



# USABILITY STUDY REPORT

Stretching by Design - LARA



## PROJECT DETAILS

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## CLIENT BRIEF

Stretching By Design have been collaborating with the HDTI over the past year developing prototypes and suggesting improvements to the design of the Leg Adductor Relaxation Assistor (LARA). LARA is an innovative product to alleviate symptoms related to long term health conditions such as Multiple Sclerosis (MS) and Cerebral Palsy. The next stage in the development of the LARA is a field trial, which will explore the opinions of people with MS to make any necessary user-led changes to the design.

LARA is the first product by Stretching By Design and is built upon the experiences of one the co-founders. LARA is a simple and portable device that is designed to apply a sustained stretch to the adductor (thigh) muscle group which in people who are diagnosed with MS are prone to tightness and leading to reduced mobility. Currently these symptoms of MS and spasticity can only be treated by physiotherapy. However, this can be costly and time consuming, whereas the LARA promotes self-management so leaving time with possible cost saving benefits to the user.

Stretching By Design have commissioned the HDTI to conduct a field trial of the final design to evaluate the concept and gather opinions of people with MS with a view to launching the LARA into the UK healthcare consumer market.

## PROCEDURE

### Objectives of the study

The objective of the evaluation was to gather opinions of people diagnosed with MS who experience tightness in their adductor muscles, to make any user-led changes to the final design of the product.

### Research Design

The research design was qualitative, using a 'grounded theory' approach.

### Participants

Six participants were recruited from a MS support group in the West Midlands.

### Procedure

Participants were briefed at the recruitment stage about the field trial and informed the product would be given to them for a two-week period. A consent form was completed by those wishing to take part. To ensure participants met the criteria detailed in the ethics form, the researcher assessed the participants using the Modified Ashworth Scale for Spasticity. Their results prior to the study are shown below:

Participant 1 = 3

Participant 2 = 1

Participant 3 = 1

Participant 4 = 3

Participant 5 = 2

Participant 6 = 2

Participants were then given a LARA prototype to use for a two-week period. In those two weeks the researcher made frequent contact to ensure the participants were not experiencing any difficulties.

At the end of the two-week period, participants were debriefed and interviewed individually to explore their experiences of the LARA. The interviews were audio recorded for transcription.

## **Ethics**

Ethical approval was granted for the field trial from Coventry University Ethics Committee.

## PRODUCT

The device is placed on the mid-thighs of an individual when they are sitting, with the handles on the upper surface, and the plates against the medial aspect of each thigh. The device is then operated by squeezing the two handles on the device until an audible click is heard. This action moves the plates along the device to move the legs apart, and thereby to stretch the adductor muscles in the legs. The user deliberately attempts to relax their thighs in the support provided by the LARA.

If the participant experiences a spasm or discomfort the device can be removed immediately, by moving the handles in the opposite direction, which operates a quick release function, allowing the user to move their legs as needed.

The device is to be used twice a day for thirty minutes. During these periods the user gradually increases the stretch slowly in order to relax the adductor muscles.

## RESULTS

Themes were extracted from the participant interview transcripts using grounded theory, which is a method of analyzing qualitative data.

Six key themes emerged from the data and these have been identified below:

- Design of the LARA prototype
- Ease of use
- Instructions
- Operation of device
- Physical benefits
- Future of the LARA

## **Design of the LARA prototype**

Participants were questioned about the design of the LARA prototype and comments they could make regarding the design following the two-week trial period.

Participants were positive about the design of the LARA prototype; their main concern was the weight of the device, which can be easily addressed in the final design.

*"Literally I have had no problems with it, at all, in using it, it was all good."* (Participant 3)

All participants agreed that the prototype design was too heavy for people with MS, and some participants needed support from a family member to operate the LARA.

