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SPECIAL ISSUE: User Centered Design for Exoskeleton & Exosuit Usage

Perspectives of End Users on the Potential Use of Trunk Exoskeletons for People With Low-Back Pain: A Focus Group Study

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Objective: The objective of this study was to identify criteria to be considered when developing an exoskeleton for low-back pain patients by exploring the perceptions and expectations of potential end users.

Background: Psychosocial, psychological, physical load, and personality influence incidence of low-back pain. Body-worn assistive devices that passively support the user's trunk, that is exoskeletons, can decrease mechanical loading and potentially reduce low-back pain. A user-centered approach improves patient safety and health outcomes, increases user satisfaction, and ensures usability. Still, previous studies have not taken psychological factors and the early involvement of end users into account.

Method: We conducted focus group studies with low-back pain patients (n = 4) and health care professionals (n = 8). Focus group sessions were audio-recorded, transcribed, and analyzed, using the general inductive approach. The focus group discussions included trying out an available exoskeleton. Questions were designed to elicit opinions about exoskeletons, desired design specifications, and usability.

Results: Important design characteristics were comfort, individual adjustability, independency in taking it on and off, and gradual adjustment of support. Patients raised concerns over loss of muscle strength. Health care professionals mentioned the risk of confirming disability of the user and increasing guarded movement in patients.

Conclusion: The focus groups showed that implementation of a trunk exoskeleton to reduce low-back pain requires an adequate implementation strategy, including supervision and behavioral coaching.

Application: For health care professionals, the optimal field of application, prevention or rehabilitation, is still under debate. Patients see potential in an exoskeleton to overcome their limitations and expect it to improve their quality of life.

Keywords: assistive device, design requirements, user-centered approach, qualitative, patients

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INTRODUCTION

Low-back pain, often termed a pandemic of the modern world, represents a large socioeconomic burden. In the Global Burden of Disease Study from 2010 (Institute for Health Metrics and Evaluation), low-back pain was ranked highest in terms of years lived with disability. A variety of risk factors are believed to contribute to its incidence. Based on epidemiological research, three groups of risk factors for low-back pain have been identified: biomechanical, psychosocial, and individual (Balagué, Mannion, Pellisé, & Cedraschi, 2012; Griffith et al., 2012).

Many studies have investigated the effects of ergonomic interventions, aiming to reduce biomechanical risk factors (Davis & Marras, 2000; Kingma et al., 2004). However, ergonomic interventions are rather limited in their applicability, and reductions in back loading are attenuated by changes in lifting behavior (Faber, Kingma, & van Dieën, 2007; Hoozemans, Kingma, & de Vries, 2008). With recent advances in robotic technologies, a shift has occurred toward external lifting devices that help the user to handle loads that are too heavy or require awkward lifting postures. Still, for handling loads within human capacity, users often prefer manual lifting, as external lifting devices are often slow to use and not always easily accessible (Kazerooni, 2002). This suggests that a wearable lifting device may be more usable. Several studies have found that wearing devices that passively support the user's trunk reduces spinal loading during lifting, bending, and static holding tasks (Abdoli-Eramaki, Stevenson, Reid, & Bryant, 2007; Graham, Agnew, & Stevenson, 2009; Ulrey &

Fathallah, 2013; Wehner, Rempel, & Kazerooni, 2009). Thus, developing such an exoskeleton might be helpful to reduce the risk of low-back pain.

Besides biomechanical risks, psychosocial risk factors need to be considered in this context. Systematic reviews have revealed that psychological factors, such as stress, anxiety, pain behavior, and somatization, play a significant role in the transition from acute to chronic low-back pain (Linton, 2000; Pincus, Burton, Vogel, & Field, 2002). Exposing individuals to negative psychosocial environments or demanding mental tasks during lifting also leads to increased spinal loading (Davis, Marras, Heaney, Waters, & Gupta, 2002; Marras, Davis, Heaney, Maronitis, & Allread, 2000), indicating an interaction between biomechanical and psychological risk factors. Therefore, end users' perceptions of their environment, such as social, emotional, and occupational aspects, need to be considered to truly minimize the risk of low-back pain (Marras, 2012).

