt that donning and doffing the equipment could be improved. All participants felt that FES interventions should be a regular part of rehabilitation programs and further suggested that the equipment should be available for outpatient and fitness programs.

DISCUSSION

We compared the outcomes of four groups of SCI individuals with upper extremity paralysis or paresis. One group consisted of individuals with complete SCI that received conventional occupational therapy, which is commonly a part of their rehabilitation. The second group consisted of individuals with complete SCI that were administered FET combined with

conventional occupational therapy. The third group consisted of individuals with incomplete SCI that were administered conventional occupational therapy. The fourth group was individuals with incomplete SCI that were administered FET combined with conventional occupational therapy. These preliminary results show that the subjects who were treated with the neuroprosthesis for grasping showed overall better outcomes compared to the controls, but the improvements are not statistically significant.

Our treatment protocol stresses the importance of applying a surface FET intervention that can be tailored and adjusted to patients' needs on a daily basis and can evolve as the patients improve their function. Furthermore, our findings suggest that if a participant who attempts to execute a grasping task is assisted with the FET to carry out that task, he/she is effectively voluntarily generating the motor command (desire to move the arm, i.e. *command input*). It is suggested that FET is providing the afferent feedbacks (*system's output*), indicating that the command was executed successfully. We hypothesize that by providing both the command input and system's output to the central nervous system (CNS) repetitively for prolonged periods of time, this type of treatment facilitates functional reorganization and retraining of intact parts of the of CNS and allows them to take over the function of the damaged part of the CNS[8]. It is important to add that during the intervention the participants were performing grasping tasks repetitively. We believe that diversity of meaningful tasks combined

with high repetition may play an important role in retraining grasping functions.

The results presented in this article indicate that patients with SCI show considerable improvements in FIM scores if they were trained with FET compared to controls. This result is very different from the one we have reported in the study where FET was applied to patients with severe hemiplegia[10]. This finding can be easily explained because individuals with SCI usually have bilateral disability, which is not the case with individuals with hemiplegia. Individuals with hemiplegia, with time and intensive therapy, learn how to reach and grasp objects using the healthy arm. Hence, in these subjects, improving the function in the disabled arm does not produce significant changes in FIM scores. However, in SCI individuals, who typically have bilateral disability, even minute changes in the hand function precipitate in measurable improvements in FIM and SCIM scores. This clearly explains why participants who had FET therapy and have improved hand function considerably have shown improvements in FIM and SCIM scores. Therefore, these results suggest that FET applied to hand function in SCI individuals has a potential to positively impact performance in activities of daily living and to provide needed independence measured by FIM and SCIM.

Another very important and unexpected finding is that individuals with complete SCI appear to benefit relatively more from FET compared to

individuals with incomplete SCI. In other words, the relative changes in the outcome measures are higher in individuals with complete SCI compared to individuals with incomplete SCI. This finding suggests that individuals with complete SCI who were unable to perform a function on their own prior to the intervention were stimulated with the FET to improve the function beyond what is achievable with conventional therapy. This strengthens our hypothesis that by providing both the command input and system's output to the CNS repetitively for prolonged periods of time, this type of treatment facilitates functional reorganization and retraining of intact parts of the of CNS and allows them to take over the function of the damaged part of the CNS. Since individuals with complete SCI had no means to generate the "output" signals for CNS, unlike some individuals with incomplete SCI, the FET's assistance in generating these signals was instrumental in achieving the desired functional recovery. These findings also suggest that the change most likely was central (CNS) instead of peripheral (muscle strengthening). This finding supports results obtained in a similar study with severe stroke individuals[10].

In closing, the results suggest that people with SCI can benefit functionally from FET. We have also demonstrated that FET can be applied practically and efficiently in a rehabilitation setting with suitable equipment and training of therapists.

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TABLE 1 – Participants' demographic and neurological data

Complete SCI Control Group –received conventional occupational therapy

Subject	Sex	Age	Neurological level at baseline	Cause of injury*	Intervention start date in days after SCI
AABE	M	44	C6	Fall	243
AABO	M	49	C7	MVA	158
AABX	M	58	C5	Fall	41
AADA	M	24	C6	Fall	26

Incomplete SCI Control Group –received conventional occupational therapy

Subject	Sex	Age	Neurological level at baseline	Cause of injury*	Intervention start date in days after SCI
AABN	M	51	C3	Fall	76
AABP	M	64	C3	MVA	15
AACX	M	56	C3	Fall	33
AADC	M	63	C4	Fall	41
AADH	M	70	C4	MVA	53

Complete SCI Intervention Group – received the neuroprosthesis (FET) intervention

Subject	Sex	Age	Neurological level at baseline	Cause of injury*	Intervention start date in days after SCI
AAAO	M	25	C5	MVA	86
AAAR	M	20	C7	MVA	27
AAAY	M	26	C4	Bicycle	84
AABI	M	32	C6	MVA	31
AABS	M	40	C6	Diving	19
AABW	M	16	C5	Wrestling	28

