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- Einflussfaktoren und Machbarkeit -

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Ich erkläre hiermit an Eides statt, dass ich die vorliegende Dissertation mit dem Titel:

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Inhaltsverzeichnis

Publikationsliste

Mehler-Klamt, Amrei & Schmidbauer, Lena & **Warmbein, Angelika** & Rathgeber, Ivanka & Zoller, Michael & Schröder, Ines & Kraft, Eduard & Lorenz, Andreas & Gutmann, Marcus & König, Alexander & Biedenkapp, Markus & Eberl, Inge & Fischer, Uli. (2020). Mobilisation Intensiv-Pflegebedürftiger durch einen neuen Standard in der adaptiven Robotik. 10.13140/RG.2.2.22780.87688. (Poster)

Ohneberg, Christoph & Stöbich, Nicole & **Warmbein, Angelika** & Rathgeber, Ivanka & Stahl, Oliver & Traeger, Mattias & Nast-Kolb, Julian & Kruppa, Astrid & Eberl, Inge & Fischer, Uli. (2020). REsPonSe Robotersystem zur Entlastung des Pflegedienstes von Servicetätigkeiten. 10.13140/RG.2.2.36202.64968. (Poster)

Mehler-Klamt, Amrei & **Warmbein, Angelika** & Schmidbauer, Lena & Rathgeber, Ivanka & Zoller, Michael & Schröder, Ines & Kraft, Eduard & Lorenz, Andreas & Gutmann, Marcus & König, Alexander & Biedenkapp, Markus & Fischer, Uli & Eberl, Inge. (2020). Die erste Projektphase des Projekts MobiStaR – Mobilisation Intensiv-Pflegebedürftiger durch einen neuen Standard in der adaptiven Robotik. (Conference Paper)

Mehler-Klamt, Amrei & **Warmbein, Angelika** & Rathgeber, Ivanka & Schmidbauer, Lena & Zoller, Michael & Schröder, Ines & Kraft, Eduard & Lorenz, Andreas & Gutmann, Marcus & König, Alexander & Biedenkapp, Markus & Fischer, Uli & Eberl, Inge. (2020). Beschreibung der ersten Studienphase des Forschungsprojekts MobiStaR. 10.13140/RG.2.2.13972.83841. (Poster)

Ohneberg, Christoph & Stöbich, Nicole & **Warmbein, Angelika** & Rathgeber, Ivanka & Stahl, Oliver & Traeger, Mattias & Nast-Kolb, Julian & Kruppa, Astrid & Eberl, Inge & Fischer, Uli. (2021). REsPonSe - Robotersystem zur Entlastung des Pflegedienstes von Servicetätigkeiten. (Conference Paper)

Mehler-Klamt, Amrei & Schmidbauer, Lena & **Warmbein, Angelika** & Rathgeber, Ivanka & Zoller, Michael & Schröder, Ines & Kraft, Eduard & Lorenz, Andreas & Gutmann, Marcus & König, Alexander & Biedenkapp, Markus & Eberl, Inge & Fischer, Uli. (2021). MobiStaR – Mobilisation Intensiv-Pflegebedürftiger durch einen neuen Standard in der adaptiven Robotik. (Conference Paper)

Mehler-Klamt, Amrei & Schmidbauer, Lena & **Warmbein, Angelika** & Rathgeber, Ivanka & Zoller, Michael & Schröder, Ines & Kraft, Eduard & Lorenz, Andreas & Gutmann, Marcus & König, Alexander & Biedenkapp, Markus & Fischer, Uli & Eberl, Inge. (2021). Der Einsatz eines robotischen Systems auf Intensivstationen im Rahmen des Projektes MobiStaR. 10.13140/RG.2.2.27394.61121. (Poster)

Mehler-Klamt, Amrei & Schmidbauer, Lena & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2021). Very early robot-assisted mobilization of intensive care patients – a scoping review. 10.13140/RG.2.2.19006.00325. (Poster)

Mehler-Klamt, Amrei & Schmidbauer, Lena & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2021). Very Early Robot-Assisted Mobilization of Intensive Care Patients – A Scoping Review. 10.3233/SHTI281. (Conference Paper)
Ohneberg, Christoph & Stöbich, Nicole & Warmbein, Angelika & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2021). Service Robotics in Nursing Care. The Preliminary Results of a Scoping Review. 10.3233/SHTI210351. (Chapter Public Health and Informatics)

Mehler-Klamt, Amrei & Schmidbauer, Lena & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2021). Very Early Robot-Assisted Mobilization of Intensive Care Patients – A Scoping Review. 10.3233/SHTI210350. (Chapter In book: Public Health and Informatics (pp.1073-1074) Edition: 281 Chapter: Chapter VII. Posters Publisher: Mantas, J.; Stoicu-Tivadar, L.; Chronaki, C.; Hasman, A.; Weber, P.; Gallos, P.; Chirila, O. S.

Mehler-Klamt, Amrei & Schmidbauer, Lena & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2021). Die Frühmobilisation von Intensivpatient_Innen mittels robotischem System – Ein Scoping Review. 10.13140/RG.2.2.10203.49449. (Poster)

Mehler-Klamt, Amrei & Huber, Jana & Schmidbauer, Lena & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2021). The use of robotic systems for early mobilization of intensive care patients: a scoping review. 10.13140/RG.2.2.26980.71049. (Poster)

Mehler-Klamt, Amrei & Huber, Jana & Schmidbauer, Lena & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2021). Die robotische Frühmobilisation von Intensivpatient_Innen – Ein Scoping Review. 10.13140/RG.2.2.36827.90407. (Präsentation)

Mehler-Klamt, Amrei & Huber, Jana & Schmidbauer, Lena & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2021). Der Einsatz von technisch-assistiven Systemen zur Frühmobilisation von Intensivpatient_Innen: ein Scoping Review. 10.13140/RG.2.2.16734.56644. (Poster)

Mehler-Klamt, Amrei & Huber, Jana & Schmidbauer, Lena & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2021). Frühmobilisation von Intensivpatient_Innen mit Hilfe von robotischen Systemen - ein Scoping Review. 10.13140/RG.2.2.10023.68006. (Präsentation)

Ohneberg, Christoph & Stöbich, Nicole & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2021). Assistive und serviceorientierte Robotik in der Pflege. Ergebnisse eines Scoping Reviews. 10.3205/21dkvf163. (Conference Paper)

Warmbein, Angelika & Rathgeber, Ivanka & Ohneberg, Christoph & Stöbich, Nicole & Kruppa, Astrid & Traeger, Mattias & Nast-Kolb, Julian & Stahl, Oliver & Eberl, Inge & Fischer, Uli. (2021). Läuft in der Pflege? Eine Beobachtungsstudie zu pflegefernen Tätigkeiten, zurückgelegten Laufstrecken und zur Inanspruchnahme von Personalressourcen im Pflegedienst. 10.13140/RG.2.2.35219.81449. (Poster)

Mehler-Klamt, Amrei & Huber, Jana & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2021). Frühmobilisation von Patient*innen auf Intensivstationen – Eine Analyse des IST-Zustandes mit mobilisierendem Fachpersonal an einem Universitätsklinikum.. 10.13140/RG.2.2.19943.37280. (Poster)

Mehler-Klamt, Amrei & Huber, Jana & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2021). Frühmobilisation von Intensivpatient*innen auf Intensivstationen – Eine Analyse des IST-Zustandes mit mobilisierendem Fachpersonal an einem Universitätsklinikum. (Conference Paper)

Warmbein, Angelika & Schroeder, Ines & Mehler-Klamt, Amrei & Rathgeber, Ivanka & Huber, Jana & Scharf, Christina & Hübner, Lucas & Gutmann, Marcus & Biebl, Johanna & Lorenz, Andreas & Kraft, Eduard & Zoller, Michael & Eberl, Inge & Fischer, Uli. (2022). Evaluation of effects of robot-assisted early mobilization on critically ill patients, on the mobilization behaviour and experience of the mobilizing professionals and the organizational processes in an intensive care unit -a clinical intervention study: study protocol. 10.21203/rs.3.rs-1339805/v1. (Preprint)

Ohneberg, Christoph & Stöbich, Nicole & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2022). Potential Uses of Assistive Robotic Systems in Acute Inpatient Care. 10.3233/SHTI220587. (Chapter In book: Challenges of Trustable AI and Added-Value on Health)

Hübner, Lucas & Schroeder, Ines & Kraft, Eduard & Gutmann, Marcus & Biebl, Johanna & Mehler-Klamt, Amrei & Huber, Jana & **Warmbein, Angelika** & Rathgeber, Ivanka & Eberl, Inge & Fischer, Uli & Scharf, Christina & Schaller, Stefan & Zoller, Michael. (2022). Frühmobilisation auf der Intensivstation – Sind robotergestützte Systeme die Zukunft?. Die Anaesthesiologie. 71. 1-5. 10.1007/s00101-022-01130-x. (Article)