O'Sullivan (2011) already emphasized the great need to better understand the complex mechanisms underlying low-back pain by using qualitative research methods, such as interviews and focus groups, to listen to the patient's story and explore individual beliefs. Such a user-centered approach, when used in medical device development, improves patient safety (Leape, 2009) and health outcomes (Gosbee, 2002), increases user satisfaction (Harrison, Dowswell, & Milewa, 2002), and ensures usability and functionality (De Vito Dabbs et al., 2009). Involving end users in the early development of assistive technology can help to provide a way of formulating or verifying design specifications (Clarke et al., 2011). Previous studies on developing exoskeletons have not considered psychological factors through involvement of end users. A literature review by Hill, Holloway, Morgado Ramirez, Smitham, and Pappas (2017) has shown that the scientific community responsible for developing exoskeleton technology has not sought to understand the needs and desires of individuals who may ultimately benefit from using an exoskeleton.

For assistive technology for people with low-back pain, both patients and health care professionals should be included as potential end users. According to Darlow et al. (2012), there is strong evidence that health care professionals' attitudes and beliefs are associated with the beliefs of their patients, indicating that both perspectives are important to identify criteria for an exoskeleton. Health care professionals may be in a position to facilitate or limit uptake of new technology due to communication strategies toward the patients. Therefore, the aim of this focus group study was to identify criteria to be considered in the early development phase of an exoskeleton by exploring the perceptions and expectations of patients and health care professionals toward the potential use of an exoskeleton.

METHOD

We used focus group discussions to explore and clarify the perceptions of patients and health care professionals as potential end users regarding the usability of exoskeletons. A focus group discussion is a qualitative research method that explicitly exploits group interaction to help participants to identify their own views by discussing, explaining, or disagreeing with others and offer insights into shared experiences and voiced opinions (Kitzinger, 1995; Stewart, Shamdasani, & Rook, 2015).

Participants and Recruitment

Six patients with chronic low-back pain, defined as daily or almost daily pain for at least 3 months, undergoing vocational rehabilitation were recruited at rehabilitation center Heliomare in Wijk aan Zee, The Netherlands. Excluded were patients with specific radiographic abnormalities or a history of spinal surgery. To represent a larger population of low-back pain patients, we included patients who showed different levels of disability and large differences in low-back pain influencing their daily life. Two participants could not attend the session due to personal reasons, so we conducted the focus group with four patients. The second focus group consisted of eight health care professionals with working experience with low-back pain patients

TABLE 1: Discussion Guide for Patients (Left) and Health Care Professionals (Right)

Patients	Health Care Professionals
1. Round of introductions Introducing yourself with the help of your personal key ring Tell us something about yourself by explaining the keys on your key ring.	
2. What was a key moment with regard to your low-back pain?	2. What was a key moment with regard to your work with low-back pain patients?
3. Tell us about your personal situation and how you deal with low-back pain. Exercises, medical devices, pain killer, physiotherapy What do you like/dislike?	3. Which situation sticks most in your memory? What are the problems? What are your treatment methods?
4. Try to think back to a situation in the past in which you had problems due to your low-back pain.	4. Try to think back to a situation in the past in which you had problems with regard to patients with low-back pain.
5. Could patients come up with an idea of how to solve that problem? Collect on a whiteboard	
6. Trying out and explaining an existing exoskeleton Video How does this exoskeleton work?	
7. What does an exoskeleton need to provide to make you use it? (green card) What could be a problem that would limit your use of an exoskeleton? (red card)	7. What does the exoskeleton need to provide to the patient? (green card) What could be a problem that would limit their use of an exoskeleton? (red card)
8. Do you think an exoskeleton could help you? (in the situation of Point 2)	
9. Closing Do you think you would use an exoskeleton?	

for at least 2 years in a wide range of occupations within the health care system.

All potential participants received an invitation letter to participate in the study. If interested, they could contact the main investigator (S.B.) to obtain more information and sign up for participation. This research complied with the tenets of the Declaration of Helsinki and was approved by the medical ethical committee of VU medical center (VUmc, Amsterdam, The Netherlands, NL57404.029.16). Informed consent was obtained from each participant.

