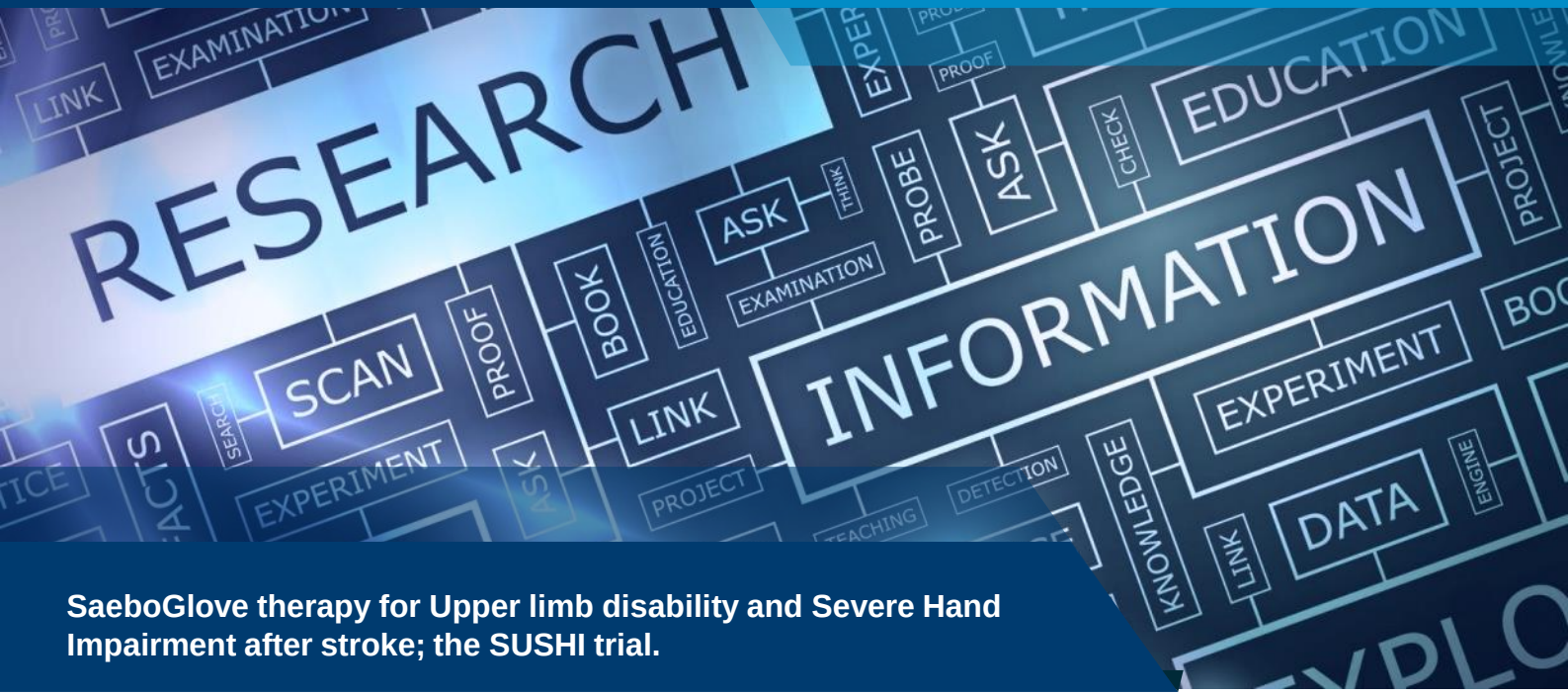
CHIEF SCIENTIST OFFICE

CODE: TCS/19/14

RESEARCH PROJECT BRIEFING



SaeboGlove therapy for Upper limb disability and Severe Hand Impairment after stroke; the SUSHI trial.

AIMS

- People with severe hand and arm weakness after stroke often have limited recovery of their hand and arm movements. Addressing this is a key priority for stroke survivors.
- Devices are now available which can help people open their hand, even when their stroke is severe. This allows them to take part in rehabilitation therapy early after their stroke.
- We aimed to assess the effect of 6 weeks use of such a device (the SaeboGlove) on recovery of hand movement and function in people with significant hand weakness early after stroke.
- The trial was designed with input from people with lived experience of stroke and the trial management committee included a stroke survivor.

KEY FINDINGS

- The glove was well used by SaeboGlove treated participants.
- Hand and arm movement and function improved by more in people who used the SaeboGlove compared to people who did not after the 6-weeks treatment.
- Two months after treatment had finished scores of hand and arm function were still higher in the people who used the SaeboGlove.
- Participants and therapists reported a high degree of satisfaction with the SaeboGlove.
- SaeboGlove treatment is a cost-effective treatment for use in the NHS.