*"To begin with I thought it was quite heavy, it takes all your energy to do it, but with time and I learnt new skills, I was able to do it (pick the LARA up)".* (Participant 1)

*"Yes, otherwise I need somebody here because it would sit on my legs forever"*  
(Participant 2)

*"I suppose it is alright for me, but for someone who has got a lot of weakness they might have a problem. "* (Participant 3)

*"If I wasn't feeling too bad, I can manage it, it was heavy. I didn't know why it had to be so heavy."* (Participant 4)

*"Yes, it might be, but in my circumstances I couldn't pick it up anyway, but other people may find it heavy for them. That's the problem with the disease other people might be ok to use it on their own. It wasn't too heavy on my lap really."* (Participant 5)

*"Yes, I found it particularly heavy"* (Participant 6)

Participants expressed their concern that the LARA was too heavy and suggested that perhaps instead of the frame being made of metal and wood, to make it lightweight, perhaps a more suitable material for the frame would be plastic. However, this also

raised concerns over whether the LARA would still be sufficiently robust for function, as pressure is needed to stretch the adductor muscles.

*"It would have to be hard plastic to hold the mechanism, because you need a certain amount of pressure to use it, and open and close it, so it would have to be a strong solid material, but necessarily plastic"* (Participant 1)

*"It like we said it is the metal basically which is the heavy bit, I suppose changing that to plastic or something to make it lighter."* (Participant 2)

*"Obviously if it is made of plastic it would be lighter, but it would also be weaker as well, I presume. I think it is not that heavy".* (Participant 3)

*"That would be better definitely. I don't know about the controls, you would have to keep those metal, but actually the thing it sits on that could be better and lighter in plastic."*  
(Participant 4)

*"The whole thing of it being portable, when it is heavy sort of goes against the grain a little bit, so probably would help (being plastic). But then you would lose that robustness and then it would break, but you wouldn't know unless you tried. There is a lot of pressure isn't there, and it would be a shame if that happened, would be better off having it heavy, if it meant you would lose it the robustness."* (Participant 5)

*"If it was made out of something lighter it would work a lot better"* (Participant 6)

It was suggested that to overcome this problem, prototypes made from plastic could be trialed for robustness.

*"I can see the problem there, would have to try it and do it all again. You can come back here, it would probably be better if it was the same people"* (Participant 5)

One participant suggested the LARA design could overcome the issue of weight by having two designs, one in plastic for people who experience weakness and difficulty in operating heavy items and then a metal version for people whose MS has not reached that stage, to work on not only stretching the adductor muscles but also the muscles in people's arms.

*"Maybe you could have an easier one that doesn't stretch so much, but gives a stretch someone who is a little more disabled". (Participant 4)*

One of the participants who experienced weakness in their hands, noted that support was needed from family members to operate the controls. However, the participant thought that trying to use the controls might build up strength in their hands. Participants did not suggest a way to overcome this problem, as it is seen as part of MS, but they suggested that for first time use a family member should be present to explore what could be problematic features in operating the device.

*"My right hand isn't great, but I could manage to do it, I can see someone who has got more disability in their hand, it would be harder". (Participant 4)*

*"The only thing in my circumstance, I wouldn't be able to, it is hard for me to use the controls. So I needed my husband or you need perhaps some people would need to support to put it on to actually use the controls. But it wasn't a problem because I had support to do it" (Participant 5)*

The operation of the release mechanism also raised concern with some of the participants, again due to the weakening of the muscles through MS. Participants overcame this problem by having support from a family member in operating the LARA. Some participants thought that trying to operate the release mechanism of the LARA, would be beneficial as it added to building the strength in their hand and arm muscles. It was reported that during the trial, one of the participants overcame this issue and developed the power within her adductor muscles to use the release mechanism, supporting that the device builds up strength within users.

*"When you are closing it, it was a bit difficult to do that sometimes". (Participant 2)*

*" I had a bit of trouble at first with trying to get it to go back, but once my son showed me, I got the hang of it and I am ok now." (Participant 4)*

*"For a bit, at first I think he (participant's husband) was perhaps a bit confused how to unlock it, I don't know why. Because you have to push it the other way, it does say it. It was only once or twice, and I said no it says on there." (Participant 5)*

None of the participants experienced any problematic issues from the plates such as pressure sores or redness.

*“No, not at all unlike other pieces of equipment, like the wedge, as you have to force that between your legs and I do get redness from it” (Participant 1)*

*" No, no none at all." (Participant 3)*

*" No, because you have only got it on for half an hour, 40 minutes it isn't really going to cause a pressure sore, unless you have got really sensitive skin." (Participant 4)*

*"No problems" (Participant 5)*

It was agreed that the plates would be better covered with material like the sheepskin to make it more comfortable when operating.