Procedure and Data Collection

Participants provided written informed consent and completed a short questionnaire to obtain information about demographic details. Patients were asked for their history of low-back pain and health care professionals were asked for their occupation. The focus group discussions were conducted by a moderator (J.K.) and an observer (main investigator S.B.) using a discussion guide (Table 1). During the focus group, participants could try out an existing exoskeleton (for device description, see the appendix) and were provided with a short explanation of the same device. Providing participants with visual material information facilitates inspiration (Bruseberg & McDonagh-Philp, 2002) and helps to give them a clear picture of the current state of the science. Therefore, the tryout was meant to give the participants an idea and a feeling of how an exoskeleton could look and work. Participants tried on the exoskeleton and performed some simple tasks, such as walking, sitting, and bending forward. The participants were clearly informed that the device used in the tryout was only an example and that questions in the focus group were still designed to elicit opinions about the potential use of exoskeletons in general. We

TABLE 2: Participants' Characteristics

Pseudonym	Focus Group	Age	Occupation	Work Experience With LBP Patients	Years With LBP	Impact of LBP on Activities and Participation
Silke	P	53	Housewife	NA	>1 year	Struggles with certain tasks
Paula	P	55	Currently not working	NA	>1 year	Wheelchair bounded
Kai	P	58	Construction foreman	NA	>1 year	Still restricted in his work
Mette	P	53	Nurse	NA	>1 year	Able to work independently
Adriaan	HCP	52	Medical doctor	>6 years	NA	
Pieter	HCP	50	Consultant for work-related musculoskeletal disorders	>6 years	NA	
Remy	HCP	38	Movement Therapist	>6 years	NA	
Robin	HCP	56	Physiotherapist	>6 years	NA	
Bram	HCP	30	Movement Therapist	>6 years	NA	
Katy	HCP	47	Reintegration Coach	>6 years	NA	
Myrthe	HCP	44	Psychologist	>6 years	NA	
Carmen	HCP	62	Reintegration Coach	>6 years	NA	

Note. LBP = low-back pain; P = patient; HCP = health care professional.

did not aim for an evaluation of the tried-out exoskeleton. We concluded both focus groups with a summary of the findings. Any additional remarks were noted. Both sessions were conducted in Dutch language and lasted between 90 and 120 min.

Data Analysis

Both sessions were audio-recorded and transcribed verbatim. The participants' names were replaced by pseudonyms to maintain anonymity. The transcripts were analyzed using the thematic analysis, a pattern-based analysis that allows to identify and report the salient features of the data (Braun & Clarke, 2013) and that is commonly used in health science research. The coding process started with repeated close reading of the text, followed by developing categories and conceptualizing them into broad themes. After linking the different categories and embedding them into a framework, major themes of the focus group discussion were identified until no new themes were generated. The coding and analysis were performed by the main investigator (S.B.). Codes, subthemes, and themes were discussed with (J.K.) until consensus was reached on all categories. Direct quotes used in the discussion were translated into English.

RESULTS

The participant characteristics of the two focus groups are presented in Table 2. The average age of the focus group with patients and health care professionals were 54.8 and 47.4 years, respectively. Each of the participants was given a pseudonym and a designation to distinguish between focus groups (P = patient, HCP = health care professional).

The main categories derived from the discussions contributing to design requirements for an exoskeleton included "problems faced as a low-back pain patient," "experience with current devices," "concerns and fears," "positive aspects and design improvements," and "field of application."

Problems Faced as a Low-Back Pain Patient

Limits in activity levels. Patients considered their limits in activity levels in the discussions about problems they face in daily life. They had, and still have, difficulties knowing their limits, often realizing too late that they exceeded those, resulting in recurrent low-back pain. One patient explained,

> I only knew my limit once I had passed it. (Paula, P)

They all acknowledged the importance of staying below their limits and learning to listen to their bodies. Still, it remains a challenge not to exceed these limits.

Three patients expressed their frustration about not being taken seriously by their doctors, who would mainly say "it [the pain] is all in your head."

Dependency and social exclusion. Patients also centered the discussion on being dependent on other people and being socially excluded due to their low-back pain. They all experienced situations in which they could not attend social events or decided not to attend in view of their low-back pain:

> [. . .] but if you're going to a party, everywhere bar tables. Well that's not possible of course [. . .] those are things that you do miss. (Kai, P)

> I'm not joining anymore [. . .] cause that takes me about a week I think, and then already days before I think oh save a bit of energy. . . well that's not worth it anymore. (Paula, P)

Limitations in daily activities. Patients reported having problems due to their low-back pain with prolonged standing and sitting; movements that require trunk flexion, such as bending forward and lifting; asymmetric movements; rotations; and unexpected movements:

> [. . .] but she [her daughter] still has to be lifted onto the bike, I don't do that anymore. I'm doing something with my back I'm not prepared for. (Mette, P)

Even though they all developed methods to deal with their limitations, they emphasized,

> [. . .] the pain always stays [. . .]. (Kai, P)

Underestimation and fear of movement. Prominent in the focus group with health care professionals was the self-perception of patients they encounter during their job. One of the reintegration coaches, who performs functional performance tests with patients to assess their functional capacity, described,

> What I see regarding low-back pain is that people underestimate themselves in what they are able to do, like: I can't lift this, and then you do a test and actually they are able to lift it. (Carmen, reintegration coach)

She defined two types of patients: those who are surprised by their actual capacity when performing the test and those who are convinced of their incapacity. Both groups lack confidence in their own capabilities.

