

# Feasibility of a traditional and teletreatment approach to mirror therapy in patients with phantom limb pain

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# Feasibility of a traditional and teletreatment approach to mirror therapy in patients with phantom limb pain: a process evaluation performed alongside a randomized controlled trial

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## Abstract

**Objective:** To evaluate the delivery, acceptance and experiences regarding a traditional and teletreatment approach to mirror therapy as delivered in a randomized controlled trial.

**Design:** Mixed methods, prospective study.

**Setting:** Rehabilitation centres, hospital and private practices.

**Subjects:** Adult patients with phantom pain following lower limb amputation and their treating physical and occupational therapists.

**Interventions:** All patients received 4 weeks of traditional mirror therapy ( $n=51$ ), followed by 6 weeks of teletreatment ( $n=26$ ) or 6 weeks of self-delivered mirror therapy ( $n=25$ ).

**Main measures:** Patient files, therapist logs, log files teletreatment, acceptance questionnaire and interviews with patients and their therapists.

**Results:** In all, 51 patients and 10 therapists participated in the process evaluation. Only 16 patients (31%) received traditional mirror therapy according to the clinical framework during the first 4 weeks. Between weeks 5 and 10, the teletreatment was used by 14 patients (56%) with sufficient dose. Teletreatment usage decreased from a median number of 31 (weeks 5–10) to 19 sessions (weeks 11–24). Satisfactory teletreatment user acceptance rates were found with patients demonstrating higher scores (e.g. regarding the usefulness to control pain) than therapists. Potential barriers for implementation of the teletreatment perceived by patients and therapists were related to insufficient training and support as well as the frequency of technical problems.

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**Conclusion:** Traditional mirror therapy and the teletreatment were not delivered as intended in the majority of patients. Implementation of the teletreatment in daily routines was challenging, and more research is needed to evaluate user characteristics that influence adherence and how technology features can be optimized to develop tailored implementation strategies.

## Keywords

Amputation, mirror therapy, telerehabilitation, augmented reality, service user involvement

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## Introduction

Phantom limb pain is a chronic painful sensation following the amputation of a limb that seems to be caused by maladaptive neuroplastic changes in the central and peripheral nervous system.<sup>1,2</sup> Up to 80% of amputees suffer from phantom limb pain<sup>3,4</sup> that shows no or only a mild decrease over time.<sup>1,5</sup> Standard pharmacological interventions to treat phantom limb pain have not yet proven to show sustainable effects.<sup>6</sup> Non-pharmacological interventions such as mental practice or mirror therapy that aim at targeting neuroplastic changes in the central nervous system have gained increasing interest during the past years in the treatment of patients with phantom limb pain.<sup>7,8</sup> However, the quality of evidence for the effectiveness of these approaches is still low.<sup>9</sup>

Given the limited evidence, a large three-arm multicentre, randomized controlled trial (PATient Centered Telerehabilitation (PACT) trial)<sup>10,11</sup> including a total of 75 lower limb amputees was conducted, in which both a clinical framework for traditional mirror therapy<sup>12</sup> as well as a novel teletreatment using augmented reality mirror therapy<sup>13</sup> were embedded. This randomized controlled trial did demonstrate only small, non-significant effects of the traditional and teletreatment approach to mirror therapy.<sup>10</sup> One reason for these limited effects may be that treating physical and occupational therapists did not deliver the interventions according to the clinical framework and patients did not use the teletreatment with sufficient dose. The present process evaluation tests this hypothesis and helps to gain more insights on how the interventions were actually used and delivered, and which experiences patients and their treating therapists made. These

insights may help to improve the feasibility of the clinical framework for mirror therapy and teletreatments for patients and health care professionals by identifying potential barriers and facilitators for successful implementation.

