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Effect on Hand Function After Six-week Use of a Wearable Soft-Robotic Glove Assisting ADL: Interim Results of an Ongoing Clinical Study

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Abstract— **In an ongoing study, an assistive wearable soft-robotic glove is tested at home for 6 weeks by subjects with decreased handgrip strength, due to different hand injuries or diseases, to assess whether use of this assistive grip-supporting glove will result in improved hand strength/ function. An interim analysis of the available dataset of 46 participants showed that (unsupported) grip strength and hand function improved after using the soft-robotic glove as assistive aid during activities of daily living (ADLs) during 6 weeks at home. After glove use is ended, this is maintained for at least 4 weeks. Considering that in the current situation the analysis is underpowered, these interim results are promising for finding a clinical (therapeutic) effect of using a soft-robotic glove as assistance during ADLs. If this is the case, this might open up entirely new opportunities for extending rehabilitation into people's homes, while also providing them with assistance to directly support performance of daily activities. Such a combination is becoming available with the development of mature and user-friendly wearable soft-robotic devices. This would enable very high doses of training throughout the day, in the most functional, task-specific way possible, and possibly prevention of learned non-use.**

I. Introduction

The human hand is a miraculous tool. When functioning correctly, the hand can accurately grasp, reach, and manipulate objects (1). However, a loss in hand function, whether of sudden onset or a disease or gradual process, can inhibit activities of daily living (ADLs), limiting performance of even the most basic tasks. Loss of hand function can be due to a variety of aetiologies, such as trauma, neurological (stroke, spinal cord injury, cerebral palsy), or orthopaedic conditions (osteoarthritis, rheumatoid arthritis) (2-4). These populations have difficulties in performing ADLs, most commonly due to decreased hand strength and dexterity. Grip strength is an essential prerequisite for proper performance of ADLs (5). Therefore, hand rehabilitation provides repetitive, active, task-specific training in order to increase strength, accuracy, and functional use of the hand (6-9). Hand rehabilitation is one of the most important aspects to improve quality of life and independence of people with impaired hand function (10). However, even after conventional rehabilitation, chronic hand dysfunction with mild disability still persists (11). Furthermore, prolonged non-use of the hand in daily life resulting from decreased hand function might limit independence even more (10). In those cases, it is important to provide suitable assistance and aids to support everyday life tasks, in addition to hand rehabilitation, but current methods have their limitations.

Numerous assistive devices have been on the market for many years to support ADLs, such as adaptive clothing, shower accessories, one-handed can openers, keyboards, etc. (12-13). While these tools are helpful to compensate for the lost hand function during daily tasks, their use does not train the hand to improve or maintain hand strength and hand function. Recent technological advances enable a promising solution to this, with the advent of soft-robotic devices. Such devices are usually wearable, more comfortable and less bulky than rigid exoskeleton type devices. That makes them very suited for use in everyday environments, to assist with daily tasks (14). The Carbonhand (Bioservo Technologies AG; Kista, Sweden) is such a wearable, soft-robotic glove, which supports the grip of its user by assisting finger flexion. It is an assist-as-needed device, which requires an active contribution to the movement, allowing users to actively participate while the glove assists during ADLs. Previous studies with this device looked at user acceptance and functional performance using the glove, showing that participants rated usability and feasibility positively and increased their pinch strength when using the glove vs not using the glove (15-16). More recently, Radder et al. compared intervention groups using the glove either as assistive device (aid) or as training tool (therapy) and found a first indication, besides a direct supportive effect, of a therapeutic effect in the training group, and remarkably also in the assistive group (17). The current study zooms in on this potential therapeutic (clinical) effect of using a soft-robotic glove as assistive aid during ADLs in a home environment for six weeks. The primary objective of this study is to examine whether prolonged (six weeks) use of an assistive soft-robotic glove during ADLs at home results in a therapeutic effect in handgrip strength and dexterity. This study (as part of the

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iHand project) is currently ongoing towards its aim to collect data of a powered sample of 63 participants. An initial interim analysis of 32 datasets has been performed before (for internal project deliverables and presented in a workshop at the European Week of Active and Healthy Ageing conference, Oct 2021, unpublished). The aim of this paper is to analyse and describe the interim results of the data available to date, in terms of changes in hand strength and hand function after six-week use of the soft-robotic glove.

