Implications of providing wrist-hand orthoses for children with cerebral palsy: Evidence from a randomised controlled trial.

PLAIN ENGLISH - EXTENDED SUMMARY

Background to the study

Children with cerebral palsy (CP) have problems with movement (e.g., spasticity) that place them at risk of developing stiffness in the muscles of the wrist and hand. This stiffness can lead to loss of movement and shortening of the muscles (known as contracture) and changes in the way the hand looks. These changes can make it hard for children to use their hands for everyday activities, such as eating, dressing and playing with toys; or hard for caregivers to do daily tasks like putting on shirts or tops.

There is not much research about how children's arm and hand bones, muscles and joints change as they grow. A Swedish study of 771 children with CP showed that 1 in 3 children developed contracture in their arm and 1 in 5 children, contracture at their wrist.

Traditionally, therapists give children with CP **wrist-hand orthoses** (also called splints) to wear at night to stretch the hand to prevent muscles stiffness and loss of movement. Therapists think that this stretch reduces the stiffness and tightness that the muscles experience during the day.

Even though orthoses are commonly given to children, there is no research that shows if they are effective over a short or longer period (i.e., 1 to 3 years). It is also not known if some children with CP may benefit more from wearing an orthosis than other children.

Aims of the study

The aim of our research was to see if children who wore an orthosis overnight for 3 years, were different from children who were not given an orthosis. We wanted to find out if having an orthosis would:

- improve or prevent loss of movement at the wrist.
- reduce muscle stiffness, pain,
- improve the ability to use hands for everyday activities, ease of care, participation in everyday life, and quality of life.

We also aimed to see whether the child's age or severity of CP made a difference.

The study was planned to run for 3 years to understand how orthoses might work over a long period of time during children's growth and development. This is important because contractures take time to develop, so we think that an orthosis would need to be worn over a prolonged period to be helpful.

How was the study run?

The study was done at five health care services across Australia. We aimed to include 194 children. We stopped the study once 74 children were involved as it was hard to locate more families willing to take part.

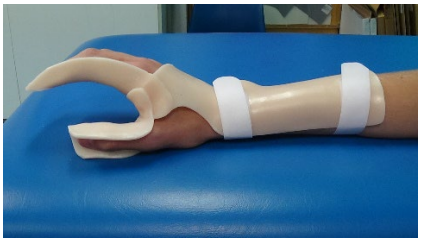
Who could take part in the study?

We invited children to take part if they had CP, were between 5 and 15 years old and if they had muscle stiffness in one or both wrists and hands.

The children and families who agreed to take part were randomly allocated (like tossing a coin) to one of two groups: the orthosis group in which children were given an orthosis, or the control group who were not.

What did we ask children and families to do?

We gave children in the orthosis group an orthosis to keep their wrist and fingers in a stretched position. We asked them to wear the orthosis when resting or sleeping (not playing) for at least 6-hours each night. All the orthoses were made using the same instructions that our study team put together; some examples are shown below.



Children in the orthosis group (or their parent/guardian) kept a diary of the hours they spent wearing the orthosis each night. Children in the control group were asked not to wear an orthosis that kept their wrist and fingers in a stretched position for the whole time they were in the study. All children received their usual therapy while they were in the study.

How did we measure each group?

At the beginning, we collected information about each child including their sex, age, type and severity of CP. Each child was then assessed every 6 months for 3 years or until the study ended.

The assessments were completed by therapists who did not know whether the child was in the orthosis or control group. All the therapists assessing the children were trained to make sure their assessments were as accurate as possible.

We kept in close contact with all the children, so that if anyone experienced any issues related to wearing or not wearing an orthosis, we could address and act on these and change the intervention if we needed to.

What did we measure?

The main measurement was passive wrist extension with the child's fingers extended. Passive movement is when a body part is moved by another person. Wrist extension with fingers extended is when the wrist is pushed up while the fingers are held straight (like a stop sign position).