Physiotherapists considered that low-back pain patients often stiffen their back and do not dare to move anymore for fear of pain. This complicates the choice for a certain therapy:

> [. . .] you are still trying to get them in kind of a movement model [. . .] (Remy, movement therapist)

and makes it difficult to prevent guarded movement in patients.

One physiotherapist commented,

> [. . .] Apparently they've learned from us not to move, assuming that it's not good or dangerous. (Robin, physiotherapist)

This movement behavior, which was adopted by the patients in the past, makes patients more vulnerable rather than stronger. He also remarked that there is

> [. . .] evidence that low-back pain isn't a disease for the majority here (Robin, physiotherapist)

indicating that most patients do not have musculoskeletal problems that explain their low-back pain. However, one reintegration coach noted that she, in contrast, sees a lot of patients

> [. . .] who perform lots of repetitive, physically demanding work, who do have mechanical problems [. . .]. (Katy, reintegration coach)

Patients responded in different ways regarding fear of movement:

> I can't really say I'm afraid, I'm not afraid to move but I know that I just do a lot of things that makes it worse. (Paula, P)

> Yes there is indeed fear. (Kai, P)

Experience With Assistive Devices

Limitations of current devices. Patients talked about devices they use for supporting their low back. Three patients reported using a back belt, but complained about discomfort and lack of versatility to use it for different tasks:

> I have a hate-love relationship with this corset. I've really tried everything, but what works when standing doesn't work when sitting [. . .]. (Paula, P)

One patient had positive experiences with assistive devices. Working as a nurse, she uses a stool to unload her back during forward bending work. Using elastic tape on the low back was another method one patient appraised positively in view of the simple application. She, however, also mentioned the difficulty of applying and removing the tape herself.

Health care professionals did not bring up the use of current devices in the discussion.

Positive experiences with the exoskeleton. When trying out the exoskeleton during the focus group, patients noted that they perceived support by the device and mentioned increased stability in the low back. One patient commented,

> It makes you feel how it could be and how it was [. . .] actually a very old, familiar feeling [. . .]. (Paula, P)

They all agreed on perceived support during forward bending and believed that the exoskeleton would help with lifting. Pain relief was mentioned by one patient.

Health care professionals mainly felt support when moving up from a forward bent posture or during static forward bending.

One reintegration coach stated that

> [. . .] you do get controlled in your movement. (Kathy, reintegration coach)

This control was attributed to the resistance of the exoskeleton. Two people perceived this resistance as a hindrance when bending forward:

> You do have to put in some effort to move forward [. . .] that costs more energy than doing it by myself. (Pieter, consultant)

Negative experiences with exoskeleton. Both focus groups complained about discomfort at the chest and hindrance during sitting, mainly due to high pressure on the upper legs. Only the group of health care professionals raised the guarded movement the user gets forced into:

> [. . .] is a bit artificial I think. A bit forced to move in a certain way [. . .]. (Bram, movement therapist)

Concerns and Fears Regarding Exoskeletons

Treat the root, not the problem. When talking about their concerns, health care professionals centered their discussion on the fact that an exoskeleton works biomechanically, whereas chronic low-back pain has a variety of causes. Using the exoskeleton in the rehabilitation setting would mean that

> [. . .] all possible causes of pain are immediately set aside [. . .] even though we know it is actually the other way around. (Robin, physiotherapist)

They confirmed the statement of the patients that pain always remains, stressing that identifying the root cause is more important than using an exoskeleton to treat the aftereffect.