II. Methods

A. Study design

A multi-center, uncontrolled intervention study was performed. All participants were assessed at five-time points: three baseline evaluations, one week apart (T0, T1, T2), averaged into one baseline value (PRE), and one post-evaluation scheduled within one week after the end of the intervention weeks (T3) and a follow-up evaluation four weeks later (T4). All participants signed informed consent prior to being admitted to the study. The study was approved by the local Medical Ethical Committee in the Netherlands (trial number: NL68135.044.19). Full details about the study protocol and the device have been published elsewhere (18).

B. Study participants

Participants were recruited from specialized hand treatment teams from eight clinical centers in the Netherlands, starting June 2019: Roessingh Center for Rehabilitation (Enschede), University Medical Center Groningen (Groningen), Isala (Zwolle), Rijndam Rehabiltation (Rotterdam), Reade (Amsterdam), Hoogstraat Rehabilitation (Utrecht), Sint Maartenskliniek (Nijmegen), Klimmendaal (Arnhem). To ensure that the protocol was standardized between the participating centers, instruction sessions took place for all involved healthcare professionals prior to the start of study activities at the local site. Participants with hand function problems, consisting of decreased handgrip strength were eligible to participate if they met the following criteria: aged 18-90 years, in a chronic and stable phase of disease, have received treatment for limitations in performing ADLs due to a decline in hand strength at the involved clinical center, have at least 10° active extension of wrist/fingers and 10° active flexion of fingers, have the ability to make a pinch grip between thumb and middle or ring finger, able to don the soft-robotic glove, have sufficient cognitive ability to understand two-step instructions, and living at home. Participants were excluded if they had: severe sensory problems or severe acute pain of the most-affected hand, wounds on their hands interfering with glove use, severe contractures limiting passive range of motion, co-morbidities limiting functional use/performance of the arms/hands, severe spasticity of the hand (≥2 points on Ashworth Scale), participation in another study that can affect functional performance of the arm/hand, receiving arm-/hand function therapy during the course of the study and insufficient knowledge of the Dutch language to understand the purpose or methods of the study.

C. Intervention

Immediately after the third baseline measurement, the soft-robotic glove was manually adjusted to the strength and sensitivity preference of each individual participant by a therapist from the involved center. All participants were instructed to use the soft-robotic glove during ADLs at home for six weeks. Instructions on glove operation and use were done at the end of the last baseline session. Participants were recommended to use the glove for at least 180 minutes per week during their most common ADLs that they experienced limitations in, such as lifting and carrying items, performing hobbies, and household activities. However, they were allowed to use the glove as much, or as little, as they felt they could make use of the glove in their normal daily routine. Participants were called weekly by the involved therapist to ensure everything was going well with using the device.

The soft-robotic glove (see also (18)) used in this study was the Carbonhand system (Bioservo Technologies AG; Kista, Sweden) a fully wearable, battery-powered device (700g in total), which supports a person's grip (Figure 1). The system consists of a control unit and a glove. The control unit contains a battery, a microcontroller, and three motors actuating three fingers: thumb, middle, and ring finger. The glove applies force generated by the motors in the control unit via sensory input from touch sensors at the fingertips. Actuation of finger flexion is triggered by pressure sensors at the tips of the glove. The forces are applied by artificial tendons sewn into the glove, which induce flexion of the fingers. The Carbonhand system can be worn as a regular glove, with the control unit supported on the waist or hip, using a clip or a belt. Actual glove use time was collected automatically by the system and stored on the control unit.

Figure 1. The Carbonhand System with soft-robotic glove, control unit worn on the hip and the cable connecting control unit and glove.

D. Outcome measures

The primary outcome measure of this study to evaluate changes in hand strength was maximal grip strength. Secondary outcome measures included the Jebsen-Taylor Hand Function Test (JTHFT). Other outcome measures collected during this study, such as Action Research Arm Test (ARAT), pain ratings, Motor Activity Log, EuroQol-5D and glove use time, etc. (see 18), are not part of this paper and will be analyzed and published after study completion. All tests were performed without using the glove to examine the therapeutic effect. Participant characteristics, including age, gender, impairment/diagnosis, time since diagnosis, most-affected side, and dominant side were also collected.

