

BMJ Open Understanding patient experience during Lokomat rehabilitation in children and adolescents: a clinical observational study combining self-evaluation and physiological metrics

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ABSTRACT

Objectives To examine the emotional, cognitive and dispositional experience of children and adolescents undergoing Lokomat rehabilitation by integrating self-evaluation, therapist observations and physiological metrics across repeated sessions, with the aim of characterising how patient experience evolves throughout paediatric robot-assisted gait training.

Design Prospective observational study using a multidimensional assessment approach combining self-report, therapist ratings and physiological measures.

Setting Inpatients undergoing robot-assisted gait training (RAGT) with the Lokomat at the Scientific Institute Eugenio Medea in Bosisio Parini (Italy).

Participants 42 children and adolescents (N=42; mean age 11.66±5.59 years) undergoing RAGT.

Interventions Robot-assisted gait therapy with the Lokomat. Participants underwent 30-minute therapy sessions as per routine rehabilitation protocols, with treatment durations ranging from 15 to 20 sessions, as prescribed by their referring clinician.

Primary and secondary outcome measures Participants completed ad-hoc questionnaires about emotional, cognitive and dispositional factors before and after therapy; therapists provided structured assessments of patient engagement and psychological states.

Physiological data, such as heart rate variability (HRV) and electrodermal activity (EDA), were recorded using wearable sensors to capture physiological correlates of emotional and cognitive engagement.

Results The results showed that by the end of Lokomat therapy, patients displayed increased cognitive engagement and better emotional regulation, along with higher vagal activity (normalised high-frequency) and increased phasic EDA responses. According to the therapists, patients appeared more confident, calm and cooperative. Sympathetic activation observed during satisfaction ratings reflected the involvement of the autonomic nervous system in positive emotional experiences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Innovative approach and population: This study prioritises psychological aspects over motor ones in the Lokomat rehabilitation literature, involving both the children and the therapists, which contributes to a more comprehensive understanding of the Lokomat experience.
- ⇒ Age-appropriate self-evaluation tools: The study adapts self-evaluation metrics with graphical aids, such as emoticons, to suit the age and cognitive abilities of younger participants, enabling better expression of emotions and feedback.
- ⇒ Good sample size: Considering that the study focuses on paediatrics dealing with neuromotor impairments, the sample size is adequately large.
- ⇒ Low correlations in physiological data: The lack of strong correlations between therapists' evaluations and physiological signals (heart rate variability and electrodermal activity) may be attributed to uncontrolled variables, including the motion of participants during the therapy session.
- ⇒ Unstandardised subjective measures: the absence of psychometric validation for the subjective assessment tools limits the ability to generalise results.

Conclusions This study, therefore, emphasises a multidimensional approach to rehabilitation, which involves subjective patient self-assessments, therapist observations and physiological signals in an effort to capture a more comprehensive patient experience. The findings highlight the importance of personalised, patient-centred approaches and contribute new evidence on the psychological and physiological effects of RAGT in paediatric populations. Further research is warranted to confirm these results and explore their clinical implications.

Trial registration number NCT05767268.



INTRODUCTION

Robotic rehabilitation has advanced rapidly in recent years, and robotic-assisted gait training (RAGT) has been increasingly used for various neurological, traumatic, vascular and neurodegenerative disorders,¹ with ameliorated outcomes in gait parameters and quality of life. Robotic exoskeletons mechanically support movement by adapting to the patient's lower limbs, offering advantages such as repetitive movement and adjustable support.² Among those, the Lokomat (Hocoma AG, Volketswil, Switzerland) is an exoskeleton designed to assist locomotion on a treadmill,³ used for conditions like spinal cord injury, Parkinson's, cerebral palsy and stroke.⁴

The introduction of robotic approaches to rehabilitation, especially in paediatric and ageing chronic care, emphasises the shift of care models toward an increasing focus on the role of the patient, who is willing to co-manage his/her own health.^{5 6}

Therefore, aspects of ergonomics underlying the man-machine interaction must be better understood.⁷ This type of evaluation of rehabilitation health technologies is increasing,⁸ and it seems inevitable to consider the human factors related to cognitive ergonomics, usability, software and hardware interfaces, context and how to use the robotic technology.⁷ Traditional investigation to robot-assisted treatment still focuses more on the system functioning and improvement outcomes,⁹ while little research has been done on the psychological factors reflecting robot design, functional design and patients' expectations.⁹ Particularly, within chronic neurological conditions, the psychosocial dimensions play a significant role in the perceived impairment, yet there is a lack of information regarding the perceived sense of well-being and psychosocial acceptance associated with RAGT.¹ Investigation in this direction is still scarce, but some attempts are available. Among those, the Psychosocial Impact of the Assistive Device Scale questionnaire has been widely used to assess the perceived quality of life regarding a specific device.¹ Moreover, Zhong and colleagues designed an ad-hoc questionnaire to evaluate the user's opinions about the influence of psychological factors on robot-assisted rehabilitation programmes.⁹ Similarly, Corbianco and collaborators registered the subjective experience about fatigue, muscle relaxation, mental effort, discomfort, satisfaction and emotion during RAGT.¹⁰

Despite substantial evidence highlighting the importance of incorporating patients' subjective and psychological evaluations in human-robot rehabilitation, the focus continues to be primarily on engineering factors as discussed in a recent systematic review¹¹: safety improvement, implementation of comfort and lightweight, realisation of high human-robot interactivity and performance evaluation studies. Integration of subjective, psychological evaluation and physiological responses are still limited but highly recommended in future research.¹¹ Furthermore, considering the patient's perspective is valuable but limited if not paired with the therapist perspective.¹² The

perspective of clinicians is critical: they routinely work with children and their families, knowing the facilitators and barriers to rehabilitation robotics use¹³ and enabling patients and family in fostering engagement and motivation in therapy, improving rehabilitation outcomes.¹⁴

Recent reviews exploring patient experiences in technology-assisted rehabilitation have highlighted the use of questionnaires as a method of assessment for neurorehabilitation robotics.^{15 16} Other methods relied on the use of semi-structured interviews with children and parents, paired with field notes to describe the interactions between the child and the RAGT.¹⁷

Another way to monitor patients' psychological and emotional states is by combining physiological signals with structured interviews and questionnaires to assess patients' psychological and emotional states. By integrating biosignals, which reflect physiological indexes linked to psychological conditions, patient perspectives on Lokomat gait rehabilitation can be evaluated more comprehensively.¹⁸ There is a wide consensus in scientific literature about using a multimodal physiological system, capable of detecting various signals simultaneously. For example, in a recent work, the authors explored various biological signals to monitor the cognitive load of adult patients during RAGT therapy.¹⁹ These signals include, but are not limited to, heart rate, blood pressure, electromyographic activity, respiration and electrodermal activity (EDA). By using these signals in combination with real-time machine learning (ML) techniques, the authors were able to classify and adjust the cognitive load during therapy, ensuring that tasks were neither too easy nor too difficult. This multidimensional approach aimed to optimise patient engagement during training, tailoring the therapy more precisely to the specific needs of the patient. Equally, it is vital to minimise invasiveness of the equipment, ensuring that patients can concentrate on their rehabilitation without being distracted by intrusive machinery or wires. Among the physiological signals commonly used for emotion monitoring, heart rate variability (HRV) and EDA emerge as less invasive options, still demonstrating their efficacy in emotional assessment.^{20 21}

To the best of our knowledge, the majority of the studies combining physiological metrics and psychological states to investigate the patient experience focus on adulthood, whereas research on the paediatric population is still emerging.

The present study investigates the perspectives of children and adolescents undergoing Lokomat gait rehabilitation, adopting a patient-centred approach that engages both young patients and their therapists. Aligned with the principle of conducting research with children, not on children, this repeated-measures study integrates self-reported and observational measures with physiological processing throughout Lokomat rehabilitation sessions. Self-reported measures include patient evaluations, while observational measures capture therapist assessments. By integrating these measures with physiological data, in this

study we provide a comprehensive evaluation of patient experiences during Lokomat rehabilitation, with the aim of advancing knowledge in paediatric RAGT.

MATERIALS AND METHODS

Participants

All subjects undertaking Lokomat therapy in the period between March 2022 and June 2023 were enrolled in the study, except for those unwilling or unable to participate in the data collection process. This includes individuals with cognitive or communication impairments that hindered questionnaire completion or data interpretation, as well as those with known allergies or sensitivities to materials used in the wearable bracelet used for physiological parameter recording.

This study was performed in accordance with the Declaration of Helsinki. Informed consent was signed by participants (or legal representatives) before data collection. The study was registered on ClinicalTrials.gov (NCT05767268).

Study protocol

The study protocol included the collection of qualitative and quantitative data during two training sessions with the Lokomat. Each training session lasted approximately 1 hour and consisted of four main phases:

- ▶ Patient welcoming and questionnaire administration: 'Pre-Lokomat self-evaluation'.
- ▶ Rehabilitation session with the therapist and completion of the 'Therapists evaluation' questionnaire.
- ▶ Questionnaires administration: 'Post-Lokomat self-evaluation' and 'Bubble-comic self-evaluation'.
- ▶ Greeting the patient and talking to the therapist to obtain general comments about the session.

5 min before starting phase 1, patients wore Empatica E4 wearable sensor on the non-dominant wrist, as recommended by the manufacturer, to allow the electrodes to properly adjust to the patient's skin, ensuring a more stable and reliable EDA signal. The wristband was continuously worn throughout the rehabilitation sessions, and approximately 2 min after the final questionnaire (Phase 3) in order to record physiological parameters at rest.

A custom-built application was developed to capture triggers to characterise the different phases of the session, saving the UNIX timestamp of each recorded trigger. These triggers were then synchronised using the UNIX timestamps of the signals acquired from the E4, enabling precise segmentation of the acquired signals into different phases of the session. This meticulous data collection protocol was designed to capture subjective patient self-assessments, therapist observations and physiological signals for comprehensive analysis. The study scheme is represented in [figure 1](#).