The following research questions were addressed:

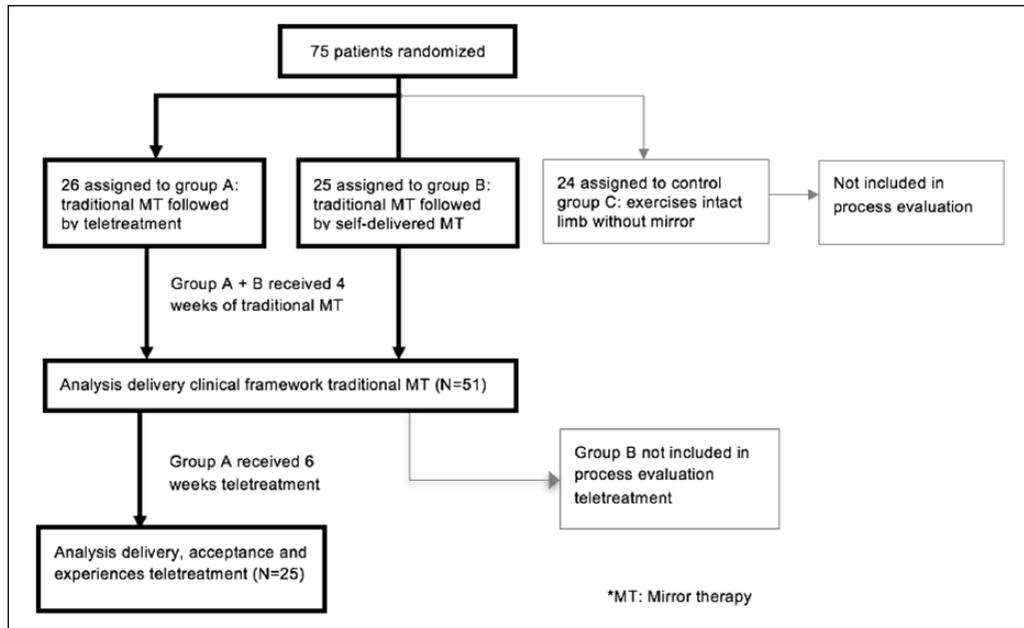
1. Did physical and occupational therapists deliver traditional mirror therapy according to the pre-defined clinical framework?
2. Which digital exercise programmes of the novel teletreatment did patients use and to what extent?
3. What were the acceptance rates and experiences of patients and health care professionals regarding the novel teletreatment?

## Methods

In this prospective process evaluation performed alongside a randomized controlled trial, both quantitative and qualitative methods were used sequentially or concurrently to evaluate the feasibility of two novel interventions.<sup>12,13</sup> The protocol of the randomized controlled trial<sup>11</sup> was approved by the ethics committee of the Medical Faculty of Cologne University, Germany (reference no. 13-304) and registered in the ClinicalTrials.gov Register (ID NCT02076490). The main report on the results of the randomized trial was recently published.<sup>10</sup>

## Participants

The process evaluation was conducted at six rehabilitation clinics, one hospital and two private



**Figure 1.** Patient flow diagram.

practices in Germany between May 2014 and September 2016. Data were collected from all patients and their treating therapists of the two experimental arms of the PACT randomized controlled trial<sup>10</sup> that received at least one session of traditional mirror therapy or the teletreatment respectively. The selection criteria for patients and therapists as well as the recruitment procedures are described in more detail in the study protocol and the main report of the trial results.<sup>10,11</sup>

### Intervention

Two interventions were evaluated in this process evaluation: traditional mirror therapy and a teletreatment using augmented reality mirror therapy.

Both experimental groups first received traditional mirror therapy according to a clinical framework<sup>12</sup> during the first 4 weeks. Thus, both groups were analysed together at 4 weeks regarding the process evaluation of the delivery of traditional mirror therapy (research question 1). Regarding the process evaluation of the teletreatment (research questions 2 and 3), only patients

allocated to the traditional mirror therapy followed by teletreatment group were analysed (Figure 1).

### Clinical framework for mirror therapy (weeks 1–4)

The framework was designed as a flexible intervention protocol in order to tailor mirror therapy to the preferences of the individual patient and has been described in detail elsewhere.<sup>12</sup> The framework consists of four different mandatory exercise categories: (1) basic motor exercises, (2) sensory exercises, (3) functional motor exercises with objects and (4) mental practice facilitated by the mirror image. All therapists were instructed to deliver exercises from all mandatory categories during the first sessions and to select those exercises, from which the individual patient perceived the most benefit. Subsequently, the actual training phase began and therapists were instructed to develop a tailored treatment programme for each individual patient depending on the identified preferences. This tailored treatment programme also

served as home programme for patients to perform self-delivered exercises.