Warmbein, Angelika & Rathgeber, Ivanka & Ohneberg, Christoph & Stöbich, Nicole & Stahl, Oliver & Traeger, Mattias & Nast-Kolb, Julian & Kruppa, Astrid & Eberl, Inge & Fischer, Uli. (2022). Läuft in der Pflege? Beobachtungsstudie zu pflegefernen Tätigkeiten, zurückgelegten Laufstrecken und zur Inanspruchnahme von Personalressourcen im Pflegedienst. 10.13140/RG.2.2.17017.75369. (Poster)

Mehler-Klamt, Amrei & Huber, Jana & Schmidbauer, Lena & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2022). The use of robotic and technical systems for early mobilization of intensive care patients: A scoping review. Pflege. 10.1024/1012-5302/a000891. (Article)

Ohneberg, Christoph & Stöbich, Nicole & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2022). Anwendungs-und Einsatzmöglichkeiten für assistenzrobotischeSysteme in der akutstationären Pflege. (Poster)

Mehler-Klamt, Amrei & Huber, Jana & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2022). Die Frühmobilisation von Intensivpatient*innen aus Sicht von mobilisierendem Fachpersonal auf Intensivstationen. 10.13140/RG.2.2.31718.29762. (Poster)

Mehler-Klamt, Amrei & Huber, Jana & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2022). Die Frühmobilisation von Intensivpatient*innen – Eine Analyse des IST-Zustandes mit mobilisierenden Fachpersonen an einem Universitätsklinikum. 10.13140/RG.2.2.23801.54887. (Poster)

Mehler-Klamt, Amrei & Huber, Jana & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2022). Frühmobilisation von Patient*innen auf Intensivstationen – Eine IST-Analyse mit mobilisierendem Fachpersonal. (Poster)

Mehler-Klamt, Amrei & Huber, Jana & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2022). Frühmobilisation auf Intensivstationen -Die Sichtweise von mobilisierendem Fachpersonal an einem Universitätsklinikum. 10.13140/RG.2.2.24754.07368. (Präsentation)

Ohneberg, Christoph & Stöbich, Nicole & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. (2022). Rahmenbedingungen für die Implementierung robotischer Assistenzsysteme im akutstationären Setting aus Nutzer*innenperspektive. 10.3205/22dkvf338. (Conference Paper)

Mehler-Klamt, Amrei Christin & Huber, Jana & Koestler, Natascha & **Warmbein, Angelika** & Rathgeber, Ivanka & Fischer, Uli & Eberl, Inge. Robot-assisted mobilisation in the intensive care unit: does it offer relief to mobilising specialists? A qualitative longitudinal study at a German university hospital. *Discov Soc Sci Health* 4, 13 (2024). https://doi.org/10.1007/s44155-024-00074-4

Lucas Huebner & **Angelika Warmbein** & Christina Scharf & Ines Schroeder & Kirsi Manz & Ivanka Rathgeber & Marcus Gutmann & Johanna Biebl & Amrei Mehler-Klamt & Jana Huber & Inge Eberl & Eduard Kraft & Uli Fischer & Michael Zoller. Effects of robotic-assisted early mobilization versus conventional mobilization in intensive care unit patients: The MobiStaR trial, 08 December 2023, PREPRINT (Version 1) available at Research Square [https://doi.org/10.21203/rs.3.rs-3695698/v1]

Amrei Mehler-Klamt, Natascha Koestler, Jana Huber & **Angelika Warmbein** &Ivanka Rathgeber & Marcus Gutmann & Johanna Theresia Biebl & Lucas Hübner & Ines Schroeder & Christina Scharf & Christoph Ohneberg & Eduard Kraft & Michael Zoller & Uli Fischer & Inge Eberl. Can mobilising specialists be relieved by a robotic system for the early mobilisation of intensive-care patients? A quantitative longitudinal study at three data collection points at a German university hospital, 19 October 2023, PREPRINT (Version 2) available at Research Square [https://doi.org/10.21203/rs.3.rs-3135275/v2]

Dissertationspublikationen

1) **Warmbein A**, Rathgeber I, Seif J, Mehler-Klamt AC, Schmidbauer L, Scharf C, Hübner L, Schroeder I, Biebl J, Gutmann M, Eberl I, Zoller M, Fischer U. Barriers and facilitators in the implementation of mobilization robots in hospitals from the perspective of clinical experts and developers. BMC Nurs. 2023 ;22(1):45. https://doi.org/10.1186/s12912-023-01202-2

   Ranking: Category NURSING 15/123 – 88,2% in 2022

2) **Warmbein A**, Hübner L, Rathgeber I, Mehler-Klamt AC, Huber j, Schroeder I, Scharf C, Gutmann M, Biebl J, Manz K, Kraft E, Eberl I, Zoller M, Fischer U. Robot-assisted early mobilization for intensive care unit patients: Feasibility and first-time clinical use. International Journal of Nursing Studies 2024, ISSN 0020-7489 https://doi.org/10.1016/j.ijnurstu.2024.104702

   Ranking: Category NURSING 1/123 – 99,6% in 2022

1. Eigenanteil an den Arbeiten

Die vorliegende kumulative Dissertation umfasst zwei Publikationen. Diese befassen sich mit der Implementierung von robotischen Systemen ins akutklinische (intensiv-)pflegerische Setting. Die Doktorandin ist Erstautorin der Publikationen.

(1) Das Design der Studie “Barriers and facilitators in the implementation of mobilization robots in hospitals from the perspective of clinical experts and developers” sowie die zugehörigen Unterlagen (Studienprotokoll, Aufklärungsschreiben, Erhebungsinstrumente) wurden durch die Doktorandin hauptsächlich und eigenständig konzipiert, entworfen und analysiert. Die Erhebungen wurden zum Großteil durch die Doktorandin durchgeführt, die Publikation wurde eigenständig verfasst.

(2) Die Studie wurde eigenständig von der Doktorandin konzipiert und die zugehörigen Unterlagen (Studienprotokoll, Aufklärungsschreiben, Erhebungsinstrumente) erstellt. Die Erhebungen erfolgten in Zusammenarbeit mit anderen Forschungsprojekt MitarbeiterInnen. Die Publikation wurde eigenständig durch die Doktorandin verschriftlicht.

Die Studien wurden durch die Doktorandin bei der Ethikkommission eingereicht. Es erfolgte ein regelmäßiger Austausch und Rücksprache mit der Promotionsbetreuungskommission sowie Beteiligten des Projektkonsortiums. Alle Ko-Autoren revidierten die Publikationen.

2. Einleitung

2.1. Hinleitung

Patienten auf Intensivstation benötigen aufgrund von schweren Erkrankungen eine hochspezialisierte und interprofessionelle Versorgung. Die Intensivpflege ist hierbei die vernetzende und dem Patienten durch die Arbeit am Bett am nächsten stehende Profession, die diagnostische Verfahren begleitet, den Gesundheitszustand überwacht sowie medikamentöse und ergänzende Therapien ausführt. Jedoch herrscht in Deutschland ein Mangel an qualifizierten Personal vor (1), welcher sich in spezialisierten Bereichen wie der Intensivpflege verstärkt zeigt. Die empfohlene Betreuung von maximal zwei Intensivpatienten durch eine Pflegefachperson (2) lässt sich nicht durchgehend ermöglichen, wodurch aufgrund von erhöhter Arbeitslast eine implizite Rationierung der Arbeitsaufgaben (3) entsteht.

Hierbei wird die Entscheidungsbefugnis bei offen formulierten Handlungsempfehlungen auf das ausführende Individuum übertragen, in welchem Ausmaß bestimmte Therapien durchgeführt werden. Dies zeigt sich insbesondere bei der therapeutischen Frühmobilisation, welche einerseits durch verordnete Bewegungstherapie durch Physiotherapeuten ausgeführt wird und andererseits durch Lagerungs- und Frühmobilisationstherapie durch die Intensivpflege abgedeckt wird. Studien belegten, dass Gründe wie Personalengpässe, ein Mangel an Hilfsmitteln oder organisatorische Gründe wie Personalbesetzungen am Wochenende (4, 5) zu einem geringeren Umfang von Mobilisationstherapien wie benötigt führten.

Dies steht im Gegensatz zu der Notwendigkeit der therapeutischen Maßnahme: Schwersterkrankte Patienten verlieren bis zu 12,5 Prozent ihrer Muskelmasse innerhalb der ersten Woche nach stationärer Aufnahme (6, 7) und entwickeln zu 40 Prozent eine Muskelschwäche (8, 9). Dies kann zu einer Critical Illness Myopathy (CIM) (10) und damit zu langfristigen Folgen in Beeinträchtigungen der neuromuskulären Funktion in Form von Schädigung von Nerven und Muskulatur des Betroffenen führen.