Intervention protocol details

The initial body-weight support (BWS) was set at 50% and gradually decreased throughout the training sessions

based on each child's recovery of muscle strength. A comfortable gait speed for each child was selected. The guidance force (GF) was initially applied at 100% for all participants and was progressively reduced to encourage greater effort and allow freer movement. Active participation in RAGT was promoted by adjusting speed, BWS or GF across sessions.

Outcomes measurements

Self-evaluation metrics

To investigate patients' self-reported viewpoint, ad-hoc questionnaires were used, focusing on measuring emotional experiences and attitudes towards the rehabilitation session. 'Pre-Lokomat self-evaluation' and 'Post-Lokomat self-evaluation' are three points Likert scale questionnaires ([table 1](#)), administered before and after each Lokomat session to gather self-evaluations of emotional states (items 1–6), and the subject's perception of the therapy (items 7–9). The items were adapted from the Paediatric Quality of Life Inventory questionnaire,^{22 23} the Clinical Outcomes in Routine Evaluation system trust²⁴ and the Unified Theory of Acceptance and Use of Technology model determinants.²⁵ Available response options were: 'not at all', 'enough' and 'very much'. Participants filled out both questionnaires autonomously, supported by visual emoticons and by the help of the researcher if needed.

To obtain a more comprehensive understanding of the subjective experience, an additional ad-hoc questionnaire (namely 'Bubble-comic self-evaluation') was designed coherently with,¹⁷ to be more suitable for younger children ([figure 2](#)). This questionnaire aimed to elicit free perspectives and feelings about walking with the Lokomat, by using a graphical representation of the rehabilitation system and four speech bubbles, thus allowing patients to express their experiences using non-predefined responses. The participants filled out the questionnaire at the end of each session of data collection, while researchers were available to answer any questions and to write down the responses or notes (transcribing their verbatim), if the participants were unable to do it.

Observational metrics

In order to obtain an assessment that was not based solely on patient self-report, therapists completed the 'Therapists evaluation' questionnaire: this decision was based on the need to combine an external assessment with the fact that children may have difficulty in recognising nuanced differences in their emotional states. The Therapists evaluation questionnaire was adapted from the Movement Assessment Battery for Children,²⁶ taking into account the specific scale to assess non-motor factors that may influence movement. It consists of 12 items (see [table 2](#) for the description of each variable) that assess a variety of psychological factors affecting patients' motor functioning during training: cognitive (eg, attention), emotional (eg, level of anxiety, ability to cope with emotions) and dispositional domains, that is, the tendency to feel and act in

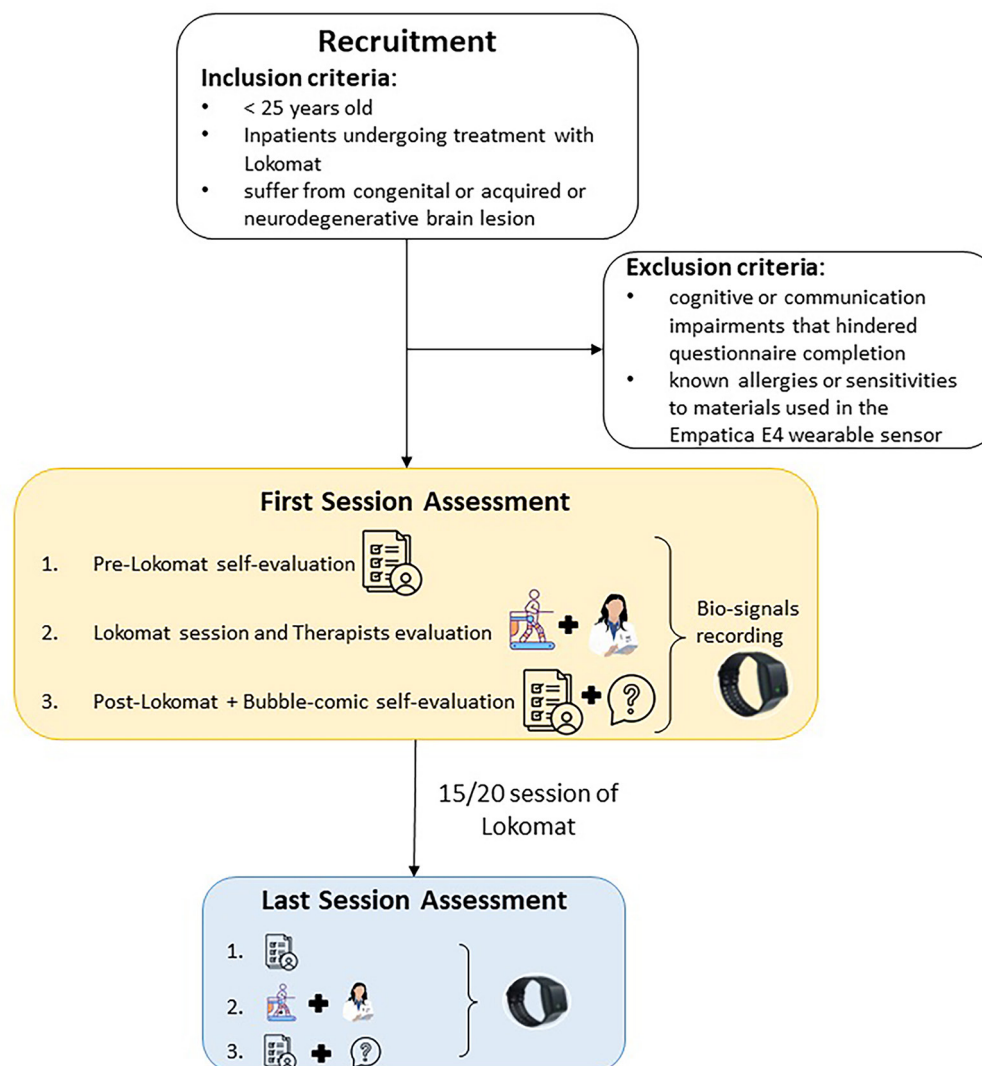


Figure 1 Study scheme about data collection.

a predictable way in different situations and over time²⁷ (eg, the tendency to underestimate/overestimate one's abilities).

Each item was rated on a 13-point semantic differential numerical scale (from '-6' to '6', with '0' indicating the 'neutral' or 'undecided' category): lower scores indicate negative qualities and higher scores indicate the opposite. The Therapists evaluation questionnaire was compiled by the therapist alongside the assistance of the researcher, collecting notes and impressions during each session of data collection and finalising the questionnaire fulfilment at the end of the Lokomat rehabilitation.

The therapist had access to an instruction sheet (table 3), describing the variables, to be consulted freely when needed, helping the therapist to maintain consistency and accuracy in the assessment.

Physiological metrics

Physiological data were collected using the Empatica E4 wearable sensor, a certified class IIa Medical Device in the European Union (EU), designed for real-time health data acquisition. The E4 wristband provides non-invasive,

continuous measurements that allow estimation of cardiac and dermal activity during the Lokomat sessions.

In particular, we were able to derive these main metrics:

- ▶ **HRV:** HRV describes how much the time between consecutive heartbeats varies. It was computed from the interbeat intervals (IBI) derived from the blood volume pulse (BVP) signal. In general, HRV is used as an indicator of autonomic regulation of heart activity.
- ▶ **EDA:** EDA reflects changes in the skin's electrical conductance related to sweat gland activity, which is commonly associated with autonomic arousal. EDA includes a slower tonic component (electrodermal level) and a faster phasic component (electrodermal responses). Since no specific stimuli were administered during Lokomat sessions, we considered non-specific electrodermal responses, that is, spontaneous fluctuations not time-locked to predefined events.

Signal processing

Data recorded via the E4 device were stored as .csv files using the Empatica Connect website, and all subsequent data processing was conducted using MATLAB (R2022b,

Table 1 Pre-Lokomat self-evaluation (left column) and Post-Lokomat self-evaluation (right column) questionnaires

Item	Pre-Lokomat questions	Post-Lokomat questions
1	"Do you feel worried?"	"Do you feel worried?"
2	"Do you feel happy?"	"Do you feel happy?"
3	"Do you feel sad?"	"Do you feel sad?"
4	"Do you feel angry?"	"Do you feel angry?"
5	"Do you feel scared?"	"Do you feel scared?"
6	"Do you feel bored?"	"Do you feel bored?"
7	"Undergoing therapy with the Lokomat will be beneficial."	"Doing therapy with the Lokomat has been helpful."
8	"I am capable of effectively managing therapy with the Lokomat."	"I have been able to effectively deal with therapy with the Lokomat."
9	"Undergoing therapy with the Lokomat will help me improve my walking."	"The Lokomat therapy has helped me to improve my walking ability."