*“Yes, my physiotherapist was impressed with the sheepskin, as she had only seen it when the plates were metal” (Participant 1)*

*"It is very soft. I think the sheepskin is fine again." (Participant 3)*

*"I don't think you need the sheepskin on both sides really, you could perhaps have it just in the inside, or wherever is the greatest pressure which would be the inside."*

*(Participant 4)*

*"I think that made it comfortable. It wasn't uncomfortable at all" (Participant 5)*

The partner of Participant 1 has an Engineering background, and suggested two ways of improving the design, which might be investigated further to increase the benefits of the device. Firstly, as the release requires a lot of strength, he suggested attaching a spring to the mechanism, to reduce the amount of pressure the user has to apply. Also

for some users whose hands are weak, a controller that increased the stretch on an impulse could be attached to the mechanism, so people did not have to use the handles. Participant 1 made these suggestions in the interview, as she and her partner thought it might increase the use of the LARA.

Participants were asked whether they thought the prototype was robust enough to suit the functionality of the LARA. All the participants agreed that the LARA was robust, and no one experienced any part of the design breaking. This theme also relates to whether the material of the LARA should be changed to plastic and what would happen to the robustness experienced while the prototype was metal.

*"Yes I would think so. I have dropped it, not from a great height but it has fallen off my knee when I was getting it off, so it is quite robust. It survived."* (Participant 4)

*"I don't see any way you could get confused or break it."* (Participant 5)

## Ease of Use

Participants were asked whether they found the LARA easy to operate and portable.

*"It was reasonably easy to use" (Participant 4)*

Participants were extremely positive about the LARA being portable, as this enabled it to fit within their daily lives.

*"Yes very much so. That's what I liked about it" (Participant 4)*

*"It was so easy to use, to be honest; you didn't have to put yourself out because there was many different ways where it could be used."*

(Participant 5)

Some participants expressed that with some equipment to strengthen muscles for people with MS, it was difficult to fit them in during the day, due to the process of setting the equipment up, and doing the activity and then clearing the equipment away. There were no problematic issues like this with the LARA, as it was easy to set up and could be operated while doing other activities like sitting as a passenger in the car.

*"Yes, sitting in front of the TV. If it was lighter, I could do my daily tasks like doing my ironing, just fit in with a routine. I think if it was made lighter, because as it was heavy needed someone there, but if it was lighter could do it as often as you liked and work it around you rather than around other people, within an exercise regime to improve your life". (Participant 1)*

*"Yes definitely, because a lot of things you think I have got to do it, but could never find the time slot to do it, like my Pilates thing." (Participant 4).*

*"It was very practical, that's I think that's the one word you would say about it, as an exercising device perhaps it was the most practical thing you can take it with you, it is not like an exercise bike you have to have. It didn't take any time at all. It probably takes me longer to get organised in my exercise bike to be honest. It is right, I thought it was very good." (Participant 5)*

*"It is not inconvenient, I used it while I was watching TV, even while I was relaxing falling asleep and I have told you before even in the car which was about half an hour, so it could even use it in that half an hour in the car". (Participant 5)*

To support the easy use of the LARA, the time it took out of the participants' day was considered to be no problem, as it was such a short period of time.

*"It is like half an hour at the end of the day. I am sure everyone can spare half an hour, so there are no problems with time." (Participant 3)*

As noted earlier some participants had difficulty in the ease of operating the LARA, but they expressed that this was due to their MS and the weakening in the hands, making the operation of controls and picking up the LARA difficult. But these problematic issues can be overcome with support from family members and carers.

## Instructions

Participants were all questioned as to whether the instructions were clear and concise, the warnings were stated clearly and that there was no ambiguity or missing information. All participants agreed that the instructions were clear and concise for someone to follow.

*"Yes, the only thing I didn't follow was the timing because I was enjoying it so much so I just left it and didn't time it, it was just perfect"* (Participant 1)

*"Yes, they were perfectly clear, it very simple to use."*  
(Participant 3)

*"Yes very easy to follow, you know it is not hard to follow".*  
(Participant 4)

*"Yes they were fine."* (Participant 5)

Participants also gave the instructions to family members to read to help with the operation of the LARA and they also found the instructions clear to use. It was mentioned that the releasing of the LARA confused some of the participant's family members, but that was put down to them not reading the instructions fully.