Incomplete SCI Intervention Group – received the neuroprosthesis (FET) intervention

Subject	Sex	Age	Neurological level at baseline	Cause of injury*	Intervention start date in days after SCI
AAAG	M	60	C5	Fall	142
AAAN	M	21	C6	MVA	64
AABD	M	65	C4	Fall	31
AABT	M	37	C6	Fall	15
AACC	M	21	C7	Diving	28
AACK	M	35	C6	Fall	27

* MVA – Motor Vehicle Accident

TABLE 2 – Consumer Perceptions: Summary of sub-themes identified from qualitative interviews

Improvements/Positive Outcomes
- Increased flexibility
- Sense of enhanced strength hands and fingers
- Improved dexterity
- Reduced chronic pain
- Enhanced sense of well being
- Enhanced Motivation

Impact on Quality of Life
- Improved Activities of Daily Living – grasping objects, dressing, eating etc.
- Increased Independence
- Enhanced sense of well-being
- Improved Self Esteem

Disadvantages of Neuroprosthesis for Grasping
- None identified

Figure Captions

Figure 1: Flow chart of the recruitment, therapies, and assessments that were applied to all participants.

Figure 2: Individualized placement of stimulation electrodes for: (a) thumb and finger flexors; (b) finger extensors.

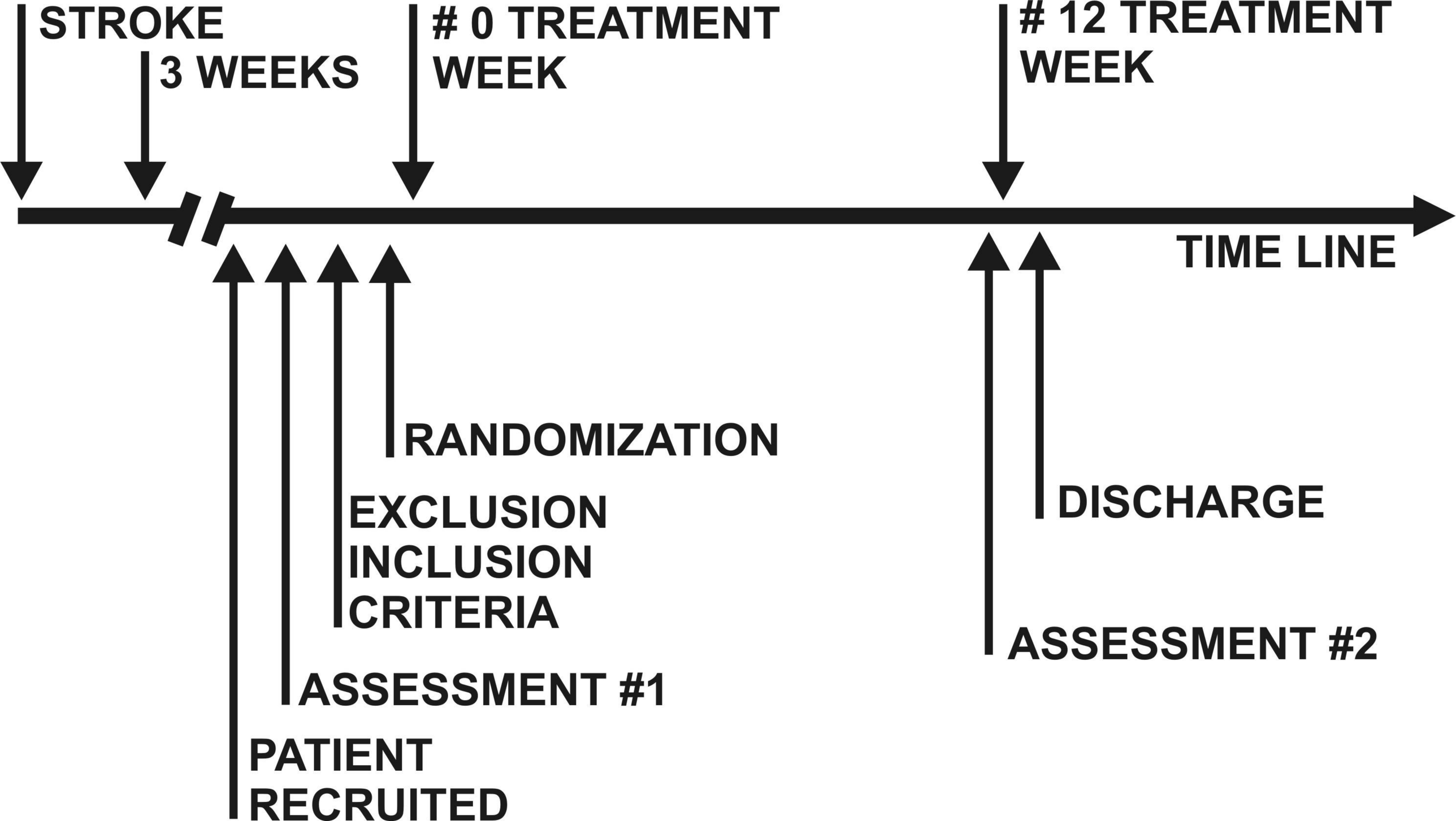
Figure 3: Increases in outcome measures for participants with complete SCI: 1) REL Test – object manipulation; 2) REL Test – wooden blocks; 3) REL Test – cylinder torque; 4) REL Test – credit card pulling force; 5) REL Test – eccentric load on wooden bar; 6) FIM; and 7) SCIM tests. The black bars represent the differences for the Control Group, and the shaded bars represent the differences for the Intervention Group.