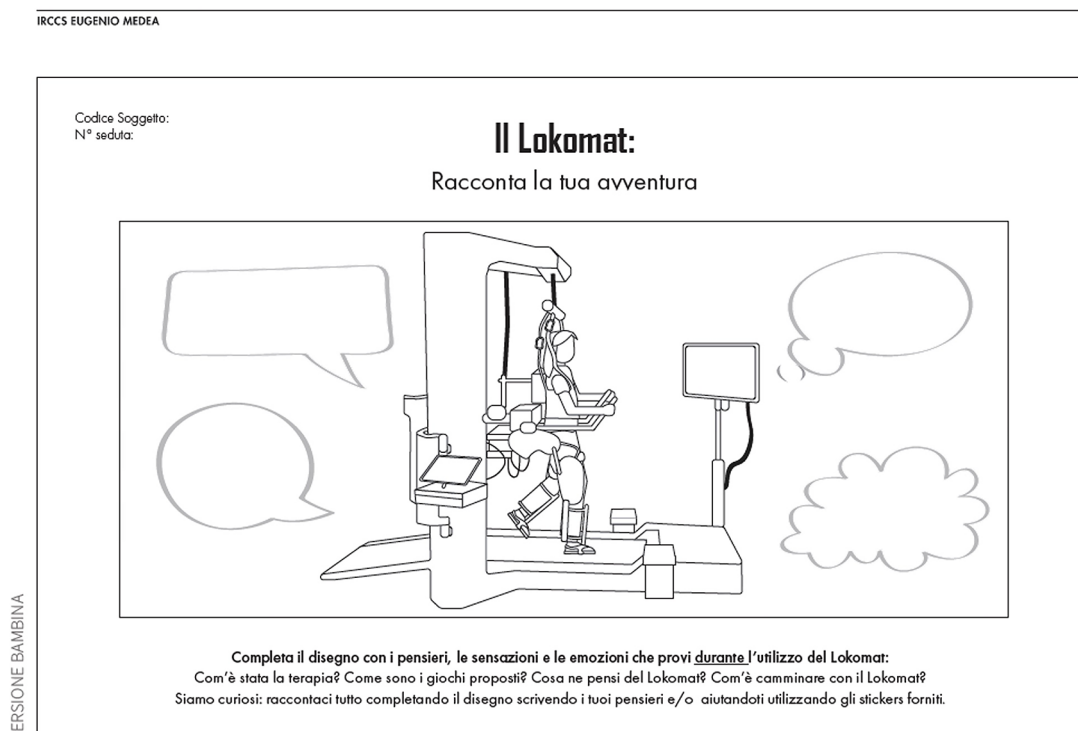
The MathWorks, Natick, Massachusetts, USA), following the procedures outlined in the study by Costantini *et al*²⁸ and briefly described below in the following paragraphs: "HRV Analysis", "EDA Analysis" and "Feature extraction procedure".

HRV Analysis

Quantitative analysis of HRV was conducted on the IBI time series derived from the BVP signal. Prior to analysis, motion artefacts were mitigated using a third-order

Butterworth band-pass filter with subject-specific cut-off frequencies determined by an automated algorithm, which leveraged the accelerometer signal to isolate frequencies relevant to the BVP signal. Diastolic fiduciary points were then extracted from the filtered BVP signal, and any inaccurately detected peaks were corrected using a custom interactive interface.

Subsequently, an artefact detection algorithm developed by Berntson and Stowell²⁹ was applied to the


Figure 2 Bubble-comic self-evaluation questionnaire.

**Table 2** Therapists evaluation questionnaire

Item	-6 -----	0 -----	----- +6
1	Passive		Active
2	Fearful		Assertive
3	Anxious		Relaxed
4	Impulsive		Thoughtful
5	Distracted		Focused
6	Hyperactive		Quiet
7	Underestimates his/ her abilities		Overestimates his/her abilities
8	Not persistent		Persistent
9	Concerned about failure		Not concerned about failure
10	Unable to derive satisfaction from success		Able to derive satisfaction from success
11	Manages emotions in a negative manner		Manages emotions in a positive manner
12	Does not actively seek information to learn		Does actively seek information to learn

BVP-derived IBIs, categorising artefacts as missing or extra beats based on consecutive heart period differences. Following artefact removal, a final visual inspection was performed to address any remaining false positives or undetected artefacts. Finally, BVP-derived IBIs were resampled at 4Hz using piecewise-cubic spline interpolation to build the HRV signal.

EDA Analysis

The raw EDA signal underwent initial preprocessing, including smoothing with a 1-second moving average filter and normalisation using z-score. Subsequently, the convex optimisation algorithm *cvxEDA*³⁰ was used to decompose the EDA signals into tonic and phasic components.

To address artefacts in the EDA signal, an artefact detection algorithm employing stationary Haar wavelet transform was applied. This algorithm aimed to identify and correct segments of the EDA signal affected by sudden changes, typically caused by contact losses between the skin and the E4 device.³¹

Feature extraction procedure

Given the considerable variability in signal duration across subjects throughout the session, standardising the signal duration for HRV and EDA feature extraction is crucial to maintain data integrity and minimise noise. To address this issue, a method for assessing the overall quality of the signals, evaluating the windows suitable for standardising BVP and EDA signals during Lokomat activity and post-training resting phases, was developed and described below.

HRV quality evaluation

To estimate the quality of the BVP signal, the Wavelet Signal Denoiser app in MATLAB was employed for visualising and denoising real-valued one-dimensional (1-D) signals while facilitating result comparison. Specifically, the following denoising settings were used: 12th level of wavelet coefficients, sym4 wavelet family, Minimax denoising method and Hard threshold rule, with level dependency.

Following denoising, a surrogate noise signal was generated, matching the length of the original BVP signal, and standardised it using z-score normalisation. A logical vector was then computed, with values of 1 indicating noise and 0 representing signal cleanliness, based on the threshold criterion, set empirically to 0.01.

The quality metric for the HRV signal, denoted as Q , was derived as follows:

$$Q = 1 - (\text{total number of noise elements}) / (\text{total number of elements})$$

This Q metric enables the evaluation of signal quality across different observation windows.

EDA quality evaluation

To evaluate the quality of the raw EDA signal, two different factors were calculated:

- ▶ The \$ factor, evaluating both signal responsiveness and motion artefacts, was determined using two logical vectors spanning the entire duration of the EDA signal:
 - The first vector, named NR hereinafter, was created through visual inspection using a dedicated graphical interface. Segments devoid of phasic activity were identified, denoted with a value of 1, while others were marked as 0.
 - The second vector, named MA, was obtained using the motion artefact detection algorithm previously described,²⁸ based on the stationary Haar wavelet transform. It indicates artefact presence with a value of 1 and 0 elsewhere.
- ▶ A logical ‘or’ operation between the NR and MA vectors was then performed, yielding a vector with a value of 0 exclusively in segments without both motion artefacts and phasic inactivity. Finally, the \$ factor was derived from this vector as the fraction of the total number of samples with no void or motion artefacts over the total number of elements.
- ▶ The P factor, extracted from prior literature,³² considers overall noise within the EDA signal. This measure is predicated on the fraction of the power spectrum’s extension beyond the functional range of the phasic EDA signal (DC-0.4 Hz) over the total power band. Greater power beyond 0.4Hz suggests heightened noise in the phasic EDA signal, thus a higher value of P indicates inferior signal quality.

Table 3 Information sheet about each item of the Therapists evaluation questionnaire

Negative item		Positive item	
Passive	Difficult to engage; requires much encouragement to participate	Easy to engage; requires little encouragement to participate	Active
Fearful	Fearful and hesitant towards proposed activities; frequently seeks help	In control of the situation, approaching therapy confidently, with few hesitations or concerns	Assertive
Anxious	Shows signs of agitation or confusion in stressful situations	Calm and composed in stressful situations	Relaxed
Impulsive	Starts before instructions are complete; impatient to receive information	Exhibits good inhibitory control, waiting for complete instructions before acting	Thoughtful
Distracted	Looks around; reacts to irrelevant noises	Concentrated and focused on the task at hand, unaffected by irrelevant noises	Focused
Hyperactive	Fidgets and moves continuously while listening to instructions, fiddles with clothes	Remains still and composed; listens calmly to instructions without fidgeting or squirming	Quiet
Underestimates his/her abilities	Complains about the task difficulties; anticipates failure before starting	Attempts to make tasks harder, rushes through tasks	Overestimates his/her abilities
Not persistent	Gives up quickly; easily frustrated	Demonstrates persistence in completing tasks	Persistent
Concerned about failure	Appears close to tears; refuses to attempt task again due to fear of failure	Not deterred by failures; failure does not affect motivation	Not concerned about failure
Unable to derive satisfaction from success	Does not react to compliments	Reacts positively to compliments received	Able to derive satisfaction from success
Manages emotions in a negative manner	Let emotions be overwhelming (eg, inconsolable if crying)	Handles emotions without being overwhelmed (eg, quickly returns to calm state after crying)	Manages emotions in a positive manner
Does not actively seek information to learn	Does not seek updates on rehabilitation progress or session content, lacks curiosity	Seeks updates on rehabilitation progress and session content, curious about learning and progress	Does actively seek information to learn

$$P = \frac{\text{Power in noise band } (f > 0.4\text{Hz})}{\text{Total power}}$$

Calculating P and \$ for each observation window enabled a comprehensive evaluation. The composite quality metric Q for the EDA signal was determined by multiplying the \$ and 1–P factors.

Signal windows selection

HRV and EDA signals during the Lokomat activity and post-training resting phases were segmented into windows. 5-minute windows were used for the Lokomat activity phase, while 2.5-minute windows were used for the resting phase, with 10-second intervals between each window.

Window selection was based on the signal quality factors Q. In the Lokomat activity phase, the top five windows with the highest Q scores were selected, ensuring they were spaced at least 2.5 min apart (with a maximum 50% overlap). Additionally, the window with the highest Q score was chosen for the resting phase.

Features extraction

The parameters for both HRV and EDA were calculated for each selected window. Subsequently, the average value

for each parameter was computed by taking the mean across all windows. This process was performed for each session and for every subject.