### *Teletreatment (weeks 5–10)*

At the end of the first 4 weeks, therapists had to schedule at least one extra session to instruct patients who were allocated to the teletreatment group on how to use the teletreatment, which was subsequently used by patients for 6 weeks at home. The main functionalities of the teletreatment<sup>13</sup> include the following: (1) monitoring of phantom limb pain, (2) digital exercise programmes using traditional mirror therapy, (3) augmented reality mirror therapy using the tablet-integrated camera, (4) audio-visual instruction of mental practice, (5) limb laterality recognition training, (6) communication with the personal therapist and other patients and (7) background information on different topics (e.g. phantom limb pain, relevance of self-delivered exercises). Until the follow-up measurement at 6 months (weeks 11–24), patients were free to use the teletreatment as often as they wished but without further support of the treating therapist.

All therapists received a half-day standardized training by the principal investigator about the theoretical background of the intervention, how to implement the mirror therapy framework and how to use the teletreatment. The therapists received additional written information about mirror therapy (e.g. course map including the framework), materials to facilitate self-delivered mirror therapy (e.g. patient logs and leaflet) and the teletreatment (e.g. user manual). During the intervention period, the principal investigator regularly called therapists to discuss potential problems regarding the implementation of the clinical framework and the use of the teletreatment.

### *Data collection*

Different qualitative and quantitative data collection methods were used to obtain information on the desired process measures as shown in Table 1.

Demographic characteristics of patients such as date, reason and level of amputation were assessed

through a self-assessment questionnaire before the start of the intervention. Background characteristics of therapists (e.g. age, profession, number of patients treated) were recorded in the first section of the acceptance questionnaire (see Supplemental Appendix).

Regarding the delivery of the clinical framework during the first 4 weeks (research question 1), the number of individual sessions that took place was assessed by extracting data from individual patient files and the therapist logs. The log was also used to evaluate therapist's adherence with the predefined clinical framework. In the log, the frequency and duration of individual sessions per week, type of exercises, co-interventions, any deviations from the treatment protocol and adverse events were recorded. In addition, therapists recorded the number of sessions they delivered to introduce patients to the teletreatment at the end of the first 4 weeks.

Regarding patients' use of the teletreatment (research question 2), the frequency, duration and type of teletreatment component used were automatically monitored by data logging and stored in an individual log file. In addition, the teletreatment automatically recorded the vividness of the visual representation of the phantom limb during traditional or augmented reality mirror therapy as well as mental practice using an electronic 11-point Likert-type scale from 0 (not at all) to 10 (extremely vivid).

With respect to the acceptance rates and user experiences of the teletreatment (research question 3), a self-administered acceptance questionnaire and an individual phone interview between each individual user and the principal investigator took place. The self-developed patient and therapist questionnaire consisted of nine items based on different categories related to the technology acceptance model<sup>14,15</sup> (see Supplemental Appendix). Each item was scored on an 11-point Likert-type scale from 0 (totally disagree) to 10 (totally agree). In addition, two open questions regarding the overall opinion on the teletreatment were provided. These open questions served as starting point for the individual phone interview in which the experiences of the users regarding the teletreatment as

**Table 1.** Overview of different measures used for process evaluation.

Measure	Process variable	Timing of measure	Completed	Response rate	Comments
Patient files ( <i>N</i> treated: 51)	Dose delivered traditional mirror therapy	Weeks 1-4	<i>N</i> = 51	100%	
Therapist logs ( <i>N</i> handed: 51)	Delivery mirror therapy framework	Weeks 1-4	<i>N</i> = 38	75%	13 logs missing (not reported)
Log files ( <i>N</i> instructed: 25)	Use of teletreatment	Weeks 5–10	<i>N</i> = 25	100%	
Acceptance questionnaire patients ( <i>N</i> handed: 25)	Acceptance teletreatment	At 10 weeks	<i>N</i> = 23	92%	2 patients dropped-out and were unavailable for measurement
Interviews patients ( <i>N</i> invited: 25)	Experiences teletreatment	At 10 weeks	<i>N</i> = 23	92%	2 patients dropped-out and were unavailable for measurement
Acceptance questionnaire therapists ( <i>N</i> handed: 10)	Acceptance teletreatment	End of randomized trial	<i>N</i> = 10	100%	
Interviews therapists ( <i>N</i> invited: 10)	Experiences teletreatment	End of randomized trial	<i>N</i> = 10	100%	

well as positive and negative aspects were assessed. The principal investigator took notes and collected individual quotes of the users.