Maximal grip strength of the most-affected hand was measured with the Jamar hydraulic hand dynamometer, Patterson Medical Ltd., Warrenville, IL, USA with the handle position set at 4 for all attempts for all subjects. The positioning of each participant was standardized as described by the American Society of Hand Therapists (19). The participant had to squeeze the handgrip of the dynamometer maximally for 5 seconds. Handgrip strength was expressed in kilograms (kg). There were three attempts and between the different attempts were at least 60 seconds rest. When a participant reached the highest force during the last attempt, another attempt is added until the value decreases. The average value of the last three attempts was used for analysis.

To assess hand function, the Jebsen Taylor Hand Function Test (JTHFT) was applied, measuring functional performance of the hand during 7 unilateral hand skill tasks related to ADL: (1) writing 1 sentence of 24 letters; (2) turning 7.6- x 12.7-cm cards; (3) picking up small, common objects (i.e., paper clips, coins and bottle caps) and move these to a box; (4) simulated eating (i.e., teaspoon with beans); (5) stacking checkers; (6) picking up large empty cans; (7) moving weighted (450 g) cans (20,21). The subject performed each task with the most-affected hand while sitting comfortably close to the table. The duration of each task from start (lifting hand from table) to completion of the task was recorded in seconds with a stopwatch (maximal duration to be scored is 120 seconds per task) and summated as the total score.

E. *Statistical analysis*

Statistical analysis was conducted using IBM SPSS Statistics version 23.0. Normality was checked with the Kolmogorov-Smirnov test (p>0.05) and visual inspection of Q-Q plots. In the majority of outcome measures, substantial deviations from the Gaussian distribution were observed. Log-transformation did not solve non-normality. Therefore, non-parametric testing was done to assess changes over time. Descriptive statistics were used with mean ± standard deviation (SD) or median and interquartile range (IQR).

To assess the effect of the intervention over time, a Friedman test for 3 related samples was used to analyze whether outcome measures changed over time. An alpha≤0.05 was considered as statistically significant. In case of a significant Friedman test result, pairwise post-hoc tests were done using Wilcoxon signed ranks test between all three sessions (pre – post, post – follow-up , pre – follow-up). In those cases, a Holm-Bonferroni correction was applied to account for multiple comparisons, using effective (corrected) alpha's of 0.0167 for the smallest p-value, 0.025 for the middle p-value and 0.05 for the highest p-value, in that order.

III. RESULTS

To date, baseline data is available from 49 participants (Table I) with limitations in hand strength and/or hand function due to various problems. Causes (Figure 2) were associated predominantly with post-traumatic injuries, including CRPS (47%), followed by peripheral muscle/nerve injuries (including neuropathies and myopathies), arthritis-related complaints and central neurologic disorders (including stroke, spinal cord injury, multiple sclerosis, cerebral paresis, etc.) in equal shares of 15%. Of all participants, 88% can be classified as having weak grip.

Of the 49 participants, 3 were in the intervention period (6 weeks glove use) and haven't had their post-intervention assessment at the time of writing. Another 2 have completed the post assessment, but not the follow-up evaluation. In sum, 46 have completed the study up and until the post assessment, of which 44 participants have completed all evaluation sessions including follow-up. In a few cases, data is missing incidentally due to inability to complete the test, or covid-19-related restrictions at the time preventing physical visits to the test sites.

Grip strength increased across sessions (p=0.010), most predominantly from baseline to post evaluation, although this was highly variable between persons (Figure 3). Grip strength increased on average by 1.9 (± 4.3) kg from baseline (mean 14.2 ± 11.0 kg) to post (p=0.002) and 1.7 (± 4.9) kg from baseline to follow-up (p=0.016). The grip strength increase from pre to post corresponded with an average improvement of +25% (± 54%) with respect to baseline values, ranging from a reduction of 83% to an increase of 224% on individual basis. Although data is deviating from a Gaussian distribution at this point, it is illustrative that 95% confidence intervals were above 0 for changes from baseline to post and from baseline to follow-up (Fig. 4).

TABLE I. DESCRIPTIVE CHARACTERISTICS OF PARTICIPANTS

Characteristic (N=49)	**Value**
	Mean (±sd) and range, or count (%)
Age (years)	54 (± 12); range 25-79
Gender (M/F)	24 (49%) / 25 (51%)
Dominant hand (R/L)	43 (88%) / 6 (12%)
Most affected hand (R/L)	38 (78%) / 11 (22 %)
Time since onset (years)	9.7 (± 14.6); range 0.5-57.0
Weak grip[a] (M/F)	21 (88%) / 22 (88%)

a. Males are classified as having weak grip when baseline grip strength <37 kg, females are classified as having weak grip when baseline grip strength <21 kg.