For HRV analysis, the following time and frequency domain parameters were computed for the selected windows during both Lokomat activity and post-training resting phases across all the acquired sessions:

- ▶ Mean HR: mean heart rate frequency
- ▶ SDNN: SD of all IBI
- ▶ RMSSD: root mean square of the successive differences
- ▶ SDDSD: SD of differences between adjacent IBIs
- ▶ PNN50: count of delta IBIs exceeding 50 ms divided by the total number of all IBIs
- ▶ HRV Triangular Index: total number of all IBIs divided by the height of the histogram of all IBIs
- ▶ TINN: baseline width of the triangular interpolation of the highest peak of the IBIs histogram
- ▶ HRV skewness: skewness of the IBIs
- ▶ HRV kurtosis: kurtosis of the IBIs
- ▶ HRV nLF: normalised power in low frequency range (0.04–0.15) Hz



- ▶ HRV nHF: normalised power in high frequency range (0.15–0.40) Hz
- ▶ Sympathetic Modulation Index: LF/(total power – VLF), LF (low frequencies), VLF (very low frequencies)
- ▶ Vagal Modulation Index: HF/(total power – VLF), HF (high frequencies), VLF (very low frequencies)
- ▶ Sympathovagal Balance Index: LF/HF

For EDA analysis, the following parameters were obtained:

- ▶ Mean EDA tonic: mean value of the tonic component
- ▶ SD EDA tonic: SD of the tonic component
- ▶ IQR EDA tonic: IQR of the tonic component
- ▶ Skewness EDA tonic: skewness of the tonic component
- ▶ Kurtosis EDA tonic: kurtosis of the tonic component
- ▶ Max upspeed EDA tonic: maximum positive slope of a regression line fitted on the tonic component
- ▶ Max downspeed EDA tonic: maximum negative slope of a regression line fitted on the tonic component
- ▶ NS.EDRs: frequency of non-specific phasic peaks
- ▶ Mean EDA phasic peak amplitude: mean of the amplitude of all NS.EDRs in the interval
- ▶ St.Dev. EDA phasic peak amplitude: SD of the amplitude of all NS.EDRs in the interval
- ▶ nAUC EDA phasic: mean normalised area under the curve of phasic peaks
- ▶ Mean rise time: mean temporal distance phasic onset-peak
- ▶ Mean EDA phasic P-to-P distance: mean distance phasic peak-to-peak (p2p)
- ▶ SD EDA phasic P-to-P distance: SD phasic distance peak-to-peak (p2p)
- ▶ nVLF spectrum EDA phasic: normalised power in very low frequency range (0–0.045) Hz
- ▶ nLF spectrum EDA phasic: normalised power in low frequency range (0.045–0.15) Hz
- ▶ nHF1 spectrum EDA phasic: normalised power in high frequency range (0.15–0.25) Hz
- ▶ nHF2 spectrum EDA phasic: normalised power in high frequency range (0.25–0.40) Hz
- ▶ nVHF spectrum EDA phasic: normalised power in very high frequency range (0.4–0.5) Hz

Statistics on self-evaluation and observational metrics

After the compilation, each Bubble-comic self-evaluation questionnaire was entered electronically on an Excel database and translated from Italian to English. The translated transcripts of each Bubble-comic self-evaluation questionnaire were uploaded to ATLAS.ti qualitative data analysis software for initial coding, as the Italian language was not supported by the tool. The coding procedure was based on the artificial intelligence automatic tool ‘AI Coding’, selecting ‘paragraphs’ as the base unit for the search and the coding (see the ATLAS.ti 24 Windows – User Manual, V.24.0.29843³³ for more details). This inductive content analysis³⁴ aimed to condense broad descriptions of the rehabilitation experience into key concepts and insights, without prior hypotheses or preconceptions. However, to ensure accuracy, two researchers conducted a thorough

line-by-line review of ATLAS.ti results, referring back to the original Italian text to verify and refine the codes. Any overlapping codes or errors generated by the software were merged or corrected, and discrepancies were discussed with the coauthors, especially those involved in data collection. The data were grouped by the first and last Lokomat sessions to identify potential changes over time. Additionally, the ‘AI Summaries’ tool was used to create a concise summary of the data, providing readers with an overall picture of the participants’ experiences across sessions.

Regarding the Pre-Lokomat self-evaluation and Post-Lokomat self-evaluation questionnaires, results related to the beginning and the end of each session, as well as between the first and the last sessions, were considered. The self-evaluation questionnaires used a three-point Likert scale: due to the ordinal nature of the scale and the observed lack of significant variation across sessions, no statistical tests were performed. Instead, the data were analysed descriptively to explore general trends in patient responses over time.

Regarding the Therapists evaluation questionnaire, a statistical analysis was conducted to assess whether there were differences between the first and last acquired sessions. Due to the non-normality of the data, the Wilcoxon Signed-Rank test was conducted. Statistical significance was set at $p < 0.05$.

Statistics on physiological metrics

The statistics on physiological metrics aimed to evaluate potential changes between the initial and final acquired sessions (longitudinal analysis). Parameters calculated during Lokomat activity (Phase 2) were initially standardised with respect to the resting phase (Phase 3), to address intersubject variability. Following standardisation, a statistical examination was conducted to assess the normality of each parameter distribution. Parameters exhibiting a normal distribution underwent paired samples t-test, while the Wilcoxon test was employed for non-normally distributed data.

Correlation

A correlation analysis was conducted using Kendall’s τ coefficient to examine the relationship between changes in physiological parameters and the therapist’s perception of patient’s psychological status. Initially, differences between the physiological parameters of the first and last acquired sessions were calculated ($\Delta_{\text{Phys_Par}}$), as well as between the Therapists evaluation questionnaire responses ($\Delta_{\text{Th_Quest}}$). Subsequently, the correlation between physiological parameters ($\Delta_{\text{Phys_Par}}$) and questionnaire differences ($\Delta_{\text{Th_Quest}}$) was examined, aiming to identify potential links between objective physiological changes and therapist observations. The choice to pair the physiological signals of the patient and the therapist assessment has been made because the responses from the Pre-Lokomat self-evaluation and Post-Lokomat

self-evaluation questionnaires were not considered reliable for statistical analysis.

Sample size calculation

The sample size calculation was performed based on physiological outcomes, given the absence of preliminary data for the subjective measures. Based on prior literature,³⁵ we assumed a medium effect size for changes in physiological parameters between baseline and stressed conditions. Setting alpha at 0.05 and power at 0.9, the required sample size was estimated at 36 subjects. To ensure conservativeness, 40 participants were included, consistent with the intensity of Lokomat device use.

RESULTS

Participants

42 participants (14 females, mean±SD age: 11.66±5.59 years old) were recruited from the patients undergoing treatment with the Lokomat, with treatment durations ranging from 15 to 20 sessions, as prescribed by their referring clinician at the Scientific Institute Eugenio Medea in Bosisio Parini (Italy). We collected inpatients, presenting various neuromotor conditions. Specifically, the involved participants suffer from brain injuries that can be congenital (eg, cerebral palsy (CP), moyamoya syndrome, hydrocephalus), acquired (eg, brain tumour; cerebral arteriovenous malformation) and neurodegenerative (eg, hereditary spastic paraplegia). The details regarding the subjects are presented in Supplementary Materials (online supplemental table 1).

Self-evaluation questionnaires

Figure 3 depicts the results concerning the self-evaluation. For both the Pre-Lokomat questionnaire and the Post-Lokomat questionnaire, the percentage of responses to various questions is reported for both the first and the last rehabilitation sessions. A qualitative comparison between the first and final Lokomat sessions, based on the Pre-Lokomat questionnaire, indicated a potential increase in self-reported worry, anger and fear, along with a possible tendency toward lower self-reported happiness in the final session. This negative experience trend (not supported by statistical evidence) does not seem that consistent in the Post-Lokomat questionnaire: in the last session, after the rehabilitation, participants seemed to report higher boredom, but they also reported feeling less worried, angry and scared, and possibly happier after rehabilitation.

Looking at the Pre-Lokomat questionnaire, perceived usefulness of the therapy appeared to increase across the first and the last session. A similar perception was still suggested in the Post-Lokomat questionnaire, although participants' impressions seemed more mixed.

Bubble-comic self-evaluation

An example of a completed Bubble-comic questionnaire from a patient is shown in figure 4.

Box 1 shows the written record, output of 'AI Summaries' tool (ATLAS.ti V.23), reporting the sum-up features coming from the transcripts of the Bubble-comic self-evaluation questionnaire, grouped by the first and the last Lokomat rehabilitation session.

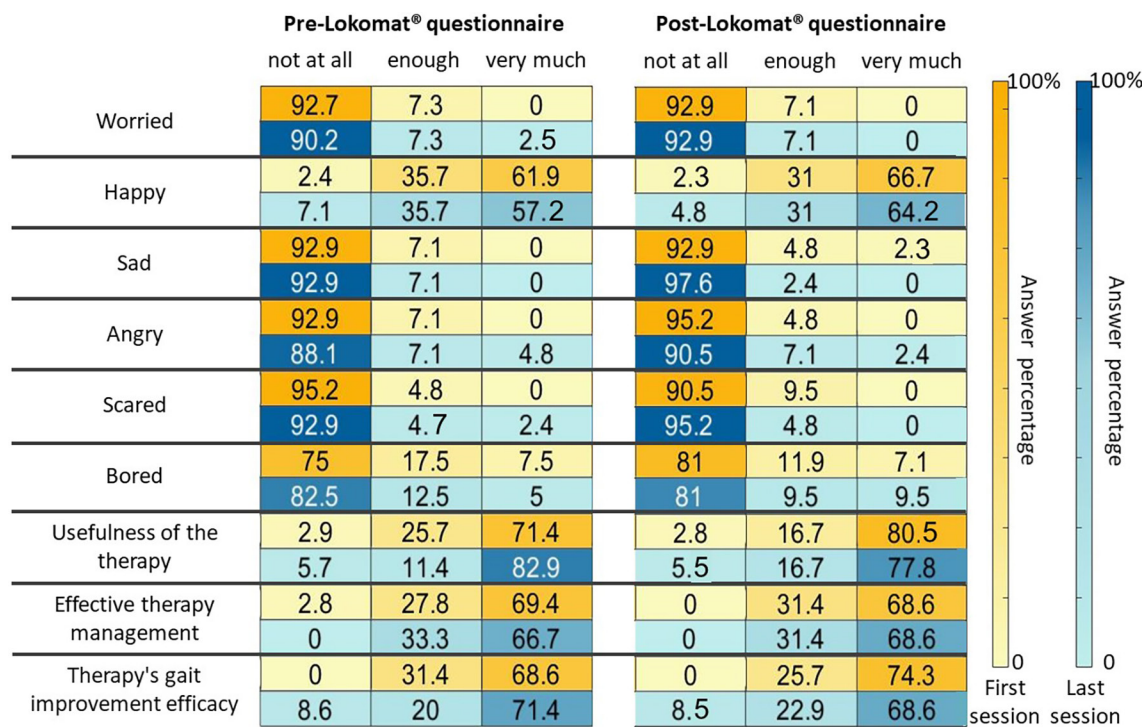


Figure 3 Percentage of Pre-Post Lokomat self-evaluation answers, divided by each of the three levels of item-response and by sessions: first (orange) and last (blue). The colour intensity reflects the percentage of answers as underlined by the two bars on the right.