### Data analysis

The quantitative data from the pre-structured patients' files and therapists' logs were extracted by a research assistant and were then summarized in an excel spreadsheet. A minimum frequency of 10 sessions of traditional mirror therapy during the first 4 weeks each lasting 30 minutes was considered as being consistent with the clinical framework. In addition to the delivery with sufficient dose, we considered traditional mirror therapy to be delivered according to the clinical framework, if all mandatory exercise categories of the framework were used.

Regarding the use of the teletreatment, the software developer (Kaasa health, Germany) sent all log files of individual patients that were automatically registered by the teletreatment to the principal investigator (A.R.) in an excel file. All individual log files were then filtered for the corresponding intervention period of weeks 5-10 and 6 months follow-up (weeks 11–24) by the principal investigator. Patients

who used at least 10 teletreatments with a minimal duration of 5 minutes during the 6 weeks of intervention period were considered as compliant with the protocol.

All quantitative data were descriptively analysed, and the sum scores for the individual items of the acceptance questionnaires were visually displayed using frequency tables and bar graphs.

All qualitative data from open questions discussed during the phone interviews with patients and therapists were summarized for every participant in a table, categorized in main and subthemes based on their content and illustrated by individual quotes of the participant. Subsequently, the summary was sent to the interviewee who was asked to check the data on completeness and correctness and to reply the approved summary.

### Results

Regarding the delivery of the clinical framework for mirror therapy during the first 4 weeks, a total of 51 patients with a mean (SD) age of 61.1 (13.9) years took part in the process evaluation as shown in Table 2. During the first 4 weeks, three patients discontinued treatment (Figure 1).

**Table 2.** Baseline characteristics of patients participating in the process evaluation.

Variable	Group A: Teletreatment (n=26)	Group A + B: Traditional mirror therapy <sup>a</sup> (n=51)
Age (mean, SD)	59.7 (16.1)	61.1 (13.9)
Gender, male	80.8 (21)	68.6 (35)
Time post amputation, months (median, IQR)	56.5 (24.5–226.3)	38.0 (25–219)
Mean intensity PLP previous week (mean, SD)	5.9 (1.9)	5.7 (2.2)
Side of amputation, right	69.2 (18)	52.9 (27)
Reason for amputation		
Trauma	38.5 (10)	35.3 (18)
Diabetes	7.7 (2)	9.8 (5)
Dysvascular	23.1 (6)	23.5 (12)
Tumour	15.4 (4)	17.6 (9)
Other (e.g. infection)	15.3 (4)	13.7 (7)

IQR: interquartile range; PLP: phantom limb pain.

Data shown as % (n), unless stated otherwise.

<sup>a</sup>Group A (traditional mirror therapy followed by teletreatment) and Group B (traditional mirror therapy followed by self-delivered mirror therapy) were analysed together during the first 4 weeks as patients received the same intervention (traditional mirror therapy).

Twenty-five out of these 51 patients received the intended introduction to the teletreatment and were involved in the process evaluation regarding the use, acceptance and experiences of the teletreatment. In addition, six physical and four occupational therapists with a mean (SD) age of 43.3 (11.0) years (Table 4), who delivered traditional mirror therapy as well as the teletreatment, participated in the process evaluation. Table 1 presents the response rates for the different measures used for process evaluation.

### *Delivery of clinical framework for mirror therapy (research question 1)*

During the first 4 weeks, thirty-seven patients (73%) received the mandatory therapy amount of at least 10 sessions. The number of individual mirror therapy sessions ranged from 1 to 20, with an average of 9.8 (SD 2.7) sessions. However, according to the therapist logs (n=38), only 16 patients (31%) received traditional mirror therapy according to the clinical framework as they had exercises from all mandatory categories of the framework as well as the mandatory treatment dose of at least 10 sessions.