2.1.1. Bedeutung von Frühmobilisation auf Intensivstation

Studien belegen, dass sich Patienten Outcomes durch regelmäßige Frühmobilisation in Hinblick auf Muskelschwund (11, 12) und körperliche Funktionalität (11, 13–15), mitunter auch auf die Entstehung einer ICU Acquired Weakness (17), verbessern können. Zusätzlich zu diesen unmittelbaren Effekten in der akutklinischen Versorgung kann sich auch ein positiver mittelfristiger Effekt in Form von reduzierter Dauer auf Intensivstation oder gar stationärer Behandlung ergeben (12, 13, 15, 16).

Im Rahmen der im Jahr 2023 publizierten S3 Leitlinie (18) wird dementsprechend empfohlen, täglich und in ausreichender Dauer im höchstmöglichen Level eine Frühmobilisationsmaßnahme durchzuführen. In der während der Durchführung der Studien geltenden S2e Leitlinie (19) wurde eine Empfehlung für zwei Therapieeinheiten mit je 20 Minuten durch zwei Fachkräfte ausgesprochen, an welcher sich die klinische Erhebung orientierte.

2.1.2. Robotik als Unterstützungssystem

Die Diskrepanz zwischen dem therapeutischen Bedarf von Frühmobilisationstherapie und der Umsetzungsproblematik in der Praxis wurde von Entwicklern in der Robotik erkannt und in den letzten Jahren adressiert (20). Eine Vielzahl von robotischen Systemen wurde entwickelt, um einerseits ein effizientes Training für Patienten zu ermöglichen und andererseits Personalressourcen zu schonen. Hierbei sind einige Systeme, wie beispielsweise der Lokomat©, inzwischen nicht mehr aus der Rehabilitation wegzudenken. Im Bereich der Allgemeinstationen finden sich inzwischen auch verschiedenste Robotiksysteme, wie beispielsweise Elevon (Fraunhofer-Institut für Produktionstechnik und Automatisierung IPA, Stuttgart, Deutschland) zur Unterstützung bei Hebearbeiten am Patienten. Hierbei zeigte sich jedoch, dass diese für Patienten in der intensivmedizinischen Betreuung aufgrund von kognitiv und psychomotorischen Einschränkungen weniger

geeignet sind. Aktuell bestehen auf dem Markt zwei Systeme, die für die Mobilisation, in Form von gangartiger Bewegung und Vertikalisierung, von Intensivpatienten zertifiziert sind: Das System Erigo© (Hocoma AG, Volketswil, Schweiz) sowie der Vemotion© (ReActive Robotics, München, Deutschland). Bei ersterem konnten bereits positive Effekte auf die motorische und kognitive Funktion nach Gehirnschädigungen und Schlaganfällen nachgewiesen werden (21, 22). Bisher liegt ansonsten wenig Evidenz für die Effekte der roboter-assistierten (Früh-)Mobilisation auf die Patienten Outcomes vor. Gegenwärtig betrachten Experten die potenziell positiven Effekte auf die Mobilisationshäufigkeit und die Personalbindung als vielversprechend, insbesondere vor dem Hintergrund des aktuellen Fachkräftemangels (18, 23, 24).

Die vorliegende Dissertation wurde im Rahmen des Pflege-Forschungsprojekts MobiStaR (Mobilisation Intensivpflegebedürftiger durch einen neuen Standard in der adaptiven Robotik) erstellt. Das Projekt hatte zum Ziel, den Mobilisationsroboter Vemotion© im intensivmedizinischen Setting zu erproben.

Der Mobilisationsroboter Vemotion© der Firma ReActive Robotics GmbH wurde bereits für den Gebrauch auf Intensivstationen CE-zertifiziert. Mithilfe der Robotik können Patienten, ohne einen Transfer auf ein separates Trainingsgerät, ein gangartiges Training im Bett absolvieren. Der Vemotion© besteht aus mehreren Komponenten: Ein Patientenbett, das speziell für die Robotik entwickelt wurde, ermöglicht eine Neigung von bis zu 70 Grad und kann mit der Robotik verbunden werden. Zudem gehören ein Trolley für den Transport der Robotik sowie der Steuerung, Fuß- und Sitzadapter und patientenbezogene Einwegprodukte zu dem System.

2.2. Methode

Das Konzept dieser Dissertation besteht aus zwei Bestandteilen: Im Rahmen der Vorstudie wurden vorbereitend Barrieren und förderliche Faktoren für Implementierungen von mobilisationsassistierender Robotik ermittelt. Diese legten den Grundstein für die nachfolgende Machbarkeitsstudie und Pilotierung der Vemotion©-Robotik auf Intensivstationen.

2.2.1. Voraussetzungen zur Implementierung von Robotik – Methodik der Vorstudie

In dieser Vorstudie zur Evaluation von Barrieren und Förderfaktoren zur Implementierung von Mobilisationsrobotern ins akutklinische Setting wurde ein exploratives qualitatives Design angewendet. Hierbei wurden 13 europäische Experten aus Forschung, Entwicklung und Praxis zu ihren bisherigen Erfahrungen zu Implementierungen mittels eines halb-standardisierten Interviewleitfadens (25) befragt. Der Interviewleitfaden umfasste Fragen zu allgemeinen Erfahrungen von Integrationen, erlebte Förderfaktoren und Barrieren sowie genutzte Lösungen, um diese Barrieren zu überwinden. Die Daten wurden mit MAX QDA (26) transkribiert und mittels latenter Inhaltsanalyse (27) analysiert.

2.2.2. Integration von roboter-assistierter Frühmobilisation auf Intensivstation – Methodik der Machbarkeitsstudie

Die klinische Machbarkeitsstudie umfasste eine sechsmonatige Integration des robotischen Assistenzsystems Vemotion© auf zwei anästhesiologisch geführten Intensivstationen des Universitätsklinikums. Das Ziel dieser Studie bestand darin, zu untersuchen, inwieweit sich robotergestützte Assistenzsysteme für die Mobilisierung von chirurgischen Patienten auf der Intensivstation eignen. Zu diesem Zweck wurde analysiert, inwieweit eine robotergestützte Frühmobilisierung in einer homogenen Patientenpopulation durchgeführt werden kann, ob sicherheitsrelevante Vorfälle auftreten, die zu Schäden, Unterbrechungen oder Abbrüchen führen, und wie Pflegefachkräfte diese Form der Mobilisierung bewerten. Daten wurden mittels teilnehmender Beobachtung (28) erhoben.

Durch die Studienärzte aufgeklärt und eingeschlossen wurden Patienten, die sich einer geplanten Operation mit einer voraussichtlichen Beatmungszeit >48 Stunden unterzogen und die Voraussetzungen des robotischen Systems bezüglich Größe und Gewicht erfüllten. Die Kohorte umfasste Patienten, die sich einer Lungentransplantation unterzogen.

Die eingeschlossenen Patienten erhielten, nach Möglichkeit innerhalb der ersten 72 Stunden nach Aufnahme auf Intensivstation, ihre erste roboter-assistierte Therapieeinheit. Geplant war ein Umfang von zwei Mal täglich 20 Minuten roboter-assistierten Trainings für 10 Einheiten bzw. für sieben Tage. Durchgeführt wurde die Therapie durch Intensivpflegefachpersonal der jeweiligen Station, die vorab durch den Roboter Hersteller geschult und in den ersten Wochen umfassend begleitet wurden.

Erhoben wurden Daten zu Einschlussfähigkeit der Patienten, Frequenzen und Dauern der umgesetzten Therapien und der Rüstzeiten sowie die Anzahl der benötigten Fachpersonen. Die Therapieeinheit betreffend wurde der Vertikalisierungsgrad, die Anzahl der durch die Patienten getätigten Schritte sowie jedwede Form von Sicherheitsrisiken erhoben, die einen Schaden, eine Störung oder Abbruch verursacht haben. Ergänzend wurden die durchführenden Intensivpflegefachpersonen nach Abschluss der Therapieeinheit gebeten, die Umsetzbarkeit und eigene physische Belastung auf einer Likert Skala von 0 bis 7 einzuordnen.