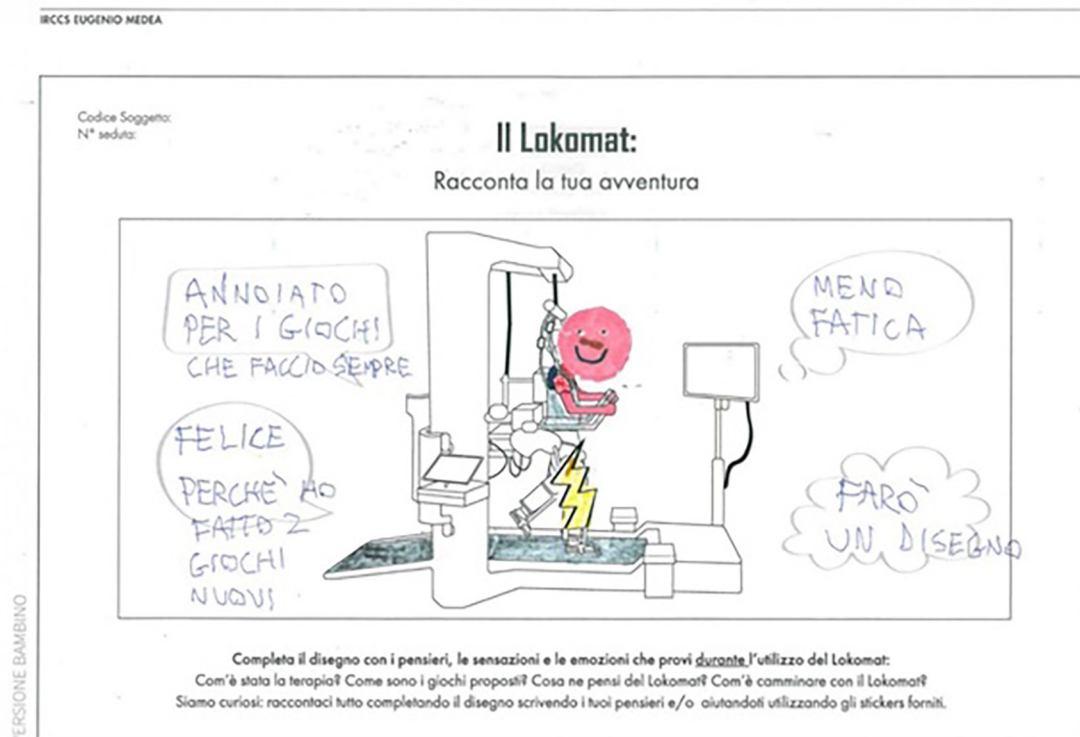


Figure 4 An example of Bubble comic compilation

Table 4 reports the output of the line-by-line inductive coding, performed by the ATLAS.ti V.23 software and using the dedicated tool 'AI Coding': transcripts were uploaded to the software and the codes were generated automatically, including the subcodes; the researchers verified each one in the text detecting any error and optimising the labels (eg, merging the similar ones, moving subcodes under the different codes, renaming them to be clearer).

Box 1 Short summary of the first and last Lokomat sessions data, collected through the Bubble-comic self-evaluation questionnaire and automatically condensed with ATLAS.ti.

First session

The Lokomat therapy is enjoyable because of the fun games and the feeling of getting stronger while walking. Games are engaging, and the overall experience brings happiness and distraction. Different individuals have varying experiences with the Lokomat, some finding it tiring but satisfying, while others struggle with certain games but enjoy the process. Overall, the Lokomat is seen as a helpful tool for improving walking capabilities and overall well-being.

Last session

Feedback regarding the Lokomat therapy from different individuals included experiences of fun, tiredness, happiness and improvement. Most individuals enjoy the games, find walking with the Lokomat pleasant and feel motivated to continue the therapy. Some find certain games boring or tiring but acknowledge the benefits of the therapy. Overall, the Lokomat therapy is considered important for improving walking abilities and is seen as a positive experience by many.

A total of nine codes resulted from the data: each code is described by the related subcodes, explained in table 4 with one quote, meaning a sentence taken from the Bubble-comic self-evaluation questionnaire as an emblematic example.

Figure 5 shows the distribution of the total number of codes divided by the first and the last session. The analysis was performed on the total sample of 42 participants, but four participants were excluded because of missing answers in the first, last or both sessions. The total number of codes (N=155) is because multiple codes could be applied to a single participant's response.

Overall, the emotional experience is stable, with a reported increment in the cognitive involvement, engagement and progress in the last session of Lokomat: by the subcodes reported in table 4, this is reflective of children being more engaged to the therapy, in the sense that they are committed and motivated to the rehabilitation process as well as more involved in the use of the RAGT and its benefits.

Therapist assessment

Considering the Therapists evaluation questionnaire, figure 6 illustrates box plots of the questionnaire items, with three items showing statistically significant differences between the first and last Lokomat sessions according to the Wilcoxon test. Specifically, the therapist's observations reveal significant changes in the patients' behaviour, with patients generally displaying increasing assertiveness, reflecting a heightened sense of

Table 4 Codes and subcodes resulting from the coding procedure and quotations (meaning the examples) from the Bubble-comic self-evaluation questionnaire

Code	Subcodes	Quote: examples	Code	Subcodes	Quote: examples
Cognitive involvement			Positive emotions		
	Curiosity	“Will there be more games?”		Connectiveness	“Happiness, the fact of not being alone”
	Focus	“I was well focused on the work”		Enjoyment	“When I see the LOKOMAT I feel good”
	Freedom	“When I see the LOKOMAT I feel happy and think about nothing”		Happiness	“During the LOKOMAT I felt happy”
	Increased control	“I felt that control was greater”		Lower frustration	“Compared to the first time lower sense of frustration”
	Usefulness of technology	“Walking with LOKOMAT helps you improve”		Novelty	“Happy because I played two new games”
Effort				Positive feedback	“I liked all the games”
	Difficulty	“With the LOKOMAT walking is difficult”		Relaxation	“It’s relaxing”
	Physical fatigue	“It’s tiring to walk with the LOKOMAT”		Relieve	“After the LOKOMAT I feel relieved”
	Physical strength	“With the LOKOMAT walking is beautiful because I feel stronger”		Sense of security	“No, the thought of not hurting myself”
Engagement			Negative emotions		
	Commitment	“I have to do the exercises well”		Annoyance	“I am a little bothered by the bracelet finished LOKOMAT”
	Compliance	“Better than yesterday because I tried to execute what the physiotherapist asked me to do”		Anxiety	“In the straight game I was going a little bit haywire”
	Motivation	“I want to get out soon and get well”		Aversion	“When I see the LOKOMAT I don't want to do it”
	Satisfaction	“Satisfying”		Boredom	“I feel bored because of the games I always play”
Physical discomfort				Confusion	“Sense of confusion”
	Ergonomic discomfort	“I feel tight”		Dislike	“The games were bad”
Physical sensations				Frustration	“I struggled”
	Bodily sensations	“I feel the body, I feel I have body parts that I know I have but as I walk I don't feel”		Impatience	“I wanted to finish the games right away”
	Easiness of walk	“I have less difficulty walking With the LOKOMAT”		Pain	“During the LOKOMAT my legs ached”
	Ergonomic comfort	“Walking with the LOKOMAT fits”	Mixed emotions		
Progress				Mixed emotions	“A little bit I'm fed up”
	Improvement	“Thanks to the LOKOMAT, I have improved my walking”			



	First Session	Last Session	Totals	Totals	
Cognitive Involvement		9		13	22
Effort		16		13	29
Engagement		5		10	15
Mixed emotions		2		2	4
Negative emotions		9		7	16
Physical discomfort		2		2	4
Physical sensations		6		5	11
Positive emotions		24		24	48
Progress		1		5	6
Totals		74		81	155

Figure 5 Distribution of the total number of codes divided by the first and the last session

control. Additionally, they are evaluated as more relaxed and quiet during the last session.

