

Interviewing future end-users and clinicians regarding wearable functional electrical stimulation devices

Framework to be used during interview

 Thank you for agreeing to participate in this study about these F.E.S. garments. We are not audio-recording <u>vet</u>: if you want to, tell briefly to the group <u>who you are</u>, and what viewpoint you are bringing to the discussion. I will start the round table: My name is Bastien, I am a physiotherapist and I'm doing research since 2010. I worked in stroke rehabilitation previously and now I'm focused on spinal cord-injury rehabilitation.

[Participants and researchers introduction]

As you see, we purposefully made a diverse group, with various perspectives.
We want this to be a safe place to talk: here everybody's opinion matters!
I am now going to give you a brief presentation about the project.
Please refrain from asking questions for now: we will have lots of time to discuss after.

[Presentation of the slides and videos on the technology]

Before we begin taping the discussion, here is how we would like things to work today.
First, as you know, this discussion is going to be <u>audio-recorded</u>.

So, please let each person finish without interrupting.

This will help us when listening to the tapes afterwards.

Don't worry, we will ensure that everyone has the <u>opportunity</u> to have their say.

Second, please remember that whatever is discussed today should <u>not</u> be shared outside.

Since this is for research, we want to make sure everyone's <u>privacy</u> is respected.

Third, if at any time anyone wants to stop participating, please just signal it and feel free to leave. Additionally, you can say "<u>pass</u>" if you don't want to discuss a certain topic.

4. Does anyone have questions or concerns before we begin taping?

[Recording begins – few seconds of silence for filtering]

5. Here we go! Now here are the wearable devices, please feel free to examine them.

What are your spontaneous comments or questions based on the presentation and on those prototypes?

- 6. What features of these wearable devices do you like?
 - i. What do you thing of the texture? Of the look?
 - ii. What features appeal you the most?
- 7. What features do you think could be *improved or changed*?
 - iii. What can be done to make it easier to use?
 - iv. What would make it more attractive to use?
 - v. How could it be safer to use?
- 8. How do you think this type of device can be used to help someone with a SCI/Stroke?
 - vi. If science was not limited, what activities would you do with it?
 - vii. Where would it be used? (hospital, at home, in the community, etc.)
 - viii. When would you use it? How often? For how long?
 - *ix.* Realistically, what muscle or function could be exercised or compensated with it?
- 9. What could be the negative consequences of using this type of device?
 - x. What safety issues can you imagine when using it?
 - xi. How could this negatively impact your social life?
- 10. What could affect its adoption by patients and clinicians?
 - xii. If it was on the market tomorrow, what would help you get them?
 - xiii. If it was on the market tomorrow, what would prevent you using them?
 - xiv. What role does insurance, medical store, network, etc. should play to access it?
 - xv. What characteristic or organization would be the decision-maker?
- 11. In your experience with assistive devices, how could this technology become <u>available</u> to you?
 - xvi. Who should we partner with? companies, government, advocacy groups...
 - xvii. How would you advertise it to patients and clinicians?
- 12. Is there anything else you would like to add that we may not have discussed? Thank you for participating and sharing your insights, that was very helpful!

[Recording ends]