Regarding the type of exercises delivered, basic motor exercises were used in all patients, sensory exercises as well as motor exercises using objects in 35 patients (92%), and mental practice in 20 patients (53%). Only one therapist used the optional exercise category of limb laterality recognition training in one patient. Therapists reported adverse events in 10 patients (26%). Details about these events are provided elsewhere.<sup>10</sup>

### *Usage of the teletreatment (research question 2)*

In 18 out of 25 patients (72%) who received the introduction to the teletreatment, one session was used to introduce them to the teletreatment with the duration of sessions varying between 5 and 30 minutes. In six patients (24%) the session was not given additionally but was incorporated in one of the 10 mandatory mirror therapy sessions delivered during the first 4 weeks.

During the 6 weeks of teletreatment intervention period (weeks 5-10), 22 out of the 25 patients (88%) used the teletreatment. However, only 14 patients (56%) used it with sufficient dose

**Table 3.** Use of teletreatment components at 10 weeks and 6 months follow-up.

	Weeks 5–10	Weeks 11–24
Traditional mirror therapy ( <i>N</i> patients)	15	10
Traditional mirror therapy (minutes)	253 (37–592.5)	692 (126–1344.3)
Traditional mirror therapy vividness <sup>a</sup>	3.5 (2.4–6.2)	5.0 (4.2–6.5)
Augmented reality mirror therapy ( <i>N</i> patients)	19	11
Augmented reality mirror therapy (minutes)	57 (22–125)	51 (26–362.5)
Augmented reality mirror therapy vividness <sup>a</sup>	5.0 (2.2–6.2)	5.0 (3.9–7.8)
Mental practice ( <i>N</i> patients)	9	3
Mental practice (minutes)	19 (6–188)	1259 (1162–1445.5)
Mental practice vividness <sup>a</sup>	2.1 (1.5–3.3)	8.4 (7.2–8.5)
Laterality recognition training ( <i>N</i> patients)	15	10
Laterality recognition training (minutes)	30 (13.5–76)	35.5 (14.5–166.5)
Relaxation training ( <i>N</i> patients)	5	1
Relaxation training ( <i>N</i> sessions)	2 (1–5)	78
Number online sessions	31 (12–50)	19 (9–104)
Usage time (minutes)	198 (86.5–527)	361 (48–1091)

Data shown as median (interquartile range), except stated otherwise.

<sup>a</sup>Vividness was scored on an 11-point Likert-type scale (0=not at all; 10=extremely vivid).

according to the pre-defined protocol. The majority of patients ( $n=19$ ; 76%) performed augmented reality mirror therapy, and 15 patients (60%) used the digital exercise programme of traditional mirror therapy as well as limb laterality recognition training. Patients performed a total median number of 31 (interquartile range (IQR)=12–50) sessions with a total median usage time of 198 minutes (IQR=86.5–527) as shown in Table 3.

Between weeks 11 and 24 (follow-up at 6 months), the frequency and duration of teletreatment usage decreased, with 17 patients (68%) still using the teletreatment. Again, the majority of patients used augmented reality mirror therapy ( $n=11$ ; 44%) and 10 patients (40%) used the digital exercise programme of traditional mirror therapy as well as laterality recognition training (Table 3). The median number of teletreatment sessions in this time period decreased to 19 (IQR=9–104) and the median usage time to 361 minutes (IQR=48–1091). Three patients (12%) intensively used the digital exercise programme of mental practice up to the follow-up at 6 months with a median usage time of 1259 minutes (IQR=1162–1445.5).

### *Acceptance rates of patients regarding the teletreatment (research question 3)*

Overall, patients showed moderate to high agreement related to the different aspects of the acceptance questionnaire ranging from average scores of 6.1 (SD 3.7) to 9.3 (SD 1.3) on the 11-point Likert-type scale (Table 4, Supplemental Figure S1).

Items related to the perceived ease of use and behavioural control to use the system and the conformance to user requirements were rated the highest with average scores ranging from 8.8 (SD 1.7) to 9.3 (SD 1.3).

