POSTER PRESENTATIONS
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PI.63 Participants’ views on the blinding aspect of a RCT study - Experiences from evaluation of TES concept for self-administered treatment of spasticity

Leif Sandsjö¹, Jenny Alwin², Ann Sörbo³, Marie Lindgren⁴, Per Ertzgaard²
¹University of Borås, ²Linköping University, ³Södra Älvsborg Hospital, ⁴Linköping University Hospital

BACKGROUND AND AIM: Spasticity is a common consequence of injury to the central nervous system negatively affecting patients’ everyday activities. Drug therapies, physiotherapy and electrotherapy are established treatments in spasticity but depend on the access to healthcare personnel. A treatment concept based on an assistive technology (AT) Mollii® (Inerventions, Stockholm, Sweden) with electrodes for multifocal transcutaneous electrical stimulation (TES) integrated in a full body garment makes self-administration of individualized electrotherapy possible. We have evaluated this concept in a randomized, controlled, double-blind, cross-over study in spasticity due to stroke or CP (Ertzgaard et al.; Epub ahead of print; DOI: 10.23736/S1973-9087.17.04791-8), showing general improvements in mobility, but without any statistically significant difference between the active (TES) and control (wearing the garment but with no TES) treatment periods. In order to not reveal any information about the active/non-active treatment, i.e. keeping the intervention blind to the participants, no communication was allowed between the therapist and the participant during the programming of the individualized TES concept at the start of the study. The AIM of the present study was to investigate the blinding aspect of the RCT based on the study participants’ response in a follow-up questionnaire.

METHODS: The participants (n=27) used the AT with and without electrical stimulation (active/non-active period) for six weeks each. The RCT study protocol included a questionnaire item after the 2 six weeks periods asking whether the participants could tell which of the two periods that was the active period and, if so, Why do you believe that was the active treatment period?.

RESULTS: Nineteen participants (70%) could point out which period was active while three (11%) stated the wrong treatment period. Five (19%) responded I cannot tell which the active period was. The reasons given by the 19 who was right about the active treatment period included reports in line with the intended therapeutic effect of the stimulation (e.g. The second period because then the left hand was less spastic) from 6 participants. Five mentioned tingling sensations (likely caused by the electrical stimulation) while 8 participants mentioned both therapeutic effects and tingling (e.g. Felt like tingling and more flexible in the body) in their responses. DISCUSSION: Incidental findings from these questionnaire responses include that about half of the participants (14 out of 27) reported a therapeutic effect in line with the intervention. The intention to keep the RCT’s intervention blind to the participants, e.g. not allowing communication about stimulation levels when programming the AT, may have resulted in that the TES were set too low to generate beneficial outcome related to spasticity in participants who could not tell which was the active period.

CONCLUSIONS: The results tell that the intention to keep the RCT-study fully blind to the participants did not work out as planned. As the compliance of the RCT was low (only fifteen of the participants adhered to the recommended use) the possibility to reveal the active/inactive period may have affected the compliance and the outcome of the study.