2.3. Ergebnisse

2.3.1. Ergebnisse der Vorstudie zu beeinflussenden Faktoren für Implementierungen

Die Studie ergab relevante Einflussfaktoren im Kontext der Entwicklung (I), Implementierung (II) und Routineanwendung (III) eines Robotersystems. Herausforderungen zeigten sich in finanziellen Belastungen, prozessualen Anpassungen und dem Mangel an Ausnahmeregelungen sowie der unzureichenden Unterstützung seitens Hersteller und Entwickler. Hingegen erwiesen sich benutzerfreundliche Schnittstellen, partizipative Entscheidungsprozesse zwischen Endnutzern und Entscheidungsträgern der einzelnen Einrichtungen, präzise Prozessgestaltung und die kollaborative Entwicklung des Robotersystems durch Endnutzer und technische Experten als förderliche Faktoren. Die Komplexität und die strategische Planung im Hinblick auf finanzielle Ressourcen, prozessuale Anpassungen und die Schaffung adäquater Regelungen stellen demnach Schlüsselaspekte für die erfolgreiche Implementierung von Robotersystemen dar. In diesem Kontext ist eine präzise Abstimmung auf die Bedürfnisse der Endnutzer und eine effektive Zusammenarbeit zwischen den verschiedenen Stakeholdern von essenzieller Bedeutung.

I. Vor Integration der Robotik in die Praxis wiesen die Experten auf mehrere erfolgsbeeinflussende Faktoren hin. Strukturelle Bedingungen vor Ort (wie Raum, Bodenbeschaffenheit und Lärmpegel) sind vorab zu prüfen, ebenso wie die Kostendeckung ohne etwaige Subventionen durch Krankenversicherungen. Durch die Entwickler ist sicherzustellen, dass die Robotik die Anforderungen für den klinischen Einsatz bereits im Rahmen der Entwicklung erfüllt.
II. Im initialen Integrationsprozess ist es entscheidend, dass ein Kernteam von Pflegekräften geschult wird. Diese Schlüsselanwender sollten motiviert sein und die Implementierung unterstützen. Darüber hinaus müssen standardisierte Prozesse für die roboterunterstützte Therapie entwickelt werden. Diese können stationsbezogen oder krankenhausbezogen sein und sollten in Zusammenarbeit mit dem Stations- oder Teammanagement erstellt werden.
III. Die Leitung muss auch sicherstellen, dass den Pflegekräften ausreichend Zeit in der Routinearbeit freigestellt wird, wie es bei der Integration von medizinischen Geräten üblich ist. Ebenso sind Freistellungen für Schulungssitzungen erforderlich, um eine sichere Handhabung zu gewährleisten und Schlüsselanwender für das Gerät zu werden. Hersteller sollten umfassende Unterstützung und Hilfe während des Integrationsprozesses bieten. Wiederholte Schulungen im Laufe der Zeit sollten ebenfalls angeboten werden, um eine kontinuierliche Schulung der Nutzer zu gewährleisten.

2.3.2. Ergebnisse der klinischen Machbarkeitsstudie

Unter den 23 eingeschlossenen Patienten wurden 16 mittels robotischer Unterstützung mobilisiert, 7 Patienten wurden aus der Studie ausgeschlossen (Einschluss = 69%). Im Durchschnitt waren 1,9 Pflegekräfte pro Therapieeinheit involviert. Patienten erhielten im Mittel 5,6 robotergestützte Mobilisationseinheiten. Die Vorbereitung vor und nach der Therapie dauerte durchschnittlich 18 Minuten, die Therapieeinheit 21 Minuten. Die Mobilisierung begann im Durchschnitt etwa 18 Stunden nach der Aufnahme. Gesamt wurden acht Mobilisationseinheiten vorzeitig abgebrochen, einmal aufgrund eines unerwünschten Ereignisses in Form von Schmerzen des Patienten und einmal aufgrund eines Anwenderfehlers. Diese Ereignisse stellen mit 1,8% aller Mobilisationseinheiten die relevantesten Abbrüche dar. In vier weiteren Fällen wurde die Intervention wegen Erschöpfung des Patienten vorzeitig beendet, wobei ein Abbruch sicherheitsrelevant war. Zwei weitere Abbrüche waren interventionsunabhängig (medizinische Behandlung sowie spontane Darmentleerung). Gesamt wurden 22 Ereignisse dokumentiert, wovon 14 während der Intervention gelöst werden konnten (64%). Es fanden keine schwerwiegenden unerwünschten Ereignisse und gesamt zwei unerwünschte Ereignisse statt. Der Großteil der dokumentierten Ereignisse stellten Anwenderfehler dar, welche als vermeidbar eingestuft wurden. Die Pflegekräfte bewerteten ihre physische Belastung als gering (Mittelwert 2,0 ± 1,3) und die Intervention als machbar (Mittelwert 5,3 ± 1,6).

2.4. Schlussfolgerung und Ausblick

Die Ergebnisse der Dissertation zeigen die Komplexität der Integration von robotischen Systemen ins (intensiv-) pflegerische Setting auf. Neben den in der Vorstudie vor Integration definierten Barrieren und unterstützenden Faktoren zeigten sich im Rahmen der klinischen Interventionsstudie andere Hürden, denen bei zukünftigen Integrationen Beachtung geschenkt werden sollte. Obwohl die Umsetzbarkeit durch die Pflegefachpersonen als positiv bewertet wurde, entstanden im Rahmen von 90 Mobilisationseinheiten 22 Ereignisse, die einen Einfluss auf die Durchführung der roboter-assistierten Frühmobilisation hatten, jedoch nur in zwei Fällen zu einem sicherheitsrelevanten Abbruch führten.

Hierin zeigt sich, dass neben der Komplexität der Integration der Robotik in die stark strukturierten Tagesabläufe einer Intensivstation auch die Komplexität in der korrekten Anwendung der Technologie trotz umfassenden Einführungs-, Schulungs- und Begleitungsangebots mehr Aufmerksamkeit benötigt. Die Handlungsabläufe müssen vereinfacht und intuitiver gestaltet und ein Kernteam für die Anwendung am Patienten definiert werden.

Um neuartige Technologien wie Robotik an vulnerablen Personen- oder Patientengruppen anzuwenden, ist die Bildung von neuen Kompetenzen in den gesundheitlichen Berufen essenziell. Dies wurde bereits beispielsweise bei roboter-assistierten Operationsverfahren umgesetzt, indem die neuen Behandlungsmethoden durch umfassende Fortbildungen gelehrt und geübt werden. Ebenso ist dies auch in nicht-invasiven Bereichen wie dem roboter-assistierten Bewegungstraining vonnöten, um den Patienten eine bedarfsgerechte und den Richtlinien entsprechende Versorgung zukommen zu lassen.

3. Zusammenfassung

Die Ergebnisse dieser Arbeit zeigen, dass robotische Assistenzsysteme wie Vemotion© unter spezifischen Rahmenbedingungen eine praktikable Lösung für die Frühmobilisation auf Intensivstationen darstellen können. Um diese komplexe Thematik umfassend zu untersuchen, wurde ein mehrdimensionaler Ansatz gewählt, der sowohl qualitative als auch quantitative Forschungsmethoden umfasst.

Im Rahmen einer Expertenbefragung wurden Einflussfaktoren auf eine Implementierung von robotischen Assistenzsystemen evaluiert. Hierbei zeigte sich, dass bereits in der Entwicklungsphase der partizipative Ansatz zwischen Hersteller und Endanwendenden entscheidend ist, um im Praxiseinsatz eine intuitive Bedienbarkeit, Handhabbarkeit und Akzeptanz zu schaffen. Gleichzeitig wurden strukturelle Herausforderungen wie kurze Förderzeiträume und fehlende Freistellungen für Endnutzende deutlich, die eine aktive Mitgestaltung erschweren. Diese Ergebnisse unterstreichen, dass eine partizipative Entwicklung essenziell ist, um die Robotik an die Bedürfnisse der Intensivstation anzupassen. In der initialen Integrationsphase wurde deutlich, dass transparente Entscheidungsprozesse und intensive Schulungsmaßnahmen die Akzeptanz bei den Endanwendenden maßgeblich fördern können. Gleichzeitig stellte sich jedoch heraus, dass nicht angepasste Arbeitsabläufe, lange Herstellerreaktionszeiten und unklare Finanzierungsmodelle die Umsetzung erheblich behindern können. Dies verdeutlicht die Notwendigkeit einer sorgfältigen Planung, die sowohl organisatorische als auch finanzielle Aspekte berücksichtigt. Damit die Robotik langfristig erfolgreich in den klinischen Alltag integriert werden kann, müssen Prozesse kontinuierlich angepasst und optimiert werden. Eine klare Prozessdefinition, ergänzende Schulungsangebote und ein regelmäßiger Austausch zwischen Klinik und Hersteller sind entscheidend, um die Anwendung nachhaltig zu sichern. Fehlende Strukturen oder unzureichende Kostenübernahmen durch die Krankenkassen stellen hierbei weiterhin wesentliche Hürden dar, die es zu überwinden gilt.