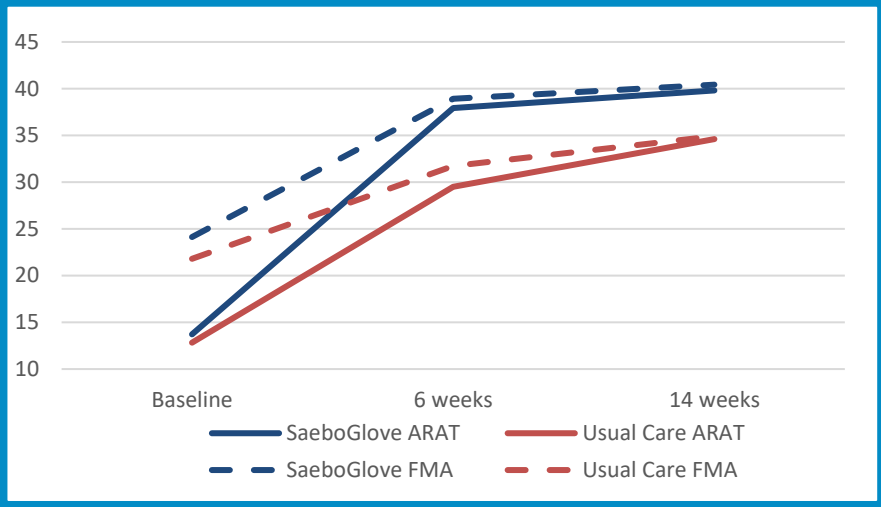
WHAT DID THE STUDY INVOLVE?

- The SUSHI trial was a multicentre, randomised controlled trial which compared recovery of hand and arm function in people who did self-directed and individualised treatment using a SaeboGlove compared to people treated with usual care. All outcomes were done by blinded assessors who were unaware of treatment given.
- We included 78 adults between 7- and 60-days post-stroke. Half received 6 weeks' of the SaeboGlove therapy in addition to usual care. The other half received usual care only. We followed participants after the 6 weeks treatment and again 2 months later.
- The primary outcome was change in the Action Research Arm Test (ARAT) at 6 weeks. This is a measure of how well people do when, moving, grasping and pinching objects.

WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

- 78 participants were included (39 treated with SaeboGlove plus usual care and 39 usual care) between November 2019 and October 2022 from 6 study sites in Scotland.
- The average age of included people was 63 years, 28 (36%) were female, and 63 (81%) had suffered an ischaemic stroke due to a blood clot in an artery (the remainder had a bleeding stroke).
- In people treated with the glove, it was used on an average of 36 days over 6 weeks.
- The ARAT score at 6 weeks improved by 7 points more in people treated with the SaeboGlove compared to those who only received usual care. The size of this improvement is likely to be meaningful in terms of function and quality of life
- Two months after the end of treatment there was a smaller difference between groups but measures were better in people treated with the SaeboGlove.
- The Fugl Meyer (FMA) score, another measure of arm movement, improved by 5 points more in people treated with the SaeboGlove at 6 weeks. This is also an important increase.
- SaeboGlove treatment was associated with lower overall costs of care and better quality of life.

The graph shows the FMA scores (dashed lines) and ARAT score (solid line) over time in SaeboGlove (blue) and usual care groups (orange). These are measures of arm movement and function. There is a greater improvement with the SaeboGlove. For reference, a difference of more than 5 points in the ARAT score and 4 points in the FMA score is regarded as clinically meaningful for stroke survivors.



WHAT IMPACT COULD THE FINDINGS HAVE?

- Our study provides the first high quality evidence that self-directed and individualised treatment using a SaeboGlove improves hand and arm function early after stroke.
- SaeboGlove based therapy should be considered for use in the NHS for people with severe hand weakness after stroke.
- Use of this therapy could accelerate recovery of hand and arm function without adding to overall costs of treatment.

HOW WILL THE OUTCOMES BE DISSEMINATED?

- The results will be submitted to the European Stroke Organisation Conference 2024 with the aim of simultaneous publication in a medical journal.
- Results will also be disseminated via Allied Health Professionals forums.
- Results will be disseminated to participants via the Scottish Stroke Research Network user group.
- We have also developed content and training materials that can be used by NHS services who want to use the SaeboGlove.

CONCLUSION

- Self-directed, individualised therapy, incorporating a SaeboGlove device is effective at improving hand movement and function in people with significant hand weakness early after stroke.
- It represents a cost-effective treatment option for people who often have poor recovery after stroke.

RESEARCH TEAM & CONTACT

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