Vulnerability and dependency. Health care professionals considered the influence of the exoskeleton on the patient's behavior as critical, indicating that wearing such a device can make the patient think:

> [. . .] with this thing you are safer [. . .] But without this thing you're more vulnerable [. . .] (Robin, physiotherapist)

Providing patients with a "pseudo-safety" will make them use the device more frequently, leading to dependency on the device, and cause a

> [. . .] decrease in confidence in your own body [. . .]. (Bram, movement therapist)

The psychologist remarked that the problem of behavioral change can be avoided if the device is used in combination with a behavioral coaching:

> I see it a bit like somebody keeps on moving. Can in principle be helpful. (Myrthe, psychologist)

Health care professionals reached consensus on the fact that supervision is essential to guarantee the correct use of the exoskeleton in terms of frequency and regarding

> [. . .] the choice [. . .] to wear or not to wear it [. . .] So it can never be like here you go, this is the device, you are taken care of. (Robin, physiotherapist)

Patients did not bring up fear of dependency during their discussion. After asking them directly, they explained they would not use the exoskeleton during the whole day. Hence, they did not expect to get dependent on it.

Muscle weakness and overloading. An issue that both groups noted was the fear of losing muscle strength when wearing the device for a longer period of time. Patients were concerned about not using their back muscles anymore, resulting in overloading and probably more pain once the device has been taken off.

Health care professionals talked about a transformation in muscle tissue in the long term, leading to an even more vulnerable patient, and a potential overloading of the knees, as the exoskeleton transfers the load from the back to the legs.

Positive Aspects and Design Improvements

Individual fit and task specific. Patients reached consensus that an assistive device should provide individual fit, being case-specific to their personal needs and maintaining independence when using the device. Consequently, using the device should not require any help for putting it on or taking it off, or for making adjustments. Another important issue raised by both groups was having a versatile device that can provide different modes of support, depending on the task performed.

Comfort and visibility. In both focus groups, improved comfort was considered as an important design requirement. Patients focused on changing the location of the chest pad to prevent pressure on the chest and to reduce the weight of the device. One patient explained she would like to have a device that is

> [. . .] less present. Not because someone might see it, but I just don't wanna feel that I have something around me. (Paula, P)

They all agreed that being seen with the device would be acceptable, if it was of light material and not too bulky.

Health care professionals considered using a backpack-like structure, instead of the chest pad, to distribute the pressure over the upper body. When discussing the visibility of the device, health care professionals raised positive and negative consequences. Wearing the device under the clothes effaces the flexibility of taking it on and off, whenever needed, and might lead to irritation of the skin. The consultant was concerned that it might confirm the patient's belief

> [. . .] that you can't do anything without it (Pieter, consultant)

whereas wearing the device over the clothes gives the impression of a temporary assistance.

Both groups remarked the risk of getting caught up in something when wearing the device over the clothes. Furthermore, visibility of the exoskeleton could, on one hand, facilitate the legitimacy of the patient's complaints as a form of "medication" making it easier to deal with problems such as coverage of costs by insurances. On the other hand, this visibility can be misused by the employer to increase work demands

> [. . .] that he [the employer] thinks: hey, he has this thing [. . .] here you go, another five hundred boxes extra. (Bram, movement therapist)

Both groups mentioned that wearing an assistive device

> [. . .] could suggest you to be more vulnerable [. . .]. (Myrthe, psychologist)

Showing vulnerability from the patient's perspective helps to protect themselves against unexpected situations. Two patients said they are often afraid of being knocked over in a crowd:

> [. . .] because if I walk without [the device] then they think there's nothing wrong. (Mette, P)

Field of Application

Health care professionals focused their discussion on the field of application and where they would see the best use of an exoskeleton.

One movement therapist emphasized,

> It really depends on the sector [. . .] Is it feasible for rehabilitation? Then I don't think so [. . .] in rehabilitation there are so many other factors that play a role than just purely physical [. . .] but is it feasible for vocational rehabilitation, if you implement it as an assistive device, then I think it is [. . .]. (Bram, movement therapist)

The psychologist agreed on the implementation of the device in the work environment:

> We currently have someone in the training who is working in construction [. . .] he has to stand in flexion almost the whole day. So this [the device] would be a nice assistance. (Myrthe, psychologist)

Patients considered wearing the device during their normal life to overcome their limitations, provided that it meets the requirements they discussed during the focus groups:

> If it completely meets all the requirements, then I think I would put it on in the morning and take it off in the evening. (Kai, P)

DISCUSSION

This focus group study was a first step in a patient-centered design approach for a novel trunk exoskeleton. We explored potential end user's perceptions of an exoskeleton to identify criteria to be considered at the start of the design process. Specifically, we investigated health care professionals' and patients' perspectives on the idea of using an assistive device to deal with low-back pain patients' main limitations.