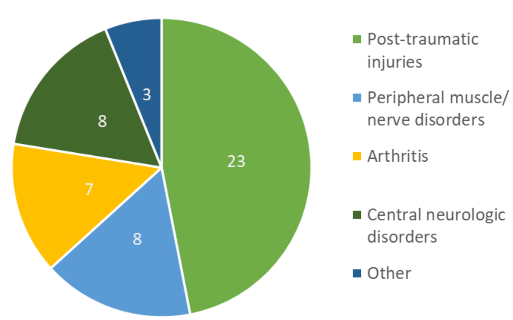

Figure 2. Categories of diagnoses of study participants to date

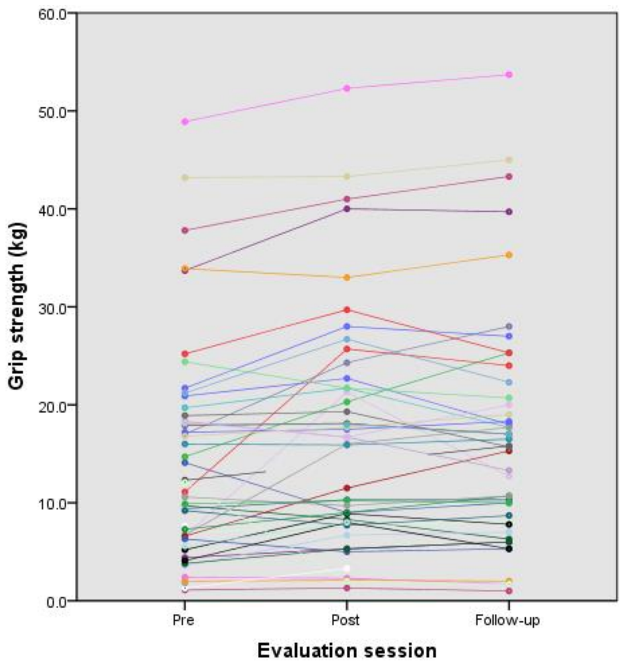

Figure 3. Individual grip strength (in kg) per session

JTHFT performance improved (i.e., completion time decreased) across baseline, post and follow-up, with average total scores of respectively 96.8 (± 73.6) s, 85.9 (± 58.4) s and 80.7 (± 48.8) s (p=0.000). Post-hoc testing showed that the differences between baseline and post and between baseline and follow-up were significant (p≤0.000). Total completion time decreased on average by 12.2 (± 19.7) s between baseline and post evaluation, and by 16.0 (± 27.2) s between baseline and follow-up. This corresponds with a relative performance improvement, with respect to baseline values, of 11% (± 11) at post evaluation and 13% (± 12) at follow-up. Individual changes again varied substantially, ranging from 6.2 s slower performance to 156.6 s faster performance from baseline to follow-up (or 11% worse to 37% better performance in relative terms). Performance between post and follow-up remained largely at the same level (p=0.261). When looking at all JTHFT items separately (Fig. 5), the same image appears, with a significant effect across sessions in all items (p≤0.021). Post-hoc tests showed that for all items, except stacking checkers, performance improved between baseline and post and between baseline and follow-up (p≤0.021), but not from post to follow-up (p≥0.207).

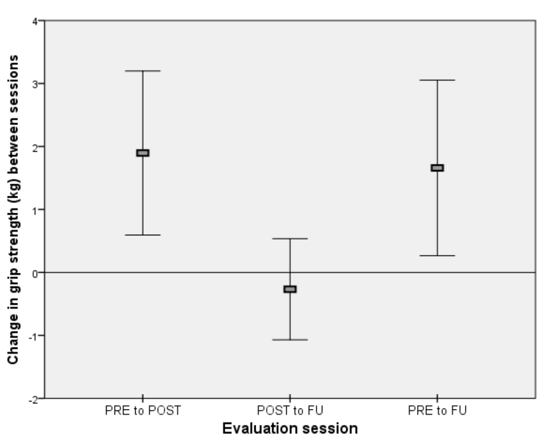

Figure 4. Average (grey rectangles) and error bars of 95% confidence intervals (whiskers) of individual changes in grip strength (kg) between sessions