Physiological metrics analysis

The longitudinal analysis of physiological signals, investigating the differences in HRV and EDA parameters between the first and the last recorded session, are reported in this section. In this case, data are available

for 36 subjects, as for the remaining 6 subjects one or both sessions were not recorded due to issues with the Empatica wristband. Table 5 presents comprehensive results concerning all parameters. Statistically significant differences were observed across various parameters. Specifically, Max Up speed EDA Tonic, reflecting the rate of positive uplift in the tonic signal over time,

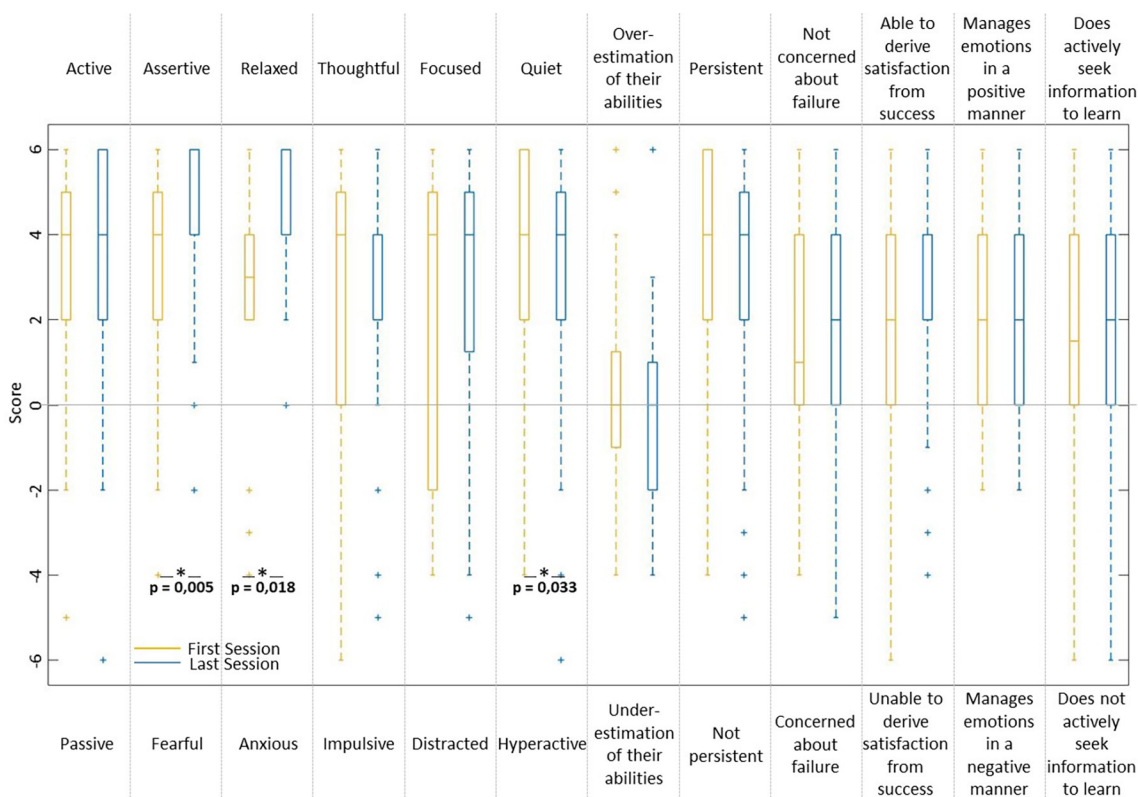


Figure 6 Boxplots representing therapist's evaluations of patients across the first and the last session of Lokomat. Significance of the results is computed with the Wilcoxon test and indicated with the *.

Table 5 HRV and EDA parameters between the first and the last recorded session. Significance of the results ($p < 0.05$) is computed with the Wilcoxon test and paired t-test, and it is indicated with bold text.

Parameter	First session Mean (std) ^a / median (IQR) ^b	Last session Mean (std) ^a / median (IQR) ^b	P value Paired t-test ^a / Wilcoxon test ^b
Mean HR	13.43 (6.94) ^a	13.30 (7.74) ^a	0.938 ^a
SDNN	-3.92 (24.30) ^a	-0.04 (24.65) ^a	0.504 ^a
RMSSD	0.28 (13.36) ^a	4.13 (15.71) ^a	0.267 ^a
SDSD	0.26 (13.37) ^a	4.12 (15.72) ^a	0.267 ^a
pNN50	-0.00 (0.04) ^a	0.01 (0.05) ^a	0.274 ^a
HRV Triangular Index	-0.07 (17.69) ^b	1.76 (19.24) ^b	0.593 ^b
TINN	-7.96 (66.58) ^a	-11.89 (80.05) ^a	0.822 ^a
HRV skewness	0.44 (0.58) ^b	0.37 (0.56) ^b	0.582 ^b
HRV kurtosis	0.93 (1.29) ^b	0.88 (1.79) ^b	0.405 ^b
HRV nLF	-3.68 (9.69) ^a	-7.06 (7.59) ^a	0.104 ^a
HRV nHF	-3.43 (22.05) ^b	3.06 (21.68) ^b	0.081 ^b
Sympathetic Modulation Index	0.03 (0.21) ^b	-0.05 (0.13) ^b	0.068 ^b
Vagal Modulation Index	-0.03 (0.21) ^b	0.05 (0.13) ^b	0.068 ^b
Sympathovagal Balance Index	0.09 (0.79) ^b	-0.14 (0.49) ^b	0.251 ^b
Mean EDA tonic	-0.51 (1.73) ^b	0.09 (1.58) ^b	0.099 ^b
SD EDA tonic	0.04 (0.13) ^b	0.11 (0.14) ^b	0.076 ^b
IQR EDA tonic	0.09 (0.29) ^b	0.17 (0.22) ^b	0.099 ^b
Skewness EDA tonic	0.06 (0.71) ^a	-0.02 (0.54) ^a	0.636 ^a
Kurtosis EDA tonic	0.35 (1.17) ^b	0.27 (0.71) ^b	0.683 ^b
Max upspeed EDA tonic	0.11 (0.29)^b	0.25 (0.15)^b	0.002^b
Max downspeed EDA tonic	-0.01 (0.21) ^b	-0.08 (0.25) ^b	0.432 ^b
NS.EDRs	0.00 (0.05)^a	0.04 (0.04)^a	0.001^a
Mean EDA phasic peak ampl.	0.01 (0.11)^b	0.05 (0.13)^b	0.014^b
SD EDA phasic peak ampl.	0.00 (0.11)^b	0.04 (0.10)^b	0.038^b
nAUC EDA phasic	0.01 (0.40)^b	0.17 (0.54)^b	0.007^b
Mean rise time	-0.31 (0.74) ^b	-0.16 (0.67) ^b	0.975 ^b
Mean EDA phasic P-to-P dist.	0.52 (8.88)^b	-2.96 (10.66)^b	0.013^b
SD EDA phasic P-to-P dist.	1.13 (10.03) ^b	1.40 (9.53) ^b	0.388 ^b
nVLF spectrum EDA phasic	-3.98 (16.24) ^a	-3.90 (21.35) ^a	0.986 ^a

Continued

Table 5 Continued

Parameter	First session Mean (std) ^a / median (IQR) ^b	Last session Mean (std) ^a / median (IQR) ^b	P value Paired t-test ^a / Wilcoxon test ^b
nLF spectrum EDA phasic	1.14 (13.25) ^a	1.62 (17.24) ^a	0.895 ^a
nHF1 spectrum EDA phasic	2.28 (4.45) ^a	2.00 (4.78) ^a	0.797 ^a
nHF2 spectrum EDA phasic	0.44 (1.26) ^a	0.24 (1.38) ^a	0.513 ^a
nVHF spectrum EDA phasic	0.12 (0.24)	0.049 (0.28)	0.255 ^a

Bold values denote statistically significant P-values ($p < 0.05$). Parameter descriptions appear in section “Feature extraction”. EDA, electrodermal activity; HRV, heart rate variability.

demonstrated an increase from the initial to the final session. Another significant parameter, NS.EDRs, indicating the frequency of non-specific peaks in the EDA signal (events unrelated to specific stimuli), displayed an increase over the sessions. Additionally, both the mean and SD of the amplitude of all NS.EDRs in the interval exhibited an upward trend over the sessions. Moreover, the mean normalised area under the curve of phasic peaks also showed an increase in the final session. Conversely, the mean p2p distance of the phasic signal decreased from the initial to the final session.

Notably, no statistically significant differences were observed in the HRV parameters between the sessions.

Correlation analysis

This section explores the correlations between the 12 items from the Therapists evaluation questionnaire and the changes (calculated as the difference between the last and first session) in HRV and EDA parameters, providing insights into the relationship between physiological signals and observational data.

The correlation analysis was conducted using Kendall’s τ coefficient: [table 6](#) shows the correlations between changes of HRV parameters and the therapist assessment of the patients’ experience.

Item 3 (anxious - relaxed) showed an inverse correlation with TINN (baseline width of the triangular peak), indicating that higher TINN values, reflecting greater global heart rate variability, are associated with greater anxiety.

Item 4 (impulsive - thoughtful) exhibited inverse correlations with SDNN, RMSSD, SDSD and the HRV Triangular Index, suggesting that increased impulsivity is associated with greater overall heart rate variability.

Item 5 (distracted - focused) was inversely correlated with nLF (normalised low-frequency power), indicating that higher nLF components are associated with increased distractibility.



Table 6 Statistically significant correlations between the changes (between the last and first session) in HRV parameters and the 12 items from the Therapists evaluation questionnaire are reported.

HRV parameter	Therapists evaluation questionnaire item	τ coefficient
SDNN	T04 (impulsive - thoughtful) / T06 (hyperactive - quiet)	-0.25/-0.33
RMSSD	T04 (impulsive - thoughtful)	-0.26
SDSD	T04 (impulsive - thoughtful)	-0.26
PNN50	T06 (hyperactive - quiet)	-0.25
HRV Triangular Index	T04 (impulsive - thoughtful)	-0.26
TINN	T03 (anxious - relaxed) / T06 (hyperactive - quiet)	-0.25/-0.27
nLF	T05 (distracted - focused)	-0.27
nHF	T08 (not persistent - persistent)	0.31
Sympathetic Modulation Index	T10 (unable - able to derive satisfaction from success)	0.27
Vagal Modulation Index	T10 (unable - able to derive satisfaction from success)	-0.27
Sympathovagal Balance Index	T10 (unable - able to derive satisfaction from success)	0.28

Yellow text indicates positive correlations, while blue text indicates negative correlations. The coefficient value is Kendall's τ correlation coefficient. If more than one item is correlated, the items and the τ coefficients are separated by the /. Parameter descriptions appear in section "Feature extraction".

Item 6 (hyperactive - quiet) showed inverse correlations with SDNN, PNN50 and TINN, indicating that higher values of these parameters, reflecting greater overall variability and dispersion of HRV signal, are associated with increased hyperactivity.