Main concerns from the patient's perspective were loss of muscle strength as a long-term effect of using an assistive device and overloading of the low back when taking it off after a long period of use. Previous research on different devices, supporting the trunk, has shown that back muscle activity decreased between 10% and 40% during lifting and up to 10% to 60% during static forward bending (de Looze, Bosch, Krause, Stadler, & O'Sullivan, 2016; Koopman, Kingma, Faber, de Looze, & van Dieën, 2019). In the long-term, this reduction in muscle recruitment might lead to a reduction in back muscle capacity, due to the decreased demand on the back muscles. A long-term study on the effect of wearing an exoskeleton on muscle strength would be needed to deal with the patients' concern. A requirement that derives from this argument is that an assistive device should be used temporarily and the level of support should be adjustable, as mentioned by the patients. Providing different levels of support allows the user to decide how much support is needed for certain tasks and how much work can still be performed by their trunk muscles.

From the health care professionals' perspective, disadvantages of using an assistive device would be confirming the patient's disability, increasing vulnerability and potential dependency on the device. Given that low-back pain patients appear to often underestimate their own capabilities, an assistive device might only confirm their wrong self-perception. Trippolini, Janssen, Hilfiker, and Oesch (2018) showed that people suffering from low-back pain indeed have reduced self-efficacy. Low levels of perceived self-efficacy influence behavior in a way that people shy away from tasks they perceive as a threat with respect to their musculoskeletal disorder (Rahman, Reed, Underwood, Shipley, & Omar, 2008). The focus group with patients confirmed that a change in movement behavior occurs due to fear of movement and fear of recurrent pain. Health care professionals even admitted partial responsibility as a result of wrong beliefs in the past that were communicated to low-back pain patients. Still, patients also confirmed that they believed to be supported in their daily activity tasks when wearing the device and indicated to be potentially more active with the exoskeleton, rather than feeling confirmed in their disability.

Adapting movement behavior is a common way of low-back pain patients to deal with their pain and may consist of lowering physical activity (Björck-van Dijken, Fjellman-Wiklund, & Hildingsson, 2008), increasing trunk muscle co-contraction, and reducing deep trunk muscle activity (van Dieën, Flor, & Hodges, 2017). This leads to consequences such as decreased movement and motor variability, increased spinal loading (van Dieën et al., 2017) and detrimental effects, such as high cumulative load on intervertebral disks and stiffening of the trunk muscles (Hodges & Tucker, 2011). Especially decreased motor control was mentioned by the health care professionals, who explained that low-back pain patients often show guarded movement. They therefore expressed their concern immobilizing patients with the exoskeleton, rather than supporting them in moving again. Patients perceived this "guarding" as more stability in the back and felt more confident.

Translating the concerns on confirming inability and adapting movement behavior into design requirements, an exoskeleton should increase patients' confidence rather than confirming inability. If users feel more confident in performing tasks when wearing the device, they may be more likely to return to work (Woby, Urmston, & Watson, 2007). This confidence cannot be achieved by only adapting the design of the device but rather depends on the implementation strategy of the device in the rehabilitation setting and on adequate communication between the patient and health care professional.

Another concern of health care professionals was the fact that low-back pain would mainly be a psychological problem, whereas the assistive device would focus on low-back pain as a biomechanical problem. Previous epidemiological research has shown that both biomechanical and psychological risk factors are associated with low-back pain (Balagué et al., 2012; Griffith et al., 2012). In contrast to our study, a cross-sectional study by Stevens et al. (2016), who investigated patients' and physiotherapists' views on triggers for low-back pain, showed that both groups endorse biomechanical risk factors as the most important risk factor category. Asking participants in a short survey to name triggers for a sudden episode of acute low-back pain, Stevens et al. provides only a rough overview of responses. Due to the qualitative approach, our study adds more insight into the spectrum of personal experience in the context of developing an assistive device. This might explain the difference we found in health care professionals' beliefs compared with the study of Stevens et al. It should still be noted that the use of a spinal assistive device is more likely to show beneficial effects for patients with mechanical low-back pain, as this is the nature of the device.