IV. Discussion

The purpose of this paper was to assess the currently available data of the ongoing study into a potential therapeutic effect on hand strength and hand function after using the assistive soft-robotic system for 6 weeks at home during ADLs. The current interim analysis showed significant improvements in hand strength and function across sessions, as measured by grip strength and JTHFT, respectively. Changes occurred predominantly between baseline and post evaluation, indicating that the period in which the glove was used actively seems to result in the largest gains in hand strength and/or function. Nevertheless, cessation of use of the glove after 6 weeks hasn't caused a decline in hand strength or hand function, as would have been expected in case of a return of 'learned non-use' phenomena after use of the glove stopped. Of course, the follow-up period was only 4 weeks, a longer follow-up period is advised for future research.

Improvements in grip strength so far are modest in terms of absolute numbers, with +1.7 (± 4.9) kg from baseline to follow-up. However, considering that the majority of participants has a weak grip to start with, relative changes are indicating participants increased their baseline grip strength by a quarter, on average. This amounts to doubling their baseline grip strength in individual cases. Concerning JTHFT performance, improvements are less pronounced, with baseline hand function performance increasing by 11% (± 11) on average, amounting to increased baseline performance by a third in individual cases. A minimal clinically important difference (MCID) for JTHFT has been reported as 6.32 for the dominant hand and 10.12 for the non-dominant hand, albeit for healthy participants without any hand conditions (22). The average improvement in JTHFT performance exceeds MCID, implying these are relevant changes for at least a substantial number of participants. Whether such improvements in hand strength and/or function transfer to improved ability to carry out ADLs or improved wellbeing is to be investigated when analyzing the full dataset (incl. for instance the Michigan Hand Outcome Questionnaire and EuroQol-5D) after completion of data collection.

Comparison with other studies is difficult, because to our knowledge the current study is one of the first user trials that applied and tested a fully wearable robotic system to support hand function at home for unsupervised use during an extended period of multiple weeks. Moreover, other studies that do examine effects of a soft-robotic glove especially focused on examining the direct, assistive effect of the glove, comparing performance with and without the glove. When assessing the findings so far against the outcomes of our previous study (17), similar results can be observed. The therapeutic and the assistive groups in the previous study of Radder et al. showed significant improvements in grip strength after four weeks of glove use. Now we have also observed a slightly less substantial average increase in grip strength from baseline to post evaluation in the present underpowered situation.