Figure 4: Increases in outcome measures for participants with incomplete SCI.

Figure 5: Complete SCI participants' box-and-whisker plots of the scaled data for REL Tests: object manipulation, wooden blocks, torques, forces, and eccentric load; FIM; and SCIM tests: a) Control group scores before treatment; b) Intervention group scores before treatment; c) Control group

scores after treatment; and d) Intervention group scores after treatment. Bold horizontal lines represent medians.

Figure 6: Incomplete SCI participants' box-and-whisker plots. Bold horizontal lines represent medians.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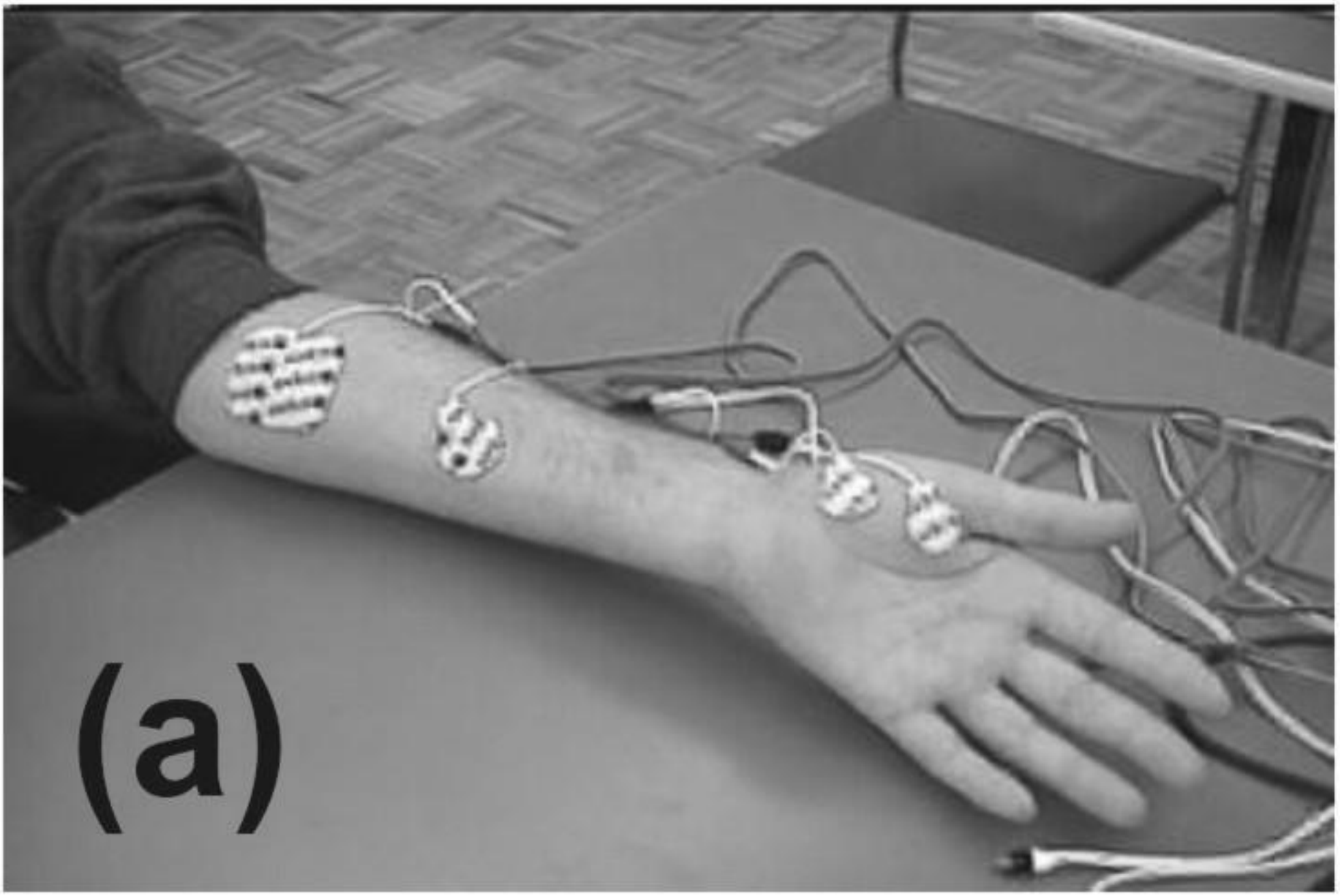
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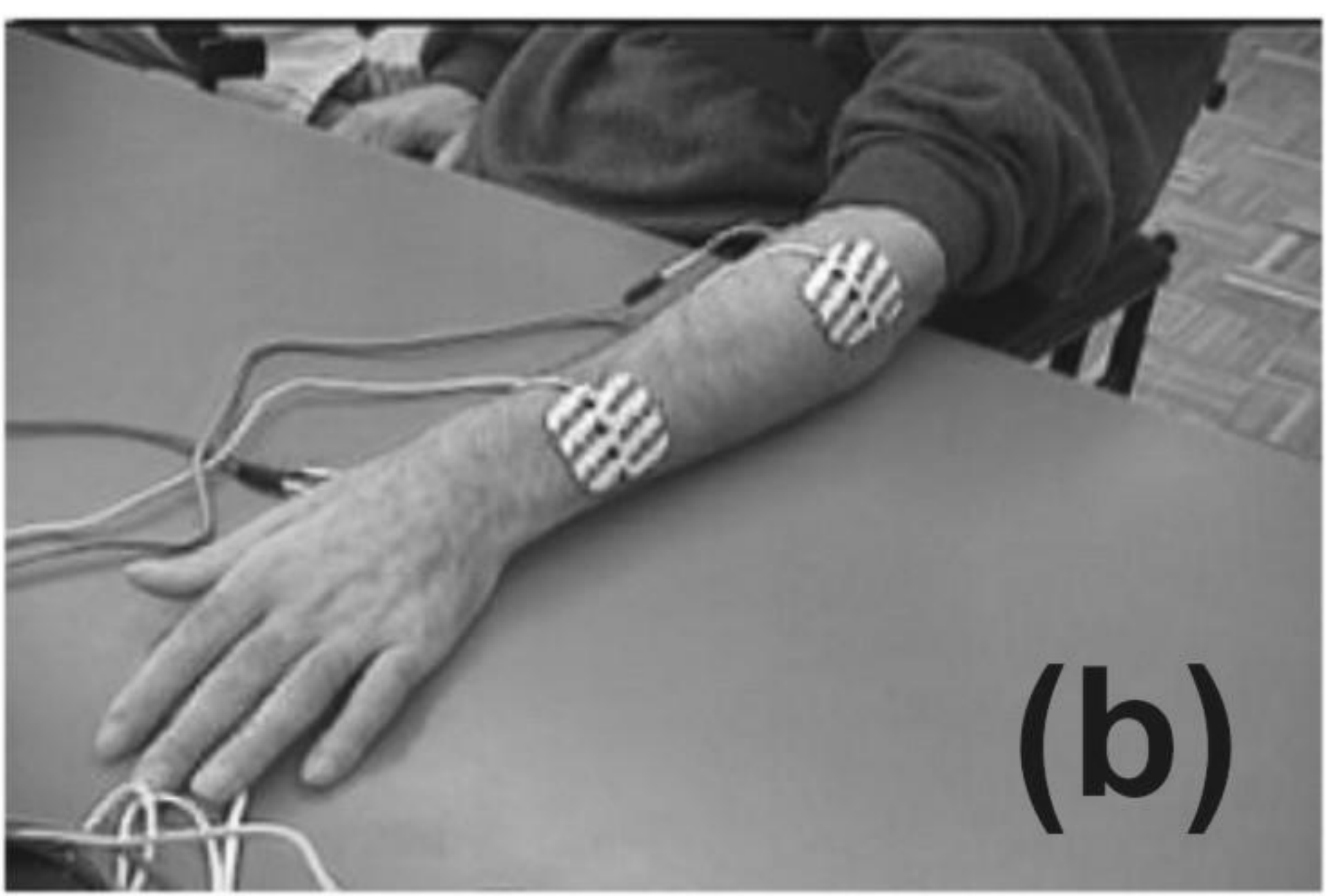
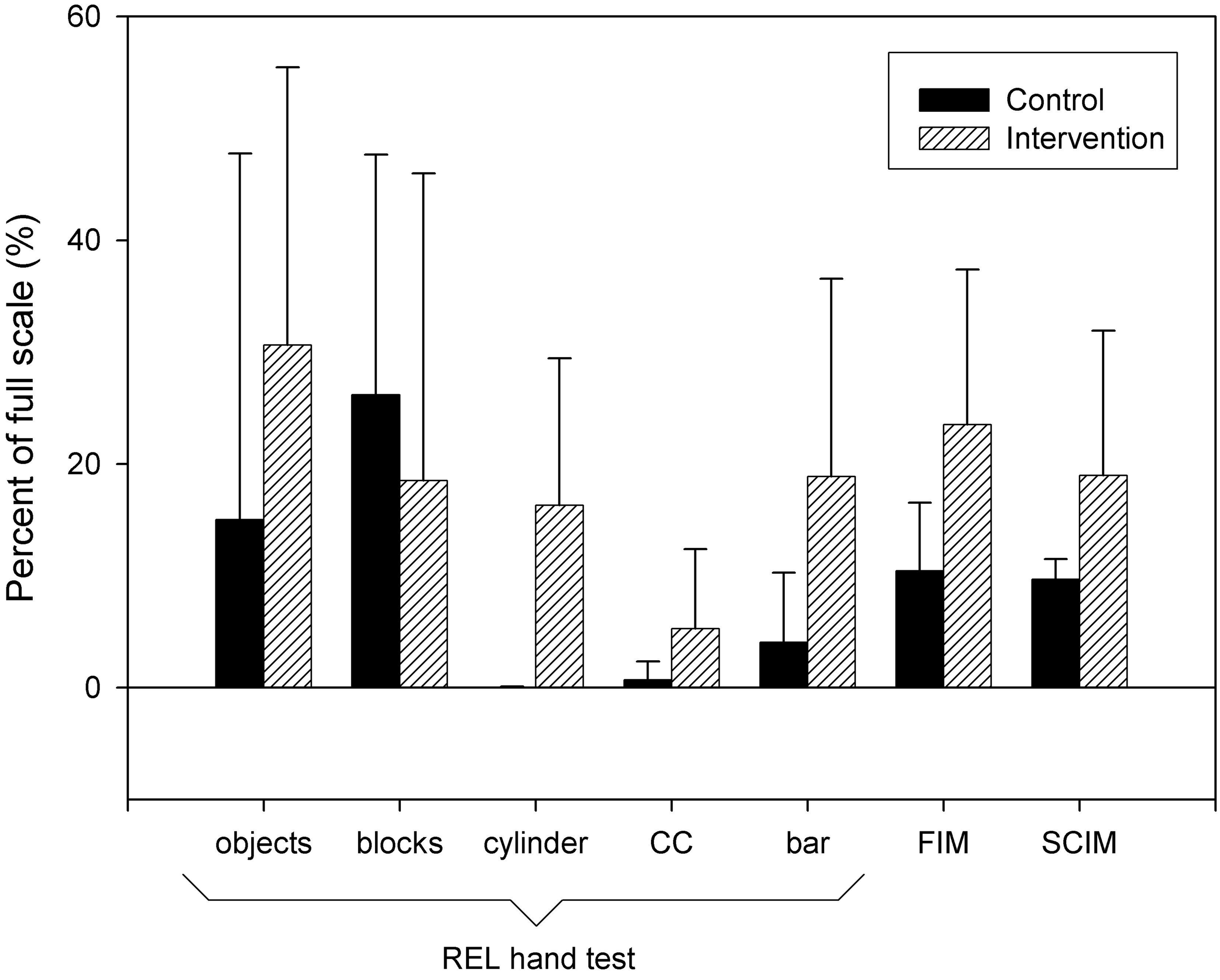
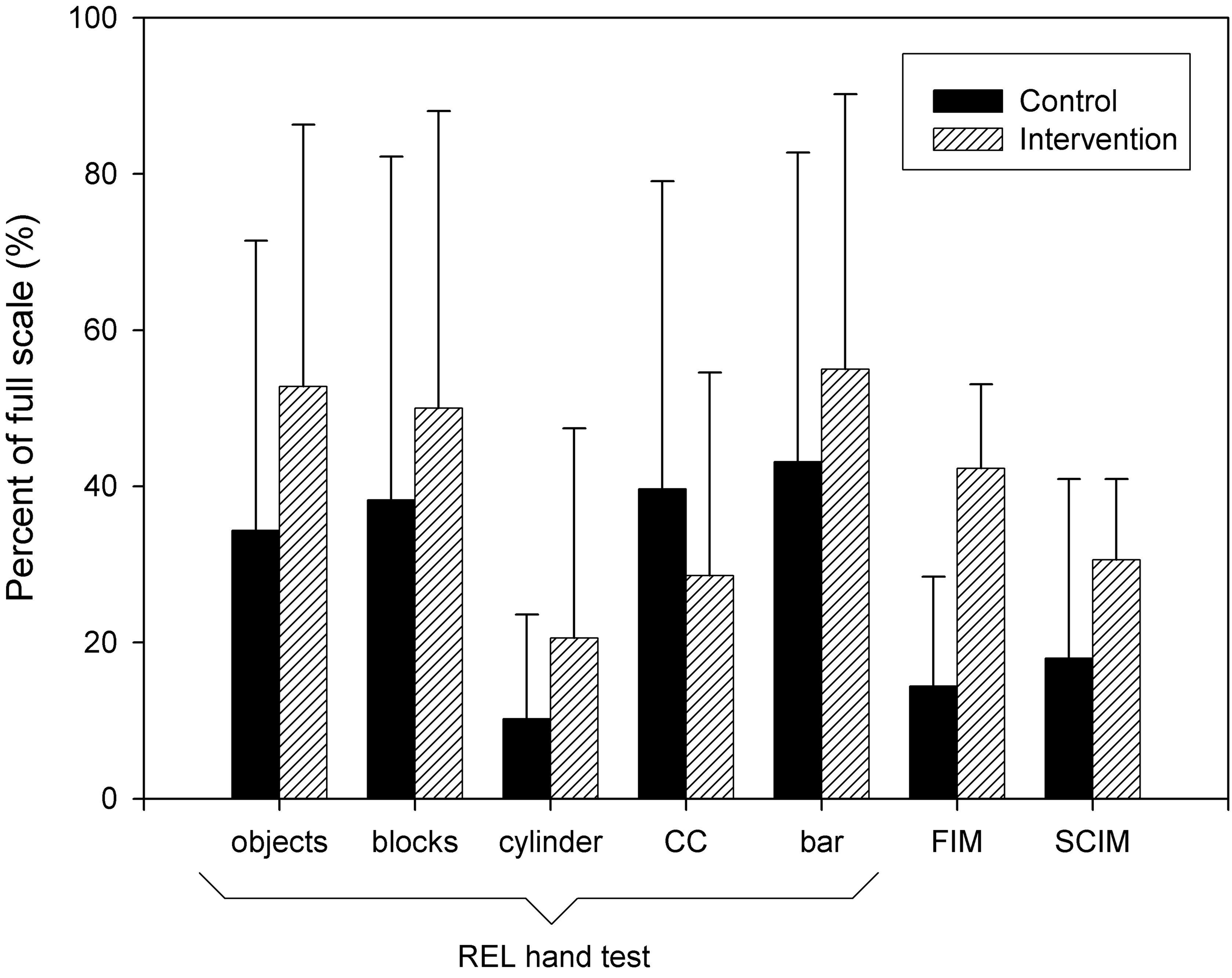