Die im Rahmen der Machbarkeitsstudie gewonnenen Daten bestätigen, dass robotische Assistenzsysteme wie Vemotion© unter realen Bedingungen eine vielversprechende Lösung darstellen können. Die praktische Erprobung umfasste roboter-assistierte Frühmobilisation bei 16 Patienten. Die Ergebnisse zeigen, dass die Therapie durchschnittlich 20 Minuten dauerte, wobei Rüstzeiten von 18 Minuten erforderlich waren. Obwohl es zu Unterbrechungen aufgrund von Anwenderfehlern oder Schmerzen kam, konnten hiervon 64 % direkt während der Intervention gelöst werden. Schwerwiegende unerwünschte Ereignisse traten nicht auf, was die Sicherheit des Systems unterstreicht. Zudem bewerteten die Pflegekräfte die körperliche Entlastung durch die Robotik positiv und schätzten die generelle Umsetzbarkeit als gut ein.

Die Ergebnisse der beiden Studien zeigen, dass Mobilisationsrobotik unter Berücksichtigung spezifischer Voraussetzungen eine vielversprechende Ergänzung für die Intensivpflege darstellt. Die partizipative Einbindung der Mitarbeitenden, die Anpassung der klinischen Prozesse sowie eine transparente Kommunikation zwischen allen Beteiligten sind dabei entscheidende Faktoren. Gleichzeitig machen die Erkenntnisse deutlich, dass technische Innovationen nur dann erfolgreich implementiert werden können, wenn die Rahmenbedingungen – von der Finanzierung bis zur praxisnahen Schulung – angepasst werden. Unter Berücksichtigung dieser Faktoren besteht das Potenzial, Pflegekräfte durch die Reduktion körperlicher Belastungen nachhaltig zu entlasten und Patienten eine bedarfsgerechte Frühmobilisation zu ermöglichen. Diese Arbeit legt damit eine fundierte Grundlage für die weitere Erforschung und Optimierung von Mobilisationsrobotik in der Intensivpflege.

4. Abstract

The results of this study show that, under certain conditions, robotic assistance systems such as Vemotion© can be a viable solution for early mobilisation in intensive care units. In order to comprehensively analyse this complex topic, a multi-dimensional approach was chosen, including both qualitative and quantitative research methods.

Factors influencing the implementation of robotic assistance systems were evaluated through a survey of experts. The results showed that a participatory approach between the manufacturer and the end-user from the development phase onwards is crucial to achieve intuitive usability, manageability and acceptance in practice. At the same time, it highlighted structural challenges such as short funding periods and lack of release for end users, which make active co-design difficult. These findings emphasise that participatory development is essential to adapt robotics to the needs of the ICU. During the initial integration phase, it became clear that transparent decision-making processes and intensive training measures can significantly promote end-user acceptance. At the same time, however, it was found that unadapted workflows, long response times from manufacturers and unclear funding models can significantly hinder implementation. This highlights the need for careful planning, taking into account both organisational and financial aspects. In order for robotics to be successfully integrated into everyday clinical practice in the long term, processes need to be continuously adapted and optimized. A clear definition of the process, additional training programmes and a regular exchange between the hospital and the manufacturer are essential to ensure sustainable use. Lack of structures or inadequate reimbursement by health insurance companies remain major hurdles to be overcome.

Robotic assistance systems such as Vemotion© can be a promising solution under real-life conditions, as confirmed by the data obtained during the feasibility study. The practical study involved robotic-assisted early mobilisation in 16 patients. The results show that therapy lasted an average of 20 minutes, with set-up times of 18 minutes. Although there were interruptions due to user error or pain, 64% of these were resolved directly during the procedure. There were no serious adverse events, demonstrating the safety of the system. In addition, nurses rated the physical relief provided by the robotics as positive and the overall feasibility as good.

The results of the two studies show that mobilisation robotics is a promising addition to intensive care, provided that specific requirements are taken into account. The participative involvement of staff, adaptation of clinical processes and transparent communication between all parties involved are key factors. At the same time, the results show that technical innovations can only be successfully implemented if the framework conditions - from funding to practical training - are adapted. If these factors are taken into account, there is the potential to reduce the physical burden on nursing staff in the long term and to enable patients to be mobilised earlier, in line with their needs. This work therefore provides a solid foundation for further research and optimisation of robotic mobilisation in intensive care.

5. Literaturverzeichnis

1. Höpflinger F. Pflege und das Generationenproblem – Pflegesituationen und intergenerationelle Zusammenhänge. In: Schroeter KR, Rosenthal T, editors. Soziologie der Pflege: Grundlagen, Wissensbestände und Perspektiven. Weinheim: Juventa-Verlag; 2005. p. 157–76 (Grundlagentexte Pflegewissenschaft).

2. Fichtner F, Mörer O, Laudi S, Weber-Carstens S, Kaisers U. S3-Leitlinie Invasive Beatmung und Einsatz extrakorporaler Verfahren bei akuter respiratorischer Insuffizienz. DIVI 2017; 4:154–63.

3. Breyer F. Implizite versus explizite Rationierung von Gesundheitsleistungen. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 2012; 55(5):652–9.

4. Winkelman C, Peereboom K. Staff-perceived barriers and facilitators. Crit. Care Nurse 2010; (30):2.

5. McWilliams DJ, Pantelides KP. Does physiotherapy led early mobilisation affect length of stay in ICU? ACPRC Journal 2008; (40):5–10.

6. Puthucheary ZA, Rawal J, McPhail M, Connolly B, Ratnayake G, Chan P et al. Acute Skeletal Muscle Wasting in Critical Illness. JAMA 2013; 310(15):1591.

7. Fazzini B, Märkl T, Costas C, Blobner M, Schaller SJ, Prowle J et al. The rate and assessment of muscle wasting during critical illness: a systematic review and meta-analysis. Critical Care 2023; 27(1):1–26.

8. Appleton RTD, Kinsella J, Quasim T. The incidence of intensive care unit-acquired weakness syndromes: a systematic review. Journal of the Intensive Care Society 2015; 16(2):126–36.

9. Jonghe B de, Bastuji-Garin S, Durand M-C, Malissin I, Rodrigues P, Cerf C et al. Respiratory weakness is associated with limb weakness and delayed weaning in critical illness. Crit care med 2007; 35(9):2007–15.

10. Friedrich O, Reid MB, Van den Berghe G, Vanhorebeek I, Hermans G, Rich MM et al. The Sick and the Weak: Neuropathies/Myopathies in the Critically Ill. Physiol Rev. 2015; (95(3):1025-109).

11. Schaller SJ, Anstey M, Blobner M, Edrich T, Grabitz SD, Gradwohl-Matis I et al. Early, goal-directed mobilisation in the surgical intensive care unit: a randomised controlled trial. The Lancet 2016; 388(10052):1377–88.

12. Schweickert WD, Pohlman MC, Pohlman AS, Nigos C, Pawlik AJ, Esbrook CL et al. Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial. The Lancet 2009; 373(9678):1874–82.

13. Morris PE, Berry MJ, Files DC, Thompson JC, Hauser J, Flores L et al. Standardized Rehabilitation and Hospital Length of Stay Among Patients With Acute Respiratory Failure: A Randomized Clinical Trial. JAMA 2016; 315(24):2694–702.

14. Paton M, Lane R, Paul E, Cuthburtson GA, Hodgson CL. Mobilization During Critical Illness: A Higher Level of Mobilization Improves Health Status at 6 Months, a Secondary Analysis of a Prospective Cohort Study. Crit care med 2021; (49(9):e860-e9.).

15. Young B, Moyer M, Pino W, Kung D, Zager E, Kumar MA. Safety and Feasibility of Early Mobilization in Patients with Subarachnoid Hemorrhage and External Ventricular Drain. Neurocrit 2019; (31(1):88-96).

16. Connolly B, O'Neill B, Salisbury L, Blackwood B. Physical rehabilitation interventions for adult patients during critical illness: an overview of systematic reviews. Thorax 2016; 71(10):881–90.

17. Raurell-Torreda M, Arias-Rivera S, Marti JD, Frade-Mera MJ, Zaragoza-Garcia I, Gallart E et al. Care and treatments related to intensive care unit-acquired muscle weakness: A cohort study. Aust Crit Care 2021; (34(5):435-45.).

18. Deutsche Gesellschaft für Anästhesie und Intensivmedizin. S3 Leitlinie 001-015: Lagerungstherapie und Mobilisation von kritisch Erkrankten auf Intensivstationen; 2023. Available from: URL: https://register.awmf.org/assets/guidelines/001-015l_S3_Lagerungstherapie-Mobilisation-von-kritisch-Erkrankten-auf-Intensivstationen_2023-07.pdf.