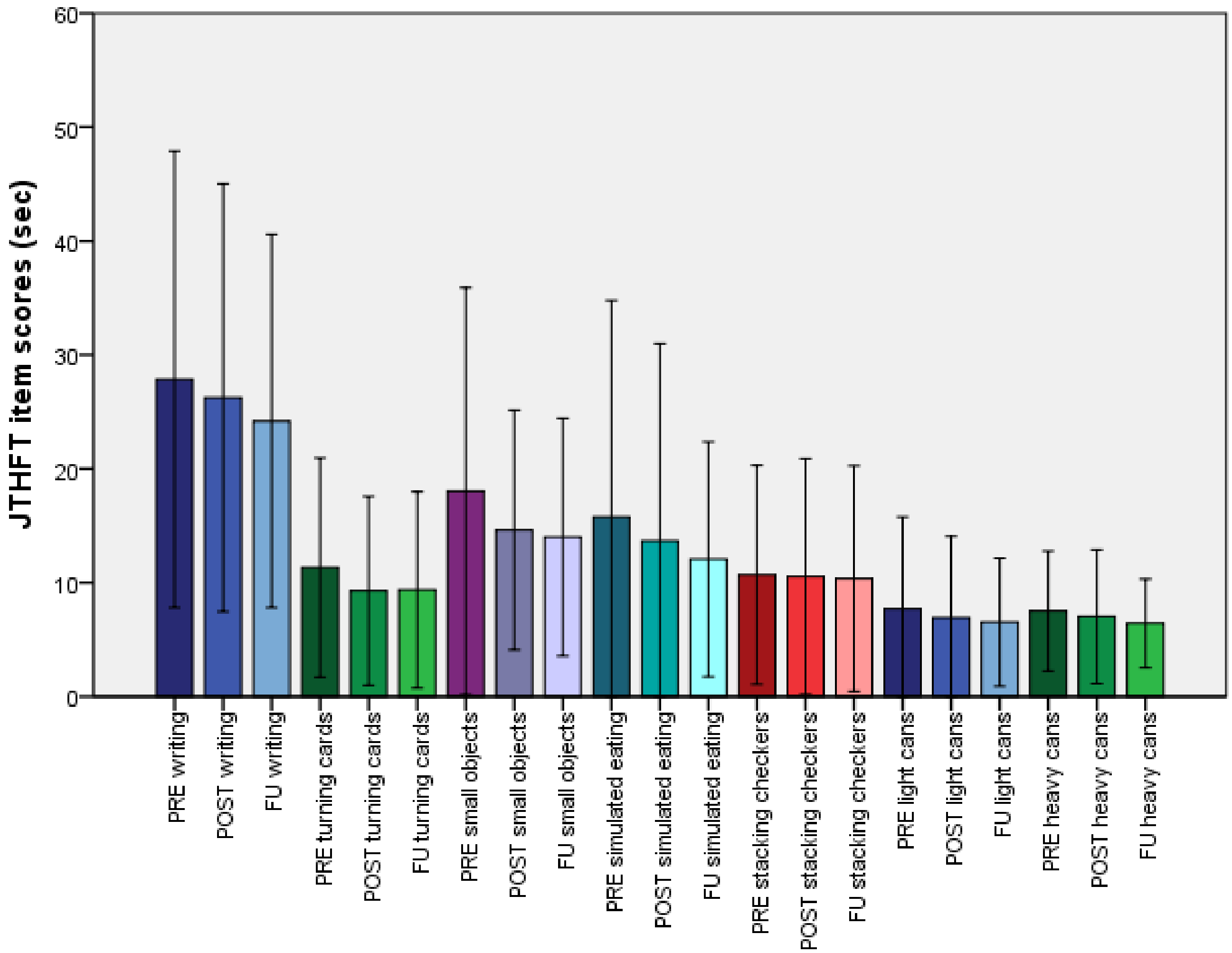

Figure 5. Average (± sd) JTHFT scores (in s) of each test item separately displayed per session

On individual basis there is a large extent of variation, with some participants showing large increases in grip strength of up to 160% with respect to baseline values, while others experienced reductions in grip strength. This may be due to the large heterogeneity of the current sample, although this was also the case in the previous study. Another factor that will be investigated once data collection is complete is a potential relation with amount of use of the glove. It is not unlikely that participants who have used the glove, and thus their hand, more in daily activities will experience a larger improvement of hand strength or hand function. In addition, other factors, such as severity of hand function limitations or differences in pathologies, may also be related to the large variation between individuals. This will be addressed in future analysis as well.

When looking at subcategories of JTHFT, we observed a significant improvement in six of the seven JTHFT subcategories, again mostly between baseline and post evaluation. The task that didn't improve after glove use was 'stacking checkers', a relatively fine motor task, that requires an ability to feel where the checkers are and if they will slip between gloved fingers, for instance. This indicates that the glove, while it can improve functional ability, may not have a significant change in improving fine motor tasks. On the other hand, another JTHFT item, picking up small objects (such as small coins and paperclips) did show increased performance in the current dataset, whereas that wasn't the case in the previous study, suggesting that some fine motor tasks can be performed well with the soft-robotic glove system. The longer use period (6 weeks as opposed to 4 weeks) could play a role in this, allowing participants to become better acquainted with how the glove influences movements and its interaction with objects (23).

Considering the abovementioned observations, and the high variation between participants in improvements of hand strength and/or function, it will be very interesting to investigate in more detail which parameters are related to large improvements during glove use, whether they achieve clinical relevance and are sustained or continued at follow-up. Getting a better understanding of correlations between gains in hand strength/function and such factors will provide insight into which individuals might have a good chance of responding well to the therapeutic potential of the soft-robotic glove system, enabling a more personalized approach. These in-depth analyses will be addressed in future analysis of the completed dataset of the present study, along with examining effects on different aspects besides hand function, such as wellbeing, acceptance and amount of use.

In summary, the present interim analysis of the therapeutic effect of using a soft-robotic glove during ADLs at home showed generally positive results. Participants showed improvements in unsupported hand strength (substantial, though not significant) and functional ability of the hand during the period of glove use. These improvements were generally were sustained, or even continued, at follow-up, implying a lasting change in hand strength and/or functional ability after 6 weeks of glove use. The fact that we observed these improvements in an underpowered situation, holds promise for the final outcome after all data is collected.

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