13. Feel free to use the comments section to write down things that you forgot to speak about.

Appendix 2: Final coding framework

Code	Definition
Acquisition- financial	Any means or barriers to purchase such FES device; insurance, private/public/personal funds, procedure to obtain such funds, how to organize/schedule payment.
Acquisition- Process	Any sequence, events, facts, actions, procedures that ultimately leads to the patient (not) having device in their hands and using it, including (re)assessment by a professional of the state, health, needs and (non-)eligibility criteria of the end-user.
Benefit-functional	Any type of benefits resulting from using the garments (or FES in general) regarding function, daily life, possibility to do things whether FES is delivered during the function or not (result of physical changes or result of using the assistance).
Benefit-health	Any type of benefits resulting from using the garments (or FES in general) regarding body composition, organs functioning, disease, health, prevention of complication.
Benefit- psychological	Any type of benefits resulting from using the garments (or FES in general) regarding mood, motivation, pleasure, excitement, self-esteem, social engagement, behavior.
Business-model	Elements regarding the purchase, rent, ownership of the devices/services, and also opportunities of (not) collaborating with other institutions, individuals, companies, to bring devices to end-users and to have a sustainable business, or examples of business that could be a (counter)example for us.
Cost	Anything affecting or pertaining to the final price of the product.
Customer-support	About anything organized by the manufacturer/retailer to provide support, information, technical assistance, to end-users (clinicians, patients, caregivers), excluding education of users and prescribers.
Customization- garment	Any type of modification/customization of the garment itself (size, fabric, electrodes position, leads) in order to adjust to a patient's specificities, needs, requests.
Customization- stimulation	Any choice (not) to customize stimulations, by whom, how much, which muscles, in what pattern, duration, intensity, frequency, to conform to end-users needs, specificities, objectives, evolution, .
Design-aesthetic	Any considerations regarding the visual appeal of the device/garment (colors, appearance, shape, and so on).
Design- donning/fastening	Any choice (not) to be made before commercialization regarding how to facilitate donning, fastening, wearing, doffing the garment by end users (patients, caregivers, clinicians).
Design-garment	Any choice (not) to be made before commercialization regarding the shape, composition, position of the garments in general, the electrodes and/or the wires, that would affect efficacy, safety, comfort, usability except information better coded by design-aesthetic and design-donning/fastening.
Design-stimulator	Any choice (not) to be made before commercialization regarding what the stimulator (hardware and software) should look like, its features, size, shape, abilities (including type and means to provide feedback to user) that would affect efficacy, safety, comfort, usability.
Disadvantage	Any (potential) inconvenience or problems coming from wearing, using, owning, showing the garment and/or FES, to the exception of things coded by the "safety" codes.

Code	Definition
Education- prescriber	About anything organized to provide education, information on the existence, prescription, acquisition, and proper use to the professionals that will prescribe, provide, assess; and need for education, gap, and misconception of prescribers.
Education-users	About anything organized to provide education, information, best usage, precautions to the end-users; and need for education, gap, and misconception of patients.
Feedback- manufacturer	Any process that would (not) allow to bring back information from end-users to the manufacturer regarding the design of the devices, on the short, middle and long terms.
Patient-limitation	Characteristics of patient's body, organs, function, psyche that affects their health, functioning, daily life, behavior; in relation or not to using garments/FES/assistive technology (but not necessarily preventing them to use the devices).
Patient- motivation	Anything affecting or pertaining to the motivation of patient to use the device, to be active, or to take care of themselves either before, during or after using the garments.
Planning-therapy	Any aspects of organization, planning, anticipation on how/when/how much the garments or FES in general, should be used in an assistive or therapeutic approach, independently and/or with therapist/prescriber.
Portability	The aspects that would make the device more/less easy to carry, displace, transport, store, attach in a practical way.
Purchasing- expectations	End-users beliefs about the product prior to using it, factors that exist or will/should impact the expectations of the end users have towards FES, recovery, garments, etc. and whether those expectations are realistic or not.
Reliability	Any aspects that would affect positively/negatively the consistency of the devices performance, toughness, durability; and the liability (responsibility) of manufacturer/retailer/prescriber related to these performance and reliability.
Safety-electricity	The risks (or not) directly related to current delivery (pain, burning, heart, implanted devices) through electrodes or wires, and procedure to reduce that risk
Safety-injury	The risks (or not) of injury related to using/owning/dealing with the device (bruise, sprain, fracture, fall, muscle tear,), other than the 2 before (not skin injury or injury related to electricity itself), and procedure to reduce that risk
Safety-skin	The risks (or not) of damaging to the skin related to donning/wearing the garments (pressure sore, scratching, breaking down because of humidity/friction, wire pinching), and procedure to reduce that risk
Toileting	The aspects that would make the garments convenient/inconvenient for patients/caregiver to manage their bladder and bowel as usual/better than usual or other information relevant to bladder/bowel management
Usability	The aspects that would make the device more/less easy to use by the patient, with or without a caregiver or a therapist for activating, using, controlling the devices.
Usage-Scenario	Examples of tasks, exercises, context, time and place, scenario of FES/NMES/ES application that could/should be done with the garments or with FES in general (and counter-example where/when it shouldn't)
User-Misuse	Any things that end-users might do that are not expected/desirable/optimal and that could result in damages to the devices, injury to themselves or to others, or reduce performance/benefits of the device
Washing	The aspects that would affect positively/negatively the easiness to maintain the garments (or the stimulators) clean and odorless