*"No I didn't and my husband didn't have any problems with it. He didn't read the instructions properly on the device".* (Participant 5)

It was suggested by one participant that on the first time of operating the LARA a family member should be present to help work through the instructions, in case of a panic situation.

*"Yes the instructions were very clear. I would say if anyone is going to use it for the first time, I would have someone with them because you can panic what do I do with this now, you know and you are at that point where you can't get your legs any wider. The first time have someone there, just to help you."*  
(Participant 4)

All of the participants were briefed by the researcher and were shown how to operate the LARA as well as talked through the instructions before agreeing to take part in the research. One participant mentioned that visually watching the researcher operate the LARA, while reading the instructions reinforced how to use the LARA, and thought this would be a good process to continue. It was recommended a DVD showing how to operate the LARA could go along with the device to reinforce how to operate the device.

*"It is a good idea, so people can actually see how to use it". (Participant 1)*

*"Yes, that would be good, to have it visual definitely." (Participant 2)*

*"Yes and your instructions as well. You have got a double barrel; you got someone else telling you as well, just in case you had any problems. But the instructions were clear enough. Yes, I think that (DVD) is a good idea." (Participant 5)*

*"Yes, because quite often people with MS have problems with their eyesight so they might not be able to read it. It would be nice if they could have a demonstration."*  
(Participant 6)

## Operating the LARA

To ensure there were no other ways in which the device could be used or whether people could operate the device incorrectly, participants were asked during their two-week trial whether they used the device incorrectly. All the participants agreed that the LARA could not be used incorrectly. The only way the LARA could be incorrectly used would be through not reading the instructions correctly, as all the information is provided for correct use.

*" I think forcing yourself to use it, ramming it between your legs to fit it in, but I think it is common sense that has to be used, with the information you have got it tells you how to use it and it is very simple to use."* (Participant 1)

*"Incorrectly used. I suppose if you don't read everything properly it could be people go at and don't think I need to read the instructions but if people read it properly I don't see that they would have problems. The information is there as long as it is read."*  
(Participant 2)

*"I don't think so".* (Participant 3)

*"No. I think it is simple and I don't think you could use it incorrectly."* (Participant 4)

*"No I don't think, no I don't see any way you could get confused or break it."* (Participant 5)

## Physical benefits

Participants were asked, whether they had felt a difference or any benefit in using the LARA over the two week trial. All participants were positive about the LARA and had all experienced a benefit even within the short time period of two weeks.

*“Over time with practice I was able to work the whole mechanism myself, including closing it, and my legs obviously became powerful enough to close the thing (LARA). I have Botox to relax my muscles so that I can stretch them, so that machine (LARA) was absolutely perfect and came at the right time.” (Participant 1)*

*“For people who have difficulty moving their legs, it is very good, it does what it says on the tin. It is very good and you can feel a difference because you can spread it quite wide.” (Participant 2)*

*“I feel a lot more relaxed if you know what I mean, I don't know if that was the aim of it. I feel a lot more elastic. Yes definitely and I have had less cramps as well in my legs and obviously that is a good thing.” (Participant 3)*

*“Yes I have. I think so, even though it has been two weeks which isn't long enough really.” (Participant 4)*

*“Funnily enough: yes. I perhaps not going outwards, but with the movement, I can feel things moving in. So it felt, this is why I have been thinking about another one at the side, I am trying to do it now; I can feel the muscles tensing. I think over the length of time, it couldn't do any harm, put it that way. I don't think it can harm, so it can only be good.” (Participant 5)*

## **The future of LARA**

Participants asked what was going to happen to the LARA after the two-week trial had finished. The researcher explained a report would be compiled from their thoughts and opinions for the company, and then the decision is with them. All participants expressed an opinion, that this product would be of great use to people with MS and would recommend its use to other people if it becomes available on the market.

*“An awful lot of people, because people in my situation it would be ideal to do it yourself and that is what is important.”* (Participant 1)

*“Yes I think it is great.”* (Participant 4)

*“Yes definitely”* (Participant 5)

Participants also expressed that if the LARA did become available they would purchase one themselves, and also for the support group for which they attend as it was of great benefit.