(b)

Increase from baseline to post-treatment (Complete SCI only)

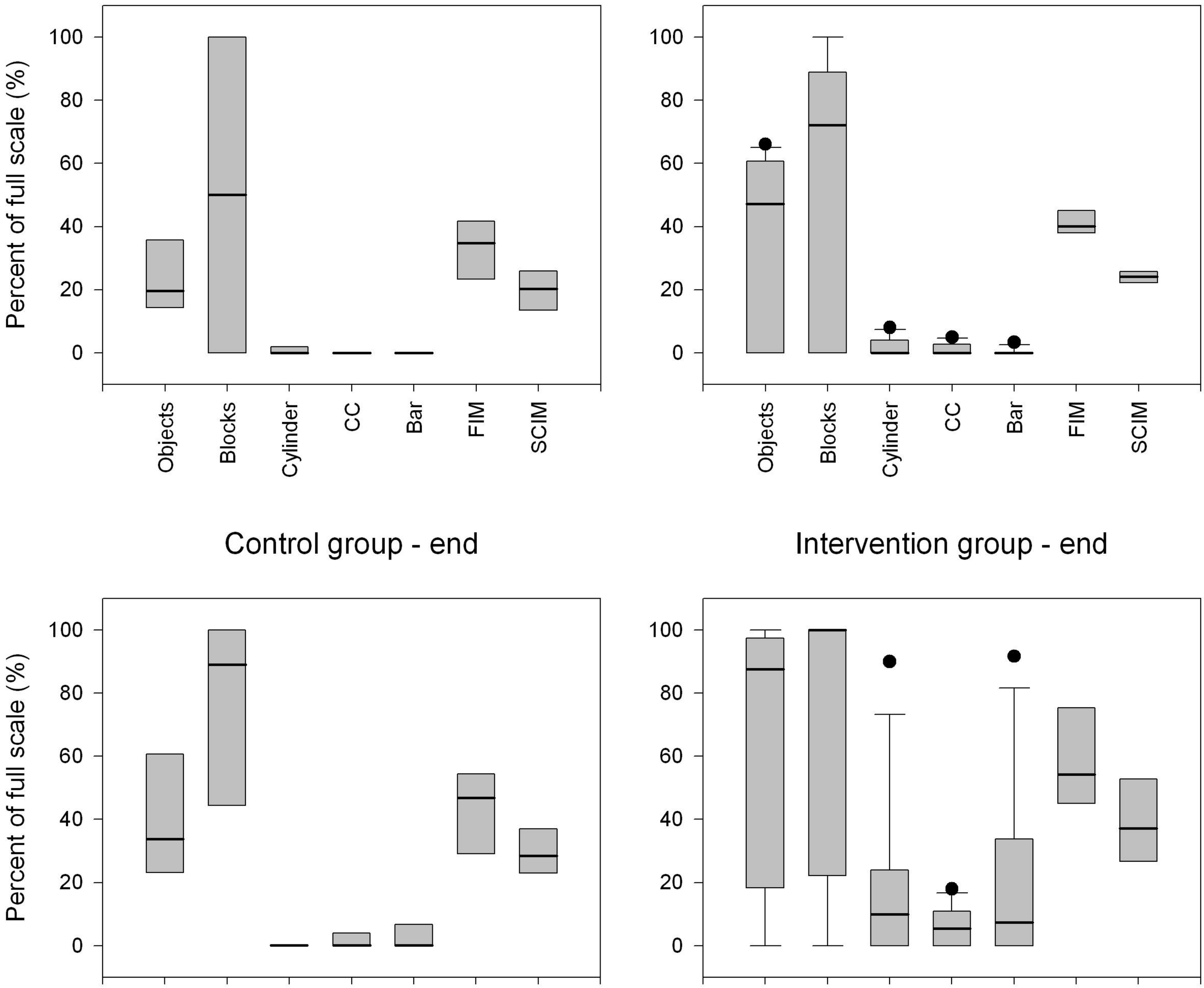


Increase from baseline to post-treatment (Incomplete SCI only)