19. Bein T, Bischoff M, Brückner U, Gebhardt K, Henzler D, Hermes C et al. Kurzversion S2e-Leitlinie - "Lagerungstherapie und Frühmobilisation zur Prophylaxe oder Therapie von pulmonalen Funktionsstörungen". Anaesthesist 2015; 64(8):596–611.

20. Yakub F, Md Khudzari AZ, Mori Y. Recent trends for practical rehabilitation robotics, current challenges and the future. International journal of rehabilitation research 2014; 37(1):9–21.

21. Calabrò RS, Naro A, Russo M, Leo A, Balletta T, Saccá I et al. Do post-stroke patients benefit from robotic verticalization? A pilot-study focusing on a novel neurophysiological approach. Restor Neurol Neurosci 2015; 33(5):671–81.

22. Rocca A, Pignat J-M, Berney L, Jöhr J, van de Ville D, Daniel RT et al. Sympathetic activity and early mobilization in patients in intensive and intermediate care with severe brain injuries: a preliminary prospective randomized study. BMC Neurology 2016; 16(1):169.

23. Deutscher Ethikrat. Robotik für gute Pflege. Stellungnahme. Berlin 2020:49–53.

24. Hermes C, Adrigan E, Dubb R, Kaltwasser A, Kuhn KF, Nessizius S et al. Reflektiert und mit Augenmaß einsetzen (Robotik zur Unterstützung der Frühmobilisierung). PflegeIntensiv 2020(4):14-21.

25. Bogner A, Littig B, Menz W. Das Experteninterview. Wiesbaden: VS Verlag für Sozialwissenschaften; 2002.

26. VERBI – Software. Consult. Sozialforschung. GmbH. MAXQDA 2022. Available from: URL: www.maxqda.de.

27. Bengtsson M. How to plan and perform a qualitative study using content analysis. NursingPlus Open 2016; 2:8–14.

28. Thierbach C, Petschick G. Beobachtung. In: Baur N BJ, editor. Handbuch Methoden der empirischen Sozialforschung. 2nd ed. Wiesbaden: Springer VS; 2019. p. 1165–81.

29. Thomsen GE, Snow GL, Rodriguez L, Hopkins RO. Patients with respiratory failure increase ambulation after transfer to an intensive care unit where early activity is a priority. Crit Care Med 2008; 36(4):1119–24.

30. Bailey P, Thomsen GE, Spuhler VJ, Blair R, Jewkes J, Bezdjian L et al. Early activity is feasible and safe in respiratory failure patients. Crit Care Med 2007; 35(1):139–45.

31. Burtin C, Clerckx B, Robbeets C, Ferdinande P, Langer D, Troosters T et al. Early exercise in critically ill patients enhances short-term functional recovery. Crit Care Med 2009; 37(9):2499–505.

32. Morris PE, Goad A, Thompson C, Taylor K, Harry B, Passmore L et al. Early intensive care unit mobility therapy in the treatment of acute respiratory failure. Crit Care Med 2008; 36(8):2238–43.

33. Reid J, Unger J, McCaskell D, Childerhose L, Zorko DJ, Kho ME. Physical rehabilitation interventions in the intensive care unit: A scoping review of 117 prospective studies. J Intensive Care 2018; 6(8):1–12.

34. Beyer J, Seidel EJ. Frührehabilitation ist erstes Glied einer nahtlosen Rehabilitationskette. Rehabilitation (Stuttg) 2017; 56(4):272–85.

35. Luca R de, Bonanno M, Vermiglio G, Trombetta G, Andidero E, Caminiti A et al. Robotic Verticalization plus Music Therapy in Chronic Disorders of Consciousness: Promising Results from a Pilot Study. Brain Sci 2022; 12(8).

36. Mehler-Klamt, A., Huber, J., Warmbein, A., Rathgeber, I., Ohneberg, C., Hübner, L., Scharf, C., Schroeder, I., Zoller, M., Gutmann, M., Biebl, J., Kraft, E., Fischer, U., Eberl, I. Frühmobilisation von Intensivpatient*innen: Eine qualitative Analyse mit mobilisierendem Fachpersonal an einem deutschen Universitätsklinikum zur Gestaltung, zum Verständnis und zu den Einflussfaktoren der Frühmobilisation. QuPuG 2022; (2):94–103.

37. Huebner L, Schroeder I, Kraft E, Gutmann M, Biebl J, Klamt AC et al. Frühmobilisation auf der Intensivstation – Sind robotergestützte Systeme die Zukunft? Anaesthesiologie 2022; 71(10):795–800.

6. Anhang

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RESEARCH Open Access

Barriers and facilitators in the implementation of mobilization robots in hospitals from the perspective of clinical experts and developers

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Abstract

Background Early mobilization can help reduce severe side effects such as muscle atrophy that occur during hospitalization. However, due to time and staff shortages in intensive and critical care as well as safety risks for patients, it is often difficult to adhere to the recommended therapy time of twenty minutes twice a day. New robotic technologies might be one approach to achieve early mobilization effectively for patients and also relieve users from physical effort. Nevertheless, currently there is a lack of knowledge regarding the factors that are important for integrating of these technologies into complex treatment settings like intensive care units or rehabilitation units.

Methods European experts from science, technical development and end-users of robotic systems (n = 13) were interviewed using a semi-structured interview guideline to identify barriers and facilitating factors for the integration of robotic systems into daily clinical practice. They were asked about structural, personnel and environmental factors that had an impact on integration and how they had solved challenges. A latent content analysis was performed regarding the COREQ criteria.

Results We found relevant factors regarding the development, introduction, and routine of the robotic system. In this context, costs, process adjustments, a lack of exemptions, and a lack of support from the manufacturers/developers were identified as challenges. Easy handling, joint decision making between the end-users and the decision makers in the hospital, an accurate process design and the joint development of the robotic system of end-users and technical experts were found to be facilitating factors.

Conclusion The integration and preparation for the integration of robotic assistance systems into the inpatient setting is a complex intervention that involves many parties. This study provides evidence for hospitals or manufacturers to simplify the planning of integrations for permanent use.

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†Michael Zoller and Uli Fischer contributed in same parts to this study.

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Keywords Robotics, Implementation, Technology, Inpatient setting, Nursing, Integration, Innovation, Hospital

Background

Severe illnesses such as strokes or cancer have increased immensely worldwide in recent decades [1, 2]. These diseases require intensive treatment, which is usually carried out in an inpatient setting in the initial stages. In addition to specialist medical care and medication, specialized therapeutic interventions can positively influence the healing process, for example, nature-based treatments [3] or exercise-related interventions.

Some studies have already shown that early mobilization may have a positive effect on the healing process [4–6]. The definition of early mobilization varies [7]. In acute care hospitals, where most initial treatment is provided, the focus of therapy is on surgery and/or medication. In addition, according to the German S2e guideline "Positioning therapy and early mobilization for prophylaxis or therapy of pulmonary dysfunctions" [8], patients receive exercise therapy, which is carried out by nursing services and physiotherapists.

In practice, many intensive care patients receiving intensive care suffer from intensive care unit (ICU)-acquired weakness or muscle atrophy [9, 10]. Studies have shown that intensive mobilization training could provide an opportunity to reduce some of these side effects [11–13] and might reduce the length of hospital/ICU stay [14]. However, a high frequency of mobilization is difficult to achieve in practice due to a lack of staff and time [15, 16], and the high physical effort required in mobilizing sedated patients causes the frequency and intensity of mobilizations to decrease [15]. Additionally, health and safety risks [17], for example, transferring the patient to a separate exercise device, are major barriers to performing mobilizations.

One way to reduce the physical strain on mobilizing professionals and to increase the frequency and intensity of training sessions is to use modern technologies such as assistive robotics. In the context of research, robotic-assisted mobilization has already been evaluated for its added value [18–21], but the focus is almost exclusively on patient outcomes [22, 23]. The difficulty of integrating new technologies and thus new processes into a highly complex environment such as intensive care has only been examined within certain hospitals [24]. However, understanding the interplay between innovation and the local environment [25, 26] is crucial for successful implementations in practice, as complex innovations in nursing lead to changes in existing processes [27]. Therefore, it is essential to identify influencing factors and include them in development and implementations [28]. So far, an overview of the experiences of integrating robot-assisted mobilization therapy into inpatient settings is still lacking.

Aim

This study aimed to provide an overview of the barriers and facilitators to the implemention of robotic systems for mobilization therapy into inpatient settings like intensive care or early rehabilitation facilities. We describe which circumstances as well as environmental and person-related factors need to be considered to facilitate implementation.