Important design characteristics that were directly mentioned during the discussions were comfort, adjustability to align the device to the individual user, and independency in taking it on and off. Furthermore, the possibility of gradual adjustment of support was considered as advantageous to provide task-specific support and versatility, hence being able to perform a variety of tasks without hindrance. Previous research has shown that comfort and versatility are indeed limitations of most assistive devices (Baltrusch, van Dieën, van Bennekom, & Houdijk, 2018; Graham et al., 2009), leading to decreased user-friendliness and limited usability in daily life.

When discussing the usability of the exoskeleton and its field of application, health care professionals believed that exoskeletons are mainly useful as preventive measures at work site, supporting tasks like forward bending, lifting, and strenuous physical work. This type of usage is supported by several studies that have shown that forward bending, lifting, and static holding are supported by assistive devices (Abdoli-Eramaki et al., 2007; Graham et al., 2009; Ulrey & Fathallah, 2013; Wehner et al., 2009). Users, however, should be aware of potential negative consequences, such as misuse of the assistive device at work or increased work expectations by the employer. Furthermore, health care professionals considered using the device in the late stage of rehabilitation, namely, vocational reintegration, provided a clear target group and an explicit implementation strategy is defined. Furthermore, long-term supervision would be crucial to ensure the correct use of the assistive device. Patients considered using the device to be of support in their daily activities and to overcome their participation limitations, such as dependency on others and social exclusion, provided the suggested features could be incorporated. The different opinions on application underlines the importance of adequate communication between the health care professional and patient, when aiming to introduce an exoskeleton in rehabilitation. Still, further research is needed to identify the optimal application for an exoskeleton.

LIMITATIONS AND FUTURES RESEARCH

As the majority of participants in this study were recruited at the same rehabilitation center in the Netherlands, transferability and applicability of the focus group findings are somewhat restricted. Results may be different in other health care centers and other countries. We, however, believe that our findings give a good insight into context-dependent views of potential end users on this important topic in research regarding the use of wearable assistive devices in the prevention and management of low-back pain.

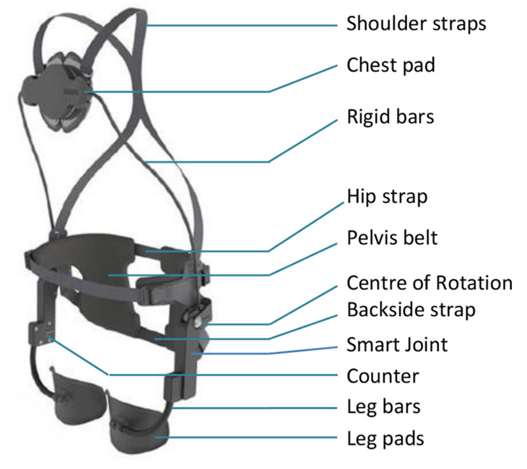
Another limitation of this study is the small sample size of the focus group with patients. As a result, the moderator had to actively facilitate the interaction. However, as an advantage of the small group, patients intensively shared their personal experience with low-back pain.

CONCLUSION

The findings presented in this study suggest many implications for the design of an exoskeleton, which can be used in future developments. The major issues offering guidance for improvements in future designs are comfort, adjustability to the body, independence in putting it on and taking it off, and gradual adjustment of support. To deal with the main concerns such as loss of muscle strength, dependency, and adapted movement behavior, an adequate implementation strategy is essential, including supervision and behavioral coaching. Furthermore, the optimal field of application is still under debate. Considering that health care professionals bear the responsibility of implementing it when used in rehabilitation, but see greater potential in the vocational reintegration or as preventive measure in the work environment, it is less likely that a spinal assistive device will find its way into the clinical rehabilitation environment.

APPENDIX

The device tested in this study was the passive exoskeleton “Laevo” (Intespring, Delft, The Netherlands), which is available on the market and used in various companies. It is worn around the waist with a belt and consists of pads at the anterior side of the chest and thighs and posterior at the level of the pelvis. The chest component is connected to the thigh component via the pelvis belt, through rigid bars running over a smart joint with spring-like characteristics. This joint generates a supporting extension moment at the level of the low back when bending forward. The chest pad can rotate in the frontal plane of the trunk to allow trunk rotation.



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KEY POINTS

- We identified criteria to be considered when developing an exoskeleton for low-back pain patients.
- We conducted focus group discussions with potential end users.
- Important design characteristics were comfort, individual adjustability, independency in taking it on and off, and gradual adjustment of support.
- Implementation of a trunk exoskeleton requires an adequate implementation strategy, including supervision and behavioral coaching.

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