*“If this was mass produced I would be more than happy to have one, like I say I just feel a lot more nimble. I would like to have one personally”.* (Participant 3)

*“I think yes we would probably get one. Yes, you can see we have done that (at the centre) with the exercise bike. Yes that would be a good idea.”* (Participant 5)

## Summarising the two week trial

The researcher asked each participant to summarise their experience of using the LARA within the short period of time, each participant was positive about the LARA and the concept behind the product.

*"I think it is better than good, it is brilliant because so many people have needed this for such a long time, because all you can do is force something between your legs and that is not good. If it was lighter that would be an improvement".* (Participant 1)

*"The idea, the principle behind it is very good."* (Participant 2)

*"It is fairly simple to use so there is no problems there and well done to the guy for creating the LARA"* (Participant 3)

*"I thought it was a very good idea and it was reasonable easy to use. It was heavy, that was the only bad thing about it."* (Participant 4)

*"Let me think how to put this, I felt a difference, I have felt a difference".* (Participant 5)

*"The device was too heavy to operate and I live by myself, so that was difficult, if it was made lighter it would be better to use."* (Participant 6)

## CONCLUSION

The purpose of this two-week field trial of the LARA was to establish if there were any user-led changes to the design and what were the thoughts and opinions of people with MS on the benefits of LARA.

The study involved interviewing six participants about their experience over a two-week field trial; there were six key themes that emerged. From this small-scale field trial, the data would suggest that the LARA was a highly beneficial product for people with MS. All the participants were positive about the concept of the LARA and would like to see it being used in the future.

The data confirms that the LARA is a portable device, which is easy to fit within daily life, and is easy to operate. The one concern of the participants' was the weight of the LARA, which could be addressed by changing the materials used for the frame of the LARA.

## RECOMMENDATIONS

The following recommendations are made for the consideration in the manufacturing and development of the LARA to progress the product to the market place.

### Design

Overall participants were positive about the concept and design of the LARA. All the participants recruited for the two-week trial were diagnosed with MS, therefore it is important to note, when summarising the findings of the design theme, that all participants experience slightly different symptoms with their MS. This is because MS affects each individual differently.

The main concern of all participants was the weight of the LARA and that it was too heavy for people to pick up and operate. This could be overcome in two ways; firstly the frame of the LARA could be constructed from plastic however this may compromise the robustness of the design. Secondly, like some of the participants in the trial, operating the LARA could be facilitated by a family member or carer.

None of the participants experienced pressure sores or redness and agreed the sheepskin material covering the plates added extra comfort in use. Therefore there are no user-led changes to be made to the plates.

The participants agreed that in its current construction, the metal frame made the LARA robust. However if the material was to be changed to something lighter such as plastic, this may compromise the strength of the product.

Therefore the company should consider this concern if the frame is to be constructed using plastic instead of metal and in line with this, trial out a plastic design to test for robustness.

In drawing upon the opinions of the participants, it would be worthwhile for the company to consider what materials are most practical and lighter in the final design of the LARA.

## **Ease of Use**

All participants were very positive about this aspect of the LARA. The operating of the LARA didn't interfere with daily activities, and some participants found it fitted in perfectly with their plans like using the LARA in a car, unlike other products for exercising.

The company should utilise these positive comments to increase the LARA's place within the market of products for people with MS.

## **Instructions**

All participants thought the instructions were clear and concise, and easy to follow when using the LARA. Some participants had support from family members in operating the LARA, and they also experienced limited difficulties. The only difficulty was remembering how to operate the release of the LARA, but with practice all participants overcame this difficulty.

It was recommended that if the LARA was to be released into the market for purchase, a DVD could support the instructions. This would enable people to view visually how to operate the LARA to overcome the difficulty of releasing the LARA.

All participants agreed that the device could not be easily used incorrectly.

## **Physical benefits**

The LARA is a stretching device for the adductor muscles, so a positive finding was that all participants experienced a benefit in taking part in the trials. Even though there was no quantitative analysis of the benefit, all participants subjectively reported that even within the two-week period they felt a physical benefit.

A suggestion would be that the company could implement a trial with a pre and post test quantitative design to analyze the physical benefits in depth.

## **Future**

All participants were impressed with their two-week trial of the LARA, and expressed an interest into what is the next stage in the process for the product. It was made clear that because it was portable, easy to operate and had a beneficial effect, all would be interested in purchasing the LARA.

Therefore it could be recommended to the company, that they stay in touch with the support group to aid the development of the LARA until the release of the final product.