Methods

Design and setting of the study

This preliminary study was part of a three-year research project conducted under the Medical Research Council's [29] framework for development of complex interventions and took place in the phase of development. A qualitative approach was chosen following the Consolidated Criteria for Reporting Qualitative Research (COREQ) [30] (see attachment). An exploratory qualitative design with a single data collection point was chosen using a semi-standardized, topic-centered interview guideline. Interviews were conducted with European experts from the fields of practice, science and development to gain a deeper insight into the integration of robotics for assisted mobilization. The experts' robotic systems were designed, evaluated, or manufactured for inpatient care with a focus on physical rehabilitation.

The research team

The research team consisted of senior researchers, PhD students, and other scientific colleagues. Most of the researchers directly involved in the data collection and analysis have worked as trained nurses. The interviews were conducted by trained female researchers and were pre-tested. No relationship had been established with the respondents prior to the study.

Characteristics and recruitment of participants

In order to obtain information regarding the barriers and facilitators in the implementation of robotic systems, we first contacted purposively identified professionals and then added further professionals using the snowball method. A total of 26 individuals were approached by phone and email via research networks and internet research. Explicit inclusion and exclusion criteria were defined. To include experts in the study, the individuals had to (a) be conducting research on, (b) be developing motion-related robotic systems, or (c) be involved in at least one integration of robotic systems for

health-promoting, inpatient settings (like rehabilitation units or hospitals). This could be, for example, inpatient patient care; the development, production, and distribution of robotic systems; or the research of robotics for physical health promotion. Through the multi-professionalism of the experts, a one-sided view should be avoided and the questions be addressed more precisely. The experts had to be proficient in German or English and have been working in their field for at least three years. This inclusion criterion is intended to ensure that the experts are firmly established in their work environment and that any barriers and support factors seen are exclusively attributable to their handling of robotics. Experts who had experience in other areas of robotics or who had been active in their field for less than three years were excluded. A total of 15 individuals agreed to participate. Eleven individuals did not respond to the interview request. The potential participants were sent the information leaflet, the consent form, and a factsheet about the overall project of which the study was a part. The documents provided information about the purpose, personal rights, and data protection. Additionally, the themes of the interview guide were shared with the participants. Of the 15 potential participants, one interview with two individuals had to be discontinued because they did not meet the inclusion criteria. All participants gave informed written consent.

In total, 11 interviews with 13 experts were conducted. Two interviews were carried out with two interviewees at a time.

Data collection

The first and the second authors (AW and IR) conducted the interviews. Both authors work in projects concerning the implementation of robotics into nursing services. The first author has previous experience in conducting qualitative research, and the second author has a nursing background and was trained in interviewing. Both authors pre-tested the interview guidelines for practicability, aims, and wording and discussed these within the research team. Due to pandemic conditions, all the interviews had to be conducted via online video tools. Data were collected from December 2020 to February 2021.

The interview guide provided the thematic structure: First, the interviewer provided structured information about herself and about the study/project. After an additional short clarification regarding the interviewee's rights and data protection, a socio-demographic questionnaire was filled in together by the interviewee and interviewer. In the questionnaire, questions regarding gender, age, setting (inpatient care, science, and development/manufacturing), job title and qualification, duration of activity in the sector, and duration of the handling of robotic systems were asked. The answers were used to map the characteristics of the study population.

Afterwards, the interview was conducted using a semi-standardized interview guide [31] with the following topics:

- Previous experiences with integrations of robotic systems,
- Experienced supporting factors in the integration (structural, person-related and environmental factors).
- Experienced barriers in the integration (structural, person-related and environmental factors).
- Used solutions to overcome barriers.

The questions were designed to be open-ended. Topics mentioned by the experts were explored in greater depth. After the interview, field notes about the atmosphere and interruptions were written down. Interviews were conducted until the statements of the interview partners became repetitive and no new insights could be gained (data saturation) [32].

Analysis

The interviews were recorded using a recording device and transcribed verbatim using MAXQDA 2022 Software [33]. Analysis was carried out using latent content analysis [34]. Within the coding process, open coding, axial coding, and selective coding were performed [35]:

- Audio records were transcribed verbatim and cross-checked by the research team.
- In the first step, open coding was performed. These codes were evolved in a two-stage process according to the method of meaning condensation [36]: Three researchers coded the transcripts separately and discussed the developed codes until agreement was reached. Where discrepancies occurred, a senior researcher was involved.
- Afterwards, the codes were grouped (axial coding) according to themes. and discussed within the research team.
- These coding groups were summarized into several main themes.

Rigour

The study was conducted according to the quality criteria of openness, flexibility and processuality, intersubjectivity, comprehensibility, appropriateness to the subject matter, and limitations [37, 38]. Within this study, credibility, transferability, confirmability and dependability were assured [39]. Credibility was achieved by conducting at least two pre-tests of the interview guide per researcher as well as comprehensive preliminary research on the topic and the field. Participants were comprehensively informed in advance about the objective and the topic areas. To improve transferability, the results of

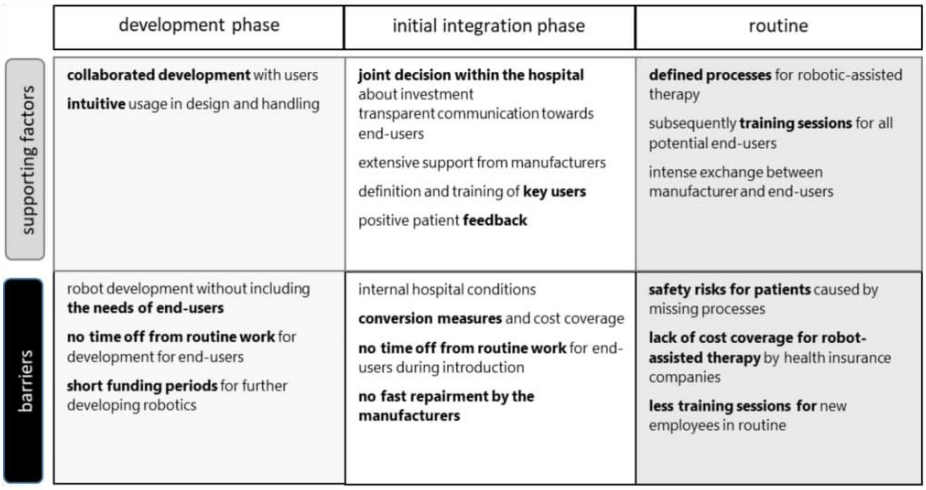

Fig. 1 Clustered overview of results according to stage of integration and support factors and barriers

each step of the analysis were discussed by at least two researchers until agreement emerged [40]. Dependability was achieved by detailing the steps of data collection, analysis, and research design in the study. Confirmability was ensured by following the participants' thematic focus in-depth.

Results

Study population

The experts came from the industry and development of robotic systems (31%), from research (23%), and from practice or clinical settings (46%). Five were female, and eight were male. Seven were in a management position. Eight individuals were from Germany and five were from Denmark (1), Austria (1), or Switzerland (3). The interview participants were on average 45 years old and had been working in their respective industry for an average of 17.5 years. On average, they had been in contact with robotics for 8.8 years. Nine interviewees had an academic degree in healthcare or engineering, and four had completed a professional training as a nurse or physiotherapist. The atmosphere of the interviews was mostly friendly and neutral; in two interviews, the atmosphere was reserved but friendly. Some interviews had been interrupted by colleagues of the interview partners. The interviews had an average length of approximately 36 min. The experts talked about integrations of robotic systems used in physical rehabilitation. The various devices either trained individual muscle areas (such as legs or arms) or were geared toward whole-body training. The majority was used in acute therapy, such as stroke treatment or postoperative early mobilization training. The robotic systems were either loaned for testing, leased for a certain period of time or sold to hospitals.

The results were assigned to three stages of integration into the acute clinical setting: development (before integration), in the initial introduction, and routine usage. For these phases, the experts explained which points were beneficial for longer-term usage on patients and which factors had a negative influence to the point of failure of the integration (see Fig. 1).

Development phase

In the implementation of a robotic system, many experts took a step back and described the important factors influencing integration that had already taken place in the development phase of a robotic system. In this phase, functionality and collaboration were important factors influencing future usage.

Supporting factors

Collaboration between end-users and manufacturers was described as beneficial for adaptations to clinical requirements and small additions. These additions were not necessarily related to the therapy, but could have been based on a simplification of the handling procedures (e.g. adding trash cans to the robotic system in order to avoid extra walking distances).

> *"[The end-users] had a whole wish list that we [the technicians] basically worked out with them at the very beginning. […] We created the development process and the robot in such a way that we come closest to their requirements." (I3 scientist).*

In parallel to the collaboration in initial development, the constant exchanges during events and trade fairs in the form of feedback loops were also considered to be very positive.