Technical problems appeared relatively frequent and it was not always possible to fix bugs immediately, which negatively affected the usability of the teletreatment.

### *Acceptance rates of therapists regarding the teletreatment (research question 3)*

Overall, therapists showed slightly lower acceptance rates compared to patients but the same trends were observed regarding the different items of the acceptance questionnaire (Table 4, Supplemental Figure S2). Again, the perceived behavioural

**Table 4.** User acceptance levels regarding the use of the teletreatment.

User group	User characteristics		Intention to use		Perceived usefulness			Perceived ease of use			Perceived behavioural control		
	Age (years)	Patients treated	High computer skills	Intention to use teletreatment	Usefulness to control pain	Usefulness for daily work	Teletreatment reduces PLP	Teletreatment increases efficacy of work	Requirements of user met	Sufficient usability	Low mental effort	Frequency technical problems	Technical problems fixed immediately
Patients	59.1 (15.7)	5.3 (3.5)	8.4 (2.5)	7.6 (2.9)	6.7 (3.3)	4.8 (2.4)	9.3 (1.1)	8.8 (1.7)	8.9 (1.4)	4.2 (3.0)	6.1 (3.7)	9.3 (1.3)	8.4 (1.6)
Therapists	43.3 (11.0)	2.5 (1.7)	4.2 (3.0)	6.9 (2.1)	5.8 (2.2)	7.6 (0.7)	7.1 (1.7)	7.5 (1.9)	6.0 (2.3)	6.6 (2.8)	6.6 (2.8)	8.4 (1.6)	8.4 (1.6)

PLP: phantom limb pain; NRS = Numeric Rating Scale.

Data shown as mean (SD). All items scored on an 11-point NRS ranging from 0 (absolutely disagree) to 10 (absolutely agree).  
<sup>a</sup>Item scored on an 11-point NRS ranging from 0 (never) to 10 (permanent).

control to use the system and items related to the perceived ease of use of the system were rated higher with average scores ranging from 7.1 (SD 1.7) to 8.4 (SD 1.6). Lower average scores of 4.8 (SD 2.4) and 5.8 (SD 2.2) were found for the perceived usefulness and efficacy of the teletreatment for the daily work of therapists (e.g. delivery and monitoring of the intervention).

### *Experiences of patients regarding the teletreatment (research question 3)*

Six main themes emerged from the patient interviews regarding their experiences related to the teletreatment as shown in Supplemental Table S1: (1) perceived benefits, (2) ease of use and conformance with user requirements, (3) providing guidance, (4) aspects related to digital exercise programmes, (5) technical problems and difficulties handling the tablet and (6) instruction, personal contact and feedback.

Perceived benefits that were mentioned by patients were related to different domains such as phantom pain, sense of control or body image:

In case of acute pain attacks, it acts like a strong drug and immediately reduces my pain by 90%. (Male, 37 years)

Patients appreciated the mobility of the teletreatment and that exercises could be performed independently of time and place, which facilitated integration in their daily routines:

I used the tablet on business trips to China in the airplane or in the hotel. (Male, 44 years)

The majority of patients experienced technical problems when using the teletreatment. In the beginning of the trial, the mobile application was not available offline and some patients were living in a district with poor mobile Internet connection. This induced problems with login and delayed data transfer. Regarding the theme 'instruction, personal contact and feedback', two patients mentioned that they were insufficiently introduced to the teletreatment by their therapist

and one patient needed additional support by a family member in order to feel more confident in using the technology:

The therapist came a long for 5 minutes and gave me the tablet without further explanation and I wasn't technologically skilled, so I didn't use it at home. (Male, 77 years)

Various suggestions for improvement of the teletreatment were made by patients referring to four different categories: (1) more variation in exercises, (2) personalize instructions, (3) messaging and (4) operation system (Supplemental Table S1).

### *Experiences of therapists regarding the teletreatment (research question 3)*

The interviews with therapists revealed seven main themes related to their experiences with the teletreatment as shown in Supplemental Table S2: (1) perceived benefits, (2) creating a long-term relationship with patients, (3) aspects related to digital exercise programmes, (4) design and usability, (5) technical problems, (6) training of the users and (7) selection of eligible patients.