We also measured other outcomes related to:

1. **Hand and arm structure and function,** e.g., hand, wrist and arm movement, stiffness of the forearm muscles.
2. **Activity levels,** e.g., children's ability to perform everyday activities such as eating, bathing and dressing.
3. **Participation,** e.g., how often children took part in school or community activities and how involved they were in these activities.

We also asked about the different therapies and services children had received since we last saw them.

What are the results of this study?

Who took part in the study?

In total, 74 children participated in this study.

- 38 children were allocated to the orthosis group and 36 to the control group
- The average age of children was 10 years in the orthosis group and 9 years in the control group.
- About half the children were female.
- 27 of the 74 children had both arms affected by CP and included in the study.
- Half of the children were able to handle objects by themselves, with or without some difficulty; the other half required assistance.

Children were similar between the orthosis and control groups at the start of the study. This is important to check because it usually means differences between groups are because of the treatment. It is why we use random allocation to group. On average children were part of the study for 18 months. Only 5 participants reached the 3-year final study point mainly because we decided to stop the study early.

What did we learn about children who wore an orthosis overnight to stretch their wrist and fingers?

We looked at the data we collected in various ways.

At the end of the study, we found that children in the orthosis group had increased range of movement by having on average 13 degrees more passive wrist extension with fingers extended at the 6-months assessment than children in the control group. At the 12 months assessment, children in the orthoses group had 21 degrees more wrist extension with fingers extended than children in

the control group. Some children had a lot more change, some had very little, and some had less range of movement at the end of the study.

Some children in the orthosis group had a stronger grip strength after wearing their orthosis for 12-months, however, the effect of orthosis wear on grip strength is not completely clear. There were also not enough children in the study after 18-months to make clear conclusions on the other outcomes that were measured.

One thing we could not do, was include the length of time the orthosis was worn into the analysis. This was because the TherApp (our tool for collecting this information) did not work as well as planned. We do know that ***when children did wear*** the orthosis, they wore it for about 28% of the days they were in the study (1 in 4 days), and for an average of 7.5 hours (ranged from 3.0 to 10.7 hours).

Our data also showed that there are common side effects from wearing an orthosis such as skin irritation, redness and trouble sleeping. These effects usually only lasted a short time – typically one week.

How can we use what we learned?

We can't clearly recommend that therapists should or shouldn't give orthoses to children aged 5-15 years with CP because we did not study enough children for long enough. Our findings show that there may be some increase in passive wrist extension, when their fingers are extended, for some children after 6 and 12-months of wearing an orthosis, and some increase in grip strength for some children after 12-months.

If children and families decide to have an orthosis, they should visit their therapist often to check it is fitting correctly and that it is providing the necessary stretch.

While side effects from the orthoses were minor, it is important for therapists to discuss the possibility of side effects with children and families if recommending the use of an orthosis.

What were the limitations of our study?

This study had to stop early because we were not able to involve enough children in the study in the time we had, and we ran out of funding to continue. Some of the reasons children and their families didn't wish to take part in the study were because they didn't want to have a wrist orthosis, or they didn't want to give up a wrist orthosis they already had.

We also had technical difficulties in recording the number of hours that children wore their orthoses and keeping the wrist measurements as accurate as possible, particularly on small hands.

Conclusion

This study shows that wrist-hand orthoses worn for 12-months might increase wrist range of movement with fingers extended or prevent loss of wrist range of motion movement for children aged 5-15 years with CP and muscle stiffness in their hand(s). Despite this potential benefit we still

don't know what other effects orthoses might have on a child's life, or whether this small potential benefit is enough to recommend prescribing wrist-hand orthoses to these children. Considering this, it is important for therapists and families to carefully discuss the potential benefits and risks to a child and family from using an orthosis.

This plain language extended summary has been written by Georgie Rose and Jacky Lipson with contributions from the Investigator team and the study's National Advisory Group of parents.

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