Item 8 (not persistent - persistent) demonstrated a positive correlation with nHF (normalised high-frequency power), indicating that higher nHF values, reflecting increased parasympathetic activity, are associated with greater persistence.

Finally, Item 10 (unable - able to derive satisfaction from success) was directly correlated with the Sympathetic Modulation Index and the Sympathovagal Balance Index, while showing an inverse correlation with the Vagal Modulation Index.

Table 7 shows the statistically significant correlations between the parameters extracted from EDA signals and the Therapists evaluation questionnaire. Regarding Item 1 (passive - active), the SD and IQR of the tonic EDA signal were positively correlated, suggesting that greater variability in the tonic signal corresponds to more active subjects.

For Item 6 (hyperactive - quiet), the mean tonic signal was positively correlated, indicating that higher mean

Table 7 Statistically significant correlations between the changes (between the last and first session) in EDA parameters and the 12 items from the Therapists evaluation questionnaire are reported.

EDA parameter	Therapists evaluation questionnaire item	τ coefficient
Mean EDA tonic	T6 (hyperactive - quiet)	0.27
Std EDA tonic	T1 (passive - active)	0.27
IQR EDA tonic	T1 (passive - active)	0.25
Skewness EDA tonic	T8 (not persistent - persistent)	-0.26
Max upspeed EDA tonic	T10 (unable - able to derive satisfaction from success)	0.25
Max downspeed EDA tonic	T10 (unable - able to derive satisfaction from success)	-0.25
Mean EDA phasic peak ampl	T7 (under - over estimation of their abilities)	-0.31
Std EDA phasic peak ampl	T7 (under - over estimation of their abilities)	-0.27
Normalised AUC EDA phasic	T7 (under - over estimation of their abilities)	-0.28
Mean rise time EDA phasic	T12 (does not - does actively seek information to learn)	0.25
Mean EDA phasic P-to-P distance	T12 (does not - does actively seek information to learn) / T10 (unable - able to derive satisfaction from success)	0.28 / -0.26
Std EDA phasic P-to-P distance	T6 (hyperactive - quiet)	-0.27

Yellow text indicates positive correlations, while blue text indicates negative correlations. The coefficient value is Kendall's τ correlation coefficient. Parameter descriptions appear in section "Feature extraction". EDA, electrodermal activity; HRV, heart rate variability.

tonic signals are associated with more relaxed subjects. In contrast, the SD of the phasic p2p distance was inversely correlated, reflecting reduced variability in phasic responses in more hyperactive individuals.

Item 7 (underestimation of their abilities - overestimation of their abilities) displayed inverse correlations with the mean peak amplitude, the SD of the peak amplitude and the nAUC (mean normalised area under the curve of phasic peaks) of the phasic EDA signal. These results suggest that higher values for these parameters, corresponding to more intense, variable and prolonged phasic responses, are associated with a tendency to underestimate one's abilities.

Similarly, Item 8 (not persistent - persistent) was inversely correlated with the skewness of the tonic signal. Skewness represents the asymmetry of the distribution of the tonic signal values. An inverse correlation suggests

that subjects with less skewed tonic signal distributions exhibit greater persistence.

The max upspeed and max downspeed of the tonic signal were directly and inversely correlated with Item 10 (unable - able to derive satisfaction from success), respectively, suggesting that greater dynamics in the tonic signal are linked to the ability to derive satisfaction from success. Additionally, the mean p2p distance of the phasic signal was inversely correlated, showing that more frequent phasic peaks are associated with greater satisfaction.

Finally, Item 12 (does not actively seek information to learn - actively seeks information to learn) demonstrated direct correlations with both the mean rise time and the mean p2p distance of the phasic signal. These findings suggest that subjects who actively seek information exhibit longer and less frequent phasic responses.

DISCUSSION

According to the latest conceptualisations of health given by the WHO International Classification of Functioning, Children and Youth (ICF-CY), the focus on the impairment or disease leaves the stage to a renewed way to intend the disability: the levels of activities and participation pairs with the assessment of body structure and function. In addition, personal factors (eg, self-motivation) as well as the environmental factors are considered as barriers and facilitators to these components: for instance, the involvement of the family, especially in paediatric care, is a key informant of patients' needs, abilities as well as the health condition, as testified in studies by Swinnen *et al* and Ouendi *et al*.^{12 13}

A recent quality evidence study discussed the overview of outcomes and experiences of young people with CP and their parents in relation to a lower limb orthopaedic surgery.³⁶ A total of six qualitative studies were grouped according to the ICF-CY framework: body function and structure, activity and participation, environmental factors and personal factors. Additionally, two themes were created by the authors: emotional well-being and goal setting, thus indicating the importance to value the rehabilitation experience.

The present study fits the growing interest to discuss the Lokomat rehabilitation addressing physiological factors, and not considering just the physical outcomes of the therapy. In the current study, the evaluation of children and adolescents experience of Lokomat therapy has been approached by qualitative and quantitative methods: the subjective point of view of the patient and the evaluation of the therapist (measured with ad-hoc questionnaires of different types) were combined with the physiological metrics to obtain an overall assessment. This approach perfectly fits this renewed way to conceptualise health, being a matter not only of the patient and being comprehensive of physical functioning and personal resources to cope with the health-related challenges. Additionally, objective metrics were collected to minimise self-reporting bias. Unlike subjective data, objective measurements are

not influenced by human judgement or biases such as social desirability, leading to more impartial and reliable outcomes.

To effectively discuss the results, it is crucial to establish an important premise. The questionnaires used to serve different purposes. The two questionnaires administered to the children, the self-evaluation and the Bubble-comic self-evaluation, are respectively designed to assess the emotional aspects and to collect attitudes regarding Lokomat therapy, as well as general thoughts about the therapy in general.

Conversely, in the Therapists evaluation questionnaire, there are questions assessing also cognitive, emotional and dispositional domains. This evaluation encompasses an expert point of view, which is the therapist one, monitoring and observing the patient behaviour during all the Lokomat sessions and, for most of the cases, knowing the patients from many years.

Based on the outcomes of the self-evaluation questionnaires completed by the children, it emerges that their assessment of the Lokomat experience remains consistent between the initial and final sessions. Generally, they express rare feelings of boredom, sadness, anger or fear, maintaining a relatively positive outlook. Regarding their perceptions of the therapy's utility, their ability to effectively engage with it and its potential to enhance their walking, there is some uncertainty in their responses. Many participants answered with 'enough', and furthermore, there was a slight decrease across these aspects between the initial and the final sessions. This ambiguity regarding the therapy resonates with findings from Phelan and colleagues,¹⁷ underscoring the mixed impressions children have towards the technology and the therapy ("It's probably helping me, but I don't really know").

The Bubble-comic self-evaluation explores aspects that could not be fully captured through self-evaluation alone. Positive emotions remained stable throughout, with subjects generally expressing more positive than negative feelings, confirming the positive outlook testified by the self-evaluation questionnaires.

According to the ATLAS.ti coding, the cognitive involvement, reflected in heightened concentration, sense of control and perceived utility of the technology, notably increased in the final session. In the final session, there was also an increase in engagement, with subjects showing greater commitment, compliance, satisfaction and motivation. This could also stem from the improved relation with the therapist, increased confidence and familiarity with the environment. Conversely, there was a decline in effort, possibly due to subjects feeling more confident and proficient with the Lokomat, corroborated by participants' slightly improved perception reported in the last session. This moderate increment is not consistently supported by the last question of the self-evaluation questionnaires, thus indicating mixed impressions about the perceived progress.

In the Therapists evaluation questionnaire, a significant difference is observed between some assessments



from the first and last sessions. The therapist perceived the patients as more assertive, indicating greater control of the situation, as well as more relaxed and quiet in the last session. This suggests an improvement in the experience over time, with patients becoming more confident in their abilities and more familiar with the situation. This observation aligns with the findings of the bubble comic self-evaluation, which showed an increase in cognitive and overall engagement. Additionally, there are corroborating findings in the literature, such as in the study by Calabrò and colleagues,³⁷ which highlighted a significant improvement in psychological well-being following Lokomat rehabilitation in adult patients.

Looking at the results concerning the parameters recorded with Empatica E4 wristband, we observed a general increase in EDA phasic activity between the first and last sessions. This increase manifests both in frequency peaks, as indicated by the rise in the number of peaks (NS.EDRs) and their frequency (decreased mean p2p distance), and in the amplitude of the peaks, with an increase both of the mean amplitude of the phasic peaks and the area under the curve (nAUC). It can be hypothesised, in line with the therapist-completed questionnaire, that this heightened phasic activity is indicative of greater cognitive engagement, although in a positive sense. In the study by Posada-Quintero and Chon,³⁸ the authors found that during the cognitive task, the frequency of phasic peaks increased. However, when the subject began to feel tired or stressed during the same cognitive task, a decrease in phasic peaks over time was observed. Accordingly, participants are engaged but not stressed or fatigued; they are in control of the situation, remaining quiet and relaxed.

In the study from Correia and colleagues,³⁹ it is reported that tasks eliciting positive stimuli prompt higher phasic activity. Indeed, the study investigated emotional responses to visual stimuli using electrodermal activity, outlining that the amplitude of phasic peaks of EDA signal increases as the negative effect of stimuli decreases.

About the correlations between the 12 items from the Therapists evaluation questionnaire and the changes in physiological parameters, we observed weak to moderate correlations across different domains, suggesting that evaluating the subject's experience may require consideration of various aspects. Indeed, while many studies focus on examining the relationships of signals with only one aspect (such as stress, mental workload or emotional states separately⁴⁰⁻⁴¹), assessing the subject's experience accurately necessitates taking into account various aspects⁴² that may equally influence the effectiveness of rehabilitative therapy.