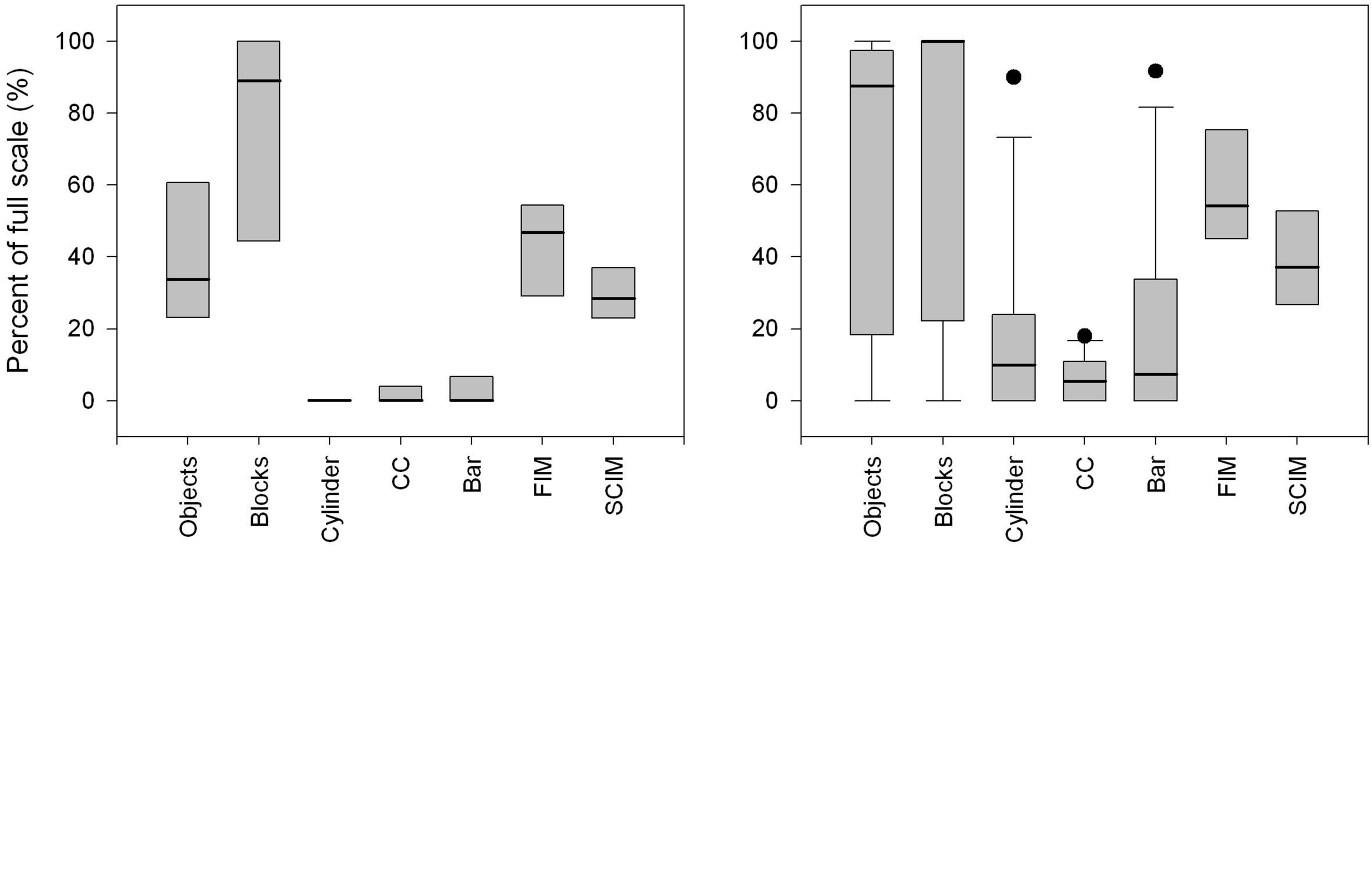
Control group - baseline

Intervention group - baseline



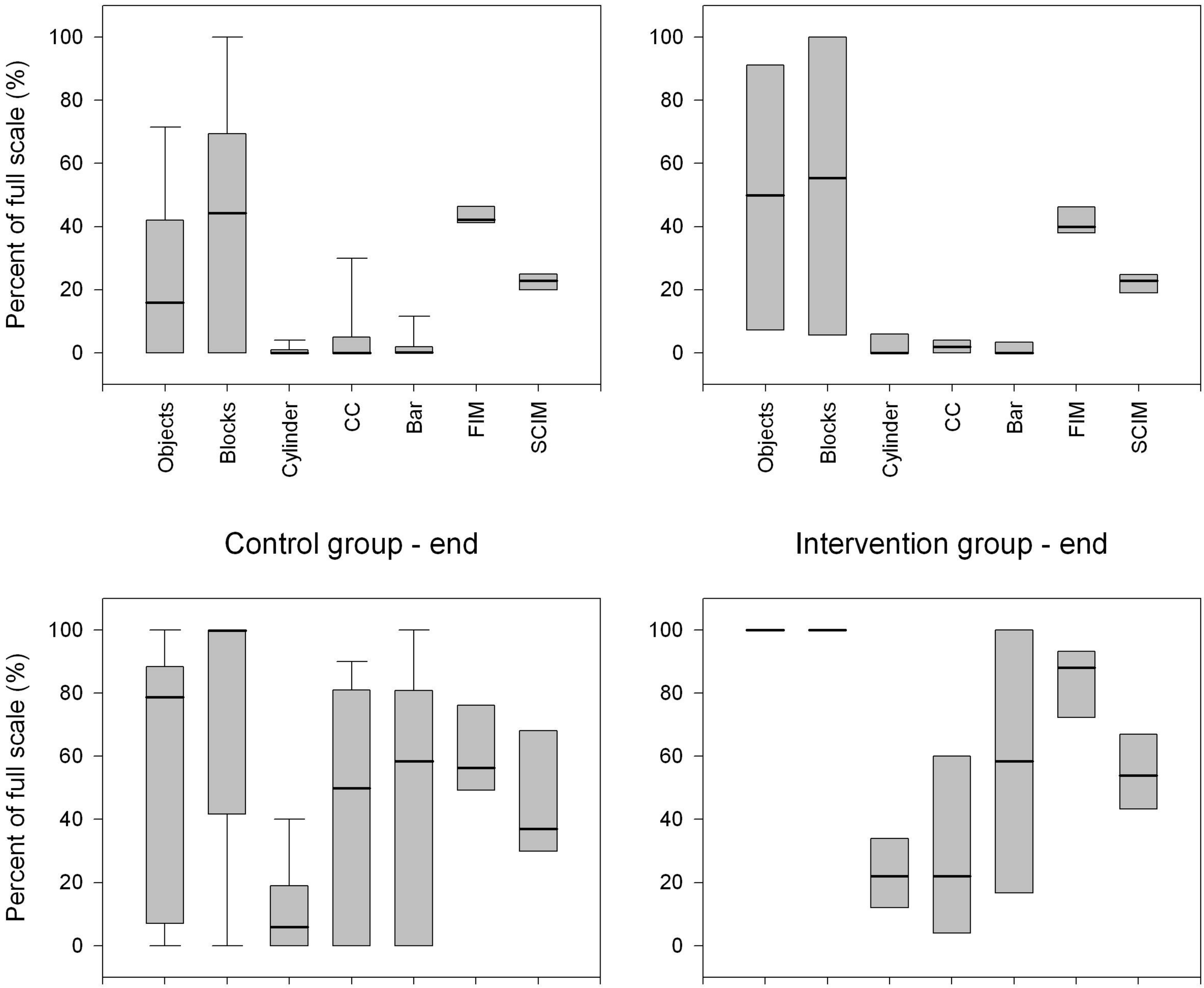
Control group - end

Intervention group - end



Control group - baseline

Intervention group - baseline



Control group - end

Intervention group - end