Regarding the main theme 'perceived benefits', most of the therapists appreciated the practicability and mobility of the teletreatment, which enabled them to work more independently regarding the space and location needed to deliver the intervention.

Furthermore, therapists confirmed the perceived benefits of the teletreatment on phantom limb pain that were already suggested by patients. Interestingly, therapists also perceived the use of the teletreatment as a sign of quality and innovation of their own work by using information and communication technology for rehabilitation purposes:

My portfolio and skills improved by using the technology and this was well received by patients. (Female, 57 years)

The majority of therapists suffered from similar technical problems that were also described by

most of the patients related to bugs during use of the teletreatment and insufficient Internet access. Regarding the theme 'training of the users', therapists mentioned that the timing and frequency of training was not adequate to facilitate their routine in using the teletreatment:

Now, we were trained before the trial started, but the first patient started 8 weeks later; because we treated just a few patients we didn't exactly know how it worked anymore. (Male, 54 years)

According to therapists it is important to carefully select eligible patients beforehand, as they assumed that, for example, a certain degree of computer literacy should be present for this type of intervention. Finally, three topics for improvement of the teletreatment were suggested by therapists: (1) enhance exercise programmes, (2) peer support and (3) incorporate online community moderator (Supplemental Table S2).

## **Discussion**

This process evaluation showed that in the majority of patients ( $n=35$ , 69%), traditional mirror therapy was not delivered according to the clinical framework. Furthermore, nearly half of patients did not use the teletreatment with the minimal mandatory treatment dose according to the pre-defined protocol ( $n=11$ , 44%). The digital exercise programmes of traditional and augmented reality mirror therapy were used most often.

Moderate to high acceptance rates regarding the teletreatment were shown in patients with average scores of 6.1 to 9.3 on the 11-point Likert-type scale. Therapists showed slightly lower acceptance rates ranging on average from 4.8 to 8.4 regarding the individual items of the acceptance questionnaire.

Analysis of user experiences showed that the majority of patients who did use the teletreatment mentioned potential benefits from delivering the intervention and intended to use it after the trial. Patients and therapists agreed on the importance of sufficient training and support of the users as well as the absence of technical problems, which

were regarded as potential facilitators for implementation.

One reason for not sufficiently delivering the clinical framework for mirror therapy might be that nine different centres including 11 different therapists were recruited and trained in the PACT trial<sup>10</sup> to ensure patient enrolment. Hereby, most therapists only treated a small number of patients during the trial and experienced difficulties in becoming sufficiently skilled in using the clinical framework.

When we developed the clinical framework for mirror therapy, we decided to supply therapists with sufficient information to guide them through the clinical process from patient intake to discharge, but at the same time enable them to tailor the intervention to the preferences of the individual patient. As a consequence, therapists particularly delivered less mental practice and limb laterality recognition training, since they also did not use them prior to the trial. This might suggest that some therapists were unable to sufficiently embed the protocol into their professional routines.

The low adherence rates observed regarding the teletreatment might be related to limited skills and experiences of patients and therapists on how to use the teletreatment. Within the PACT trial therapists were trained to deliver a second complex intervention (the teletreatment), while being unfamiliar with the technology. Probably, more time was needed to gain experience with the teletreatment as well as more intensive training and supervision during the randomized controlled trial. It has been shown that insufficient training of therapists can be an important barrier for successful implementation of self-management interventions.<sup>16</sup> For the introduction of patients to the teletreatment, a more structured and intense training of patients would probably have been useful too. A recent study<sup>17</sup> showed that patients regarded sufficient technical and Internet skills as prerequisite to successfully use eHealth.

In the PACT trial we decided to investigate the effects of traditional mirror therapy during the first 4 weeks as evidence so far was weak and not to introduce patients allocated to the teletreatment group before the last week to the technology. Therefore, the second reason for low adherence

rates might be that some patients already perceived sufficient pain reduction during the first 4 weeks of traditional mirror therapy and thus, might have had no necessity to further use the teletreatment during the subsequent study period.