In terms of HRV parameters, we found that several time-domain measures increase with hyperactivity and impulsivity. Specifically, parameters like RMSSD, SDDSD and pNN50, which reflect short-term variability and are predominantly influenced by vagal tone, showed significant correlations. Global measures such as SDNN, Triangular Index and TINN, which indicate both sympathetic

and parasympathetic activity, also correlated with hyperactivity and impulsivity. Our results suggest that increases in these HRV parameters are associated with higher levels of hyperactivity and impulsivity, and in the case of TINN, also with anxiety. These findings are somewhat contradictory to the existing literature, which typically reports a decrease in these parameters in hyperactive and impulsive individuals.⁴³ However, it is important to note that the literature also indicates a decrease in these HRV parameters in situations of negative affect.⁴⁴ In our case, the participants were not in a negative mood; rather, the therapist evaluated them as more hyperactive (table 3: fidgets and moves continuously while listening to instructions, fiddles with clothes) and impulsive (table 3: starts before instructions are complete; impatient to receive information). This increase in HRV could suggest that their impulsivity may be linked to a less negative emotional state. Therefore, while these participants exhibited impulsivity and hyperactivity, this may not reflect emotional distress but rather a heightened physiological engagement or a more neutral or even positive emotional state.

The frequency-domain parameters, like nLF and nHF, were significantly correlated with the indices of sympathetic and parasympathetic modulation. LF reflects the contribution of both autonomic nervous system branches and baroreceptor activity, while HF reflects parasympathetic activity.⁴⁵ Our results showed nLF increased with distraction, and nHF rose with persistence, suggesting higher vagal tone enhances emotional regulation and resilience, consistent with Pham *et al.*⁴⁵ who associated increased nHF with better self-control, positive mood and effective emotion regulation.

Interestingly, satisfaction from success correlated with increased Sympathetic Modulation and Sympathovagal Balance indices but reduced Vagal Modulation, reflecting the dynamic autonomic nervous system role. Positive emotions like achievement involve sympathetic activation, aligning with Kreibig,⁴⁶ who reported greater sympathetic activity in pride compared with contentment.

Regarding tonic EDA, we found that the mean tonic level increased when the therapist perceived the subject as 'quiet', which at first glance contrasts with the literature associating lower tonic levels with calming states, while higher conductance is related to sympathetic activation and stress.⁴⁷ However, in this case, 'quiet' (remains still and composed; listens calmly to instructions without fidgeting or squirming) should not be mistaken for 'relaxed' (calm and composed in stressful situations), as indicated in table 3. Instead, it refers to a state in which the subject is less frenetic but more compliant with the therapist's instructions. This might mean they are focusing more intently, which could reflect increased sympathetic activation and therefore higher tonic EDA.

Variability in tonic EDA-SD and IQR-increased with subject activity, as was also suggested by the results indicating that EDA trends were related to levels of engagement.⁴⁸ This was further supported by higher max upspeed and lower max downspeed during satisfaction.

In terms of phasic EDA, greater amplitude and higher nAUC were associated with underestimating one's abilities. This aligns with the idea that individuals who undervalue their abilities may experience stress, resulting in larger phasic peaks, which are commonly indicators of stressful experiences.⁴⁹

With active information-seeking, longer rise times and peak-to-peak distances were associated. A probably lower satisfaction and possible frustration can be associated with reduced peak frequency, coinciding with the patterns of reduced engagement reported by.³⁸

Strengths

This work has some strengths. To our knowledge, this study represents an innovative approach to investigate the experience of Lokomat rehabilitation, prioritising the psychological aspects over the motor ones. The study also deals with a population of non-adult patients, unlike most of the literature, covering a wide spectrum of medical conditions, thus making the study a valuable investigation to be taken into account for future studies.

Paucity of research is dedicated to children and young-adult patients, and the measures used are mostly age-inappropriate (being created for an adult population and adapted for younger respondents).

The tentative approach of this paper is specifically designed to meet the age-related challenge, designing self-evaluation metrics to be suitable for younger respondents that could benefit from responses set paired with graphical aids (ie, the use of emoticons to support the questions about the emotions in the self-evaluation questionnaires) and to freely express their feedback without any predetermined question (through the Bubble-comic self-evaluation questionnaire).

The involvement of the therapist represents a tangible way to conceive the rehabilitation session not just at an individual level, engaging also the healthcare professionals that represent a fruitful source of information (knowing the patient personally, including his/her medical condition). The therapists' involvement in the implementation phase provided an opportunity for them to engage in a more systematic and structured consideration of patients' subjective and psychological experiences. This engagement drew attention to aspects that are rarely formalised or systematically addressed in routine clinical practice, thereby fostering a potentially virtuous process of increased professional awareness and reflexivity.

Limits

This work has also some limitations. The correlations between the Therapists evaluation questionnaire and the parameters derived from both the HRV and EDA signals revealed generally low associations. However, it is important to note that our study was not conducted in a controlled laboratory setup, where subjects undergo specific and controlled stimuli at predetermined times. Additionally, the signals were acquired while subjects

were in motion, and physical activity is a known source of noise in physiological data that may influence responses in unexpected ways.^{50 51}

Another limitation of this study concerns the use of non-standardised and non-validated tools for the subjective assessment of the experience. Although psychometric validation would strengthen the reliability and generalisability of the results,¹⁶ such validation was beyond the scope of the present exploratory work. Importantly, human factor assessment in both adult and paediatric robotic rehabilitation remains an emerging field, and previous studies have similarly relied on adapted or newly developed questionnaires.^{52 53} In our study, the questionnaires and the Bubble-comic tool were refined through internal clinician usability review to ensure comprehensibility and appropriateness for the cognitive profiles of our participants. Nonetheless, the absence of formal psychometric testing requires that the findings be interpreted with appropriate caution.

Also, the lack of differentiation in the questionnaire scale, ranging only from 1 to 3, might have contributed to the inability to detect differences between the first and the last session. This could mean that the Likert scale was not sensitive enough to capture variations in children's responses, potentially leading to a ceiling and floor effect. Nevertheless, the three-level Likert scale was proposed taking into account the age of population and possible drawbacks of the cognitive-linguistic functioning.

Even if the questionnaires were adapted to children, the impairment of cognitive functions that can occur alongside the neurological conditions of participants included in the present research may have caused difficulties during questionnaires compilation, leading to no differences registered in the pre and post Lokomat self-evaluation. Nevertheless, participants had the opportunity to ask for clarification and to receive support from researchers.

In the conceptualisation of rehabilitation as a multi-level process involving not just the patient, this study reaches the healthcare practitioners giving their external feedback on the Lokomat session, but it does not consider parents' and caregivers' opinions, which are therefore not included in this investigation: this is a limitation. Nevertheless, parents of children performing rehabilitation may have difficulties in assessing their child's emotional states without biases; furthermore, they usually do not participate in the rehabilitation session. Future investigations, in line with Beveridge and colleagues,⁵⁴ will look for innovative ways to include parents' valuable opinion.

In addition to the aforementioned limitations, there are challenges related to the signals recorded, EDA and HRV. Assessing individual parameters may not be enough, prompting the exploration of methods like ML to integrate these signals comprehensively for analysis. Given that both EDA and BVP signals can be influenced by physical activity, employing a multimodal approach becomes essential for accurately isolating emotional responses.⁵⁵



Furthermore, a variety of techniques for signal analysis and parameter extraction, especially concerning EDA, are listed in literature, each with its own set of strengths and weaknesses.⁵⁶ The necessity to select a single analysis technique inevitably entails compromises. Alternatively, working directly with raw signals and investigating their potential to discriminate between different emotional states may prove more beneficial than relying solely on extracted parameters.

Clinical implications and future directions

The findings of this study suggest relevant clinical implications for the personalization of Lokomat therapy. Designing technologies and rehabilitation protocols aimed at promoting a positive rehabilitation experience will be a revolution in the clinical engagement of the patient and his/her families, potentially fostering motivation and active participation in therapy, and ultimately improving rehabilitation outcomes.

By highlighting how both subjective reports and physiological indicators reflect levels of engagement, cognitive involvement and emotional reactions, the results of this study may support the development of systems capable of automatically recognising patients' experiential states during rehabilitation. Integrating continuous monitoring of emotional and cognitive engagement derived from biosignals could enable real-time adjustments of therapy parameters, including game difficulty, feedback modalities and interaction style between therapist and patient. Such an adaptive approach would allow clinicians to modulate task demands based on the child's moment-to-moment experience, maximising motivation, reducing frustration and supporting a more effective tuning of the therapeutic challenge. Embedding these experiential cues into routine clinical decision-making may ultimately foster a more responsive and participatory rehabilitation process, benefiting not only motor outcomes but also the broader psychological well-being of paediatric patients.

To date, stronger evidence is needed to better account for children's experience during RAGT and to combine engagement monitoring with motor performance. From a signal processing perspective, it is necessary to further explore the integration of ML and deep learning algorithms for the analysis of raw physiological measures, adopting a multimodal approach that combines physiological measures with both self-reported and therapist-reported questionnaires. This advanced analytical framework has recently been tested in rehabilitation engagement within RAGT,⁵⁷ representing a promising step toward predicting patient engagement using structured datasets based on HRV and EDA features.

In the future, more reliable subjective metrics could be designed to investigate patient experience of children and adolescents undergoing rehabilitation

with the Lokomat. The present study could be in that sense useful, representing a valid tentative to describe the baseline of a group of patients and their therapist expressing their feelings and perspectives about Lokomat rehabilitation. The development of metrics with robust psychometric properties could be paired with expanded physiological assessment and ML analyses, providing a foundation for future studies aimed at predicting patient experience during rehabilitation.

CONCLUSION

This study highlights the importance of adopting a multidimensional approach to paediatric rehabilitation evaluation. By integrating subjective perspectives, observational measures and physiological data, we gain a comprehensive understanding of patients' experiences and outcomes, ultimately informing more effective and personalised rehabilitation interventions.

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