In this process evaluation, therapists perceived less benefits for their own work by using the teletreatment. This might suggest that the teletreatment did not succeed in making the work for therapists easier, which seems to be a key factor to clinicians' acceptance of eHealth.<sup>18</sup>

### *Strengths and limitations of the study*

A strength of this process evaluation is that within the PACT trial participants from different centres from primary and secondary care such as rehabilitation centres, hospital and private practices were included. This increases the likelihood that a representative population for the rehabilitation practice in Germany has been included. Furthermore, the combination of qualitative and quantitative methods in this study positively complemented each other leading to rich data collection.

Also, the outcomes of the PACT trial were not known at the time of data collection for this process evaluation and thereby could not have biased the outcomes.

As mentioned before, a weakness of this study is that most therapists only treated a few patients leading to a lack in gaining routine in using the teletreatment. This might have influenced the outcomes of the acceptance questionnaire and interviews. Overall, therapists seemed to be more positive about the teletreatment during the interviews with the principal investigator than in the questionnaire, which was self-reported. In addition, patients and therapists who took part in the trial and process evaluation might have had a more positive attitude towards the teletreatment than non-responders.

### *Results compared to other studies*

This study is the first process evaluation on non-pharmacological interventions such as mirror therapy and a teletreatment using augmented reality mirror therapy performed alongside a randomized

controlled trial in patients with phantom limb pain. The published protocols for mirror therapy in other effect studies on phantom limb pain often represent a more rigid programme mainly focussing on basic motor exercises<sup>19</sup> with a sparse description of intervention characteristics and potential negative side-effects. Furthermore, little is reported on how health care professionals were trained and how the implementation of the intervention was monitored. Some studies evaluated patient adherence with a training diary<sup>20,21</sup> or weekly phone calls.<sup>21</sup> All published treatment protocols seemed to be feasible, but data on different process measures is sparse.

Another process evaluation on the feasibility of a clinical framework for mental practice in stroke patients<sup>22</sup> showed that applying the framework in clinical practice was harder than expected and posed many challenges.

Regarding teletreatments for patients with phantom limb pain, we are aware of only one other study that has been published,<sup>23</sup> in which two patients following lower limb amputation received instructions how to self-deliver mirror therapy and how to self-report pain assessments by e-mail. The intervention was feasible, but no data were published regarding compliance, user acceptance and experiences related to the teletreatment.

### *Implications for research and clinical practice*

This study shows that a careful development of the intervention including an evidence-based and user-centred approach<sup>12,13</sup> does not automatically lead to user acceptance, adherence and hence effects. The implementation of novel complex interventions in clinical practice, in particular, technology-driven interventions, remains challenging as many different aspects besides the delivered intervention such as user characteristics and skills influence their adoption.<sup>17,24</sup> Thus, for successful implementation the content of the treatment as well as the ratio of face-to-face and online therapy needs to be tailored to the needs, preferences and characteristics of individual patients and therapists.<sup>24</sup> Therapists might consider offering patients with limited technical and Internet skills or increased physical and

cognitive impairments more extensive face-to-face treatment next to the teletreatment. Furthermore, training of patients and health care professionals regarding the use of the intervention needs to be personalized regarding dose and timing to provide the necessary information when it is actually needed.

Future research should identify the appropriate proportion between online and face-to-face sessions for different groups of patients in order to develop personalized blended care interventions.<sup>25,26</sup> More research is needed to evaluate user characteristics that influence teletreatment adherence, which patients benefit most from blended care and how technology features can be optimized to develop tailored implementation strategies.

#### **Clinical messages**

- Traditional mirror therapy was not delivered according to the clinic framework in the majority of patients.
- Most of the patients did not use the teletreatment with sufficient dose after 4 weeks of traditional mirror therapy.
- Patients showed higher acceptance rates and mentioned more specific benefits from using the teletreatment than the therapists reported.

#### **Author contributions**

A.R. coordinated the study and wrote the first draft of the report. A.R., S.B., A.B. and R.S. designed the study and revised the draft. All authors read and approved the final manuscript.

#### **Declaration of conflicting interests**

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## Supplemental material

Supplemental material for this article is available online.

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