> *"Basically, we [the technicians] have also received feedback directly from the market on this and overall very high feedback on the way it is implemented." (I3 scientist).*

Barriers

Robotic systems developed separately from the clinical setting were not practical enough to be used permanently. This may be due to their handleability in general or the non-adaptability to the different conditions of the patient population.

> *"It is always nice if the scientists and engineers come up with a solution, but then somehow often develop it missing the point of the market. They often forget to take the opinion leaders [of the end-users] on board." (I1 manufacturer).*

The non-participation of nurses in the development was often caused by a lack of time off in their daily work. A further aggravating factor was the lack of education regarding technology and robotics within the training to become a nurse or physiotherapist, practioners and manufacturers stated.

Another hurdle for the manufacturers and scientists was too little public funding and short funding periods for the development of a robot adapted to practical needs, as well as difficulties in obtaining approval for it.

Initial integration phase

The experts elaborated in detail about the manufacturer's support, internal hospital processes and adaptations, and financial issues within the integration phase.

Supporting factors

Before integration into the clinical environment, the hospital and the manufacturer had to make certain preparations. Moreover, the decision for robotic therapy devices had to be supported by financial managers and the clinic's management, team leaders, and employees. The decision makers' incentive focused more on the economic factors of the personnel for offering more therapies and using them as an *"exposed promotional tool" (I11 practioner).* For the end-users, a visible effect on patient recovery and a relieved burden in performing therapy were important. Motivated and open-minded end-users also enthused employees with less technological knowledge via the snowball effect.

> *"That worked out quite well, so it's starting to spread, and people are starting to influence each other on these things." (I2 manufacturer).*

Within the hospital and the departments, open and transparent communication was helpful. It was clearly communicated to users that robotics are tools or aids that would not put jobs at risk. This form of communication was also used across departments in some hospitals to create an open atmosphere toward new technologies.

> *"The robot could also be considered as a Swiss pocket knife. So, as an aid for solving the tasks properly, for support and not to replace. A robot should not and cannot do that." (I5 manufacturer).*

Intensive support from the manufacturer with extensive training and follow-up appointments within the following two weeks was important. At the beginning of the rollouts, team leaders and employees were provided with informational materials and motivated employees were invited to become key users. These employees became the main users within the departments and were part of the *"in-house expert panel" (I11 practioner)* or *"core team" (I10 practioner).* It was considered positive if the hospital gave the employees time off for the integration or testing phase and when there was guidance from more experienced users or the manufacturer as a safety mechanism.

It was crucial for employees to be able to test the device on themselves. Through their own experience, employees were able to assess how to design the training for patients.

> *"It really helped that we were all allowed to train with the robot ourselves, so the combination of watching but also experiencing walking in it was very positive. So you can really feel the difference to normal walking, or, rather said, how close it comes to normal walking." (I12 practioner).*

Clear expectation management regarding usability and limitations was also helpful. By setting realistic goals, the idea that *"false expectations are stoked"(I12 practioner)* was prevented.

Moreover, robotic-assisted therapy emerged as a form of physical relief for the users. Robotics generated a

higher frequency of movement sequences, which, without robotics, would only have been possible with greater physical effort.

> *"[Robotics] can make everyday life easier for me. […] In early mobilization, I would have had to work with greater physical effort for a leg movement. So it has to be brought to the foreground that [robotics] is also a physical relief for us." (I4 practioner).*

Additionally, nurses preferred to use robotics if the patient feedback was positive.

Barriers

Challenges to integration included internal hospital processes and structural conditions, costs, technical defects of the robot, patients, and employees.

Internal hospital processes such as hospital hygiene, work safety, and data protection requirements, as well as technical conditions (stable WLAN coverage and power supply), made integration difficult. The premises were also not designed for the integration of robotic systems: room sizes, noise levels, floor load, and heat generation were problematic, so additional costs had to be invested for conversion measures.

> *"The robot was first installed in a room for medical training therapy until they realized that it was actually too heavy for the floor and that they had to put extra plates under it." (I12 practioner).*

In cases where the devices were used at the patient's bedside or in intensive care units, conversion measures were not possible. This also ruled out larger robotic systems from the very beginning, although there would have been interest in the device.

Cost coverage was also challenging for the hospitals. The robotic devices were usually purchased or rented by the respective hospital alone without subsidies or contributions from health insurance companies.

> *"The robot, as well as the rent or the purchase, costs a considerable sum; you will never be able to cover the costs." (I10 practioner).*

Additionally, structural hurdles arose in the integration process in the hospitals. Integration into daily workflows proved difficult, with robot-assisted therapy taking up more time than conventional therapy or disrupting daily routines due to noise or lack of space. No extra time off for key users also led to one integration failure.

> *"The project just falls apart. There is nothing you can do. If there is no structurally adequate integration over a longer period of time, then it won't work." (I1 manufacturer).*

The human factor also played a major role. In the user teams, it was a hindrance if the team leadership was not supportive of the integration. Likewise, it was noted that some professionals permanently rejected the use of robotics because they "*only want to work with their hands, don't want anything modern on it" (I12 practioner).* Often, there was also a lack of safe handling or a fear of being replaced by technology.

> *"There were also many fears 'Okay, now technology is coming into the house, it will make my job redundant." (I11 practioner).*

Integration was also hampered when professionals could not see a positive effect on the patient's healing process or a workload reduction.

Furthermore, some patients did not want to work with robotics. These patients required intensive care, were elderly, or had concomitant psychological factors. Skin damages like skin tears initially appeared due to the use of one robotic device.

Additionally, outages, non-timely repairs, or the lack of extensive support from the manufacturers presented a hurdle for integration. This was mostly put in relation to the high investment costs. Similarly, it was noted that outages led to negative feedback from patients.

> *"When some part of the robot breaks and you call [the technicians], […] someone has to be there the next day to fix it. It should not take a longer period of time." (I12 practioner).*

Routine

Some experts named factors that affected the use of the robots after the intensive introductory phase. Station processes, training, and costs were highlighted.

Supporting factors

Standardized processes such as a fixed group of users or a rotation for robot-assisted therapy were claimed to be useful. It was seen as beneficial if specialist supervisors were involved.

> *"A stable robotics operation is normally given, if there are responsible persons. These persons focus on robot-assisted therapy and spend most of the day with it." (I12 practioner).*

Key users eased the start for the other nurses, who all subsequently also received training. Usually, one

employee supervised a single robot-assisted mobilization, even when multiple devices were available. In one hospital, employees were so familiar with the devices that they were able to perform four robot-assisted therapies simultaneously. So, more therapies could be carried out in the same amount of time. Since therapy units could be billed (to insurance companies or private persons), an additional source of revenue was generated. The simultaneous operation and therapies were rarely reported by the other experts.

Adapted support, periodic visits, and integrating users' feedback into further development by the manufacturers was seen beneficial. They also created the opportunity for exchange between hospitals through annual workshops so that ideas could be jointly formulated and further thought through by the users.

Barriers

Challenges arose if the robotics were not integrated into processes of the respective ward from the beginning-especially in acute or intensive care wards, where highly complex interprofessional care was provided. Standardized processes could refer to responsible professionals or defined therapy times. If these standardizations were missing, subsequent integration was made more difficult. Safety risks due to a lack of defined processes or short application times were the possible results.

> *"If I say right from the start, well, you can have this leeway, then experience has already shown me that at some point 'ah yes, it's not so bad.' And then the three degrees difference, quickly change to that 'I can allow a few more." (I4 practioner).*

In the case of mechanical occurrences of the robot, conventional therapy was mostly preferred because it is more controllable and closer contact with the patient is possible.

> *"And once that starts to get bogged down because you're potentially deciding 'do I take this therapy route or that one?' So, then therapists often decide against the devices." (I12 practioner).*

Hospitals were facing the challenge of implementing robotics in terms of cost coverage. A problem arose in the accounting with health insurance companies, as the robotic-assisted therapy had not yet been firmly integrated into the cost coverage catalog.

In the ongoing process, the training of new employees also presented a hurdle. In their work routines, no elaborate training programs or time off were provided for individual employees.

> *"If the device has been in the house for some time, then the familiarization period is usually significantly shortened compared to a new introduction. […] Then I guess you have to be very, very careful." (I4 practioner).*

This may lead to users being underprepared for intensive therapies for vulnerable patient populations, such as those in early rehabilitation.

Discussion

This study points out that the implementation of robotic assistance systems in acute inpatient care settings requires profound preparation and structuring due to a variety of underlying reasons.

Nursing care in acute inpatient settings, especially intensive care, is highly complex and characterized by situational flexibility regarding the patient's condition. Workflows are built on standardized processes that follow national guidelines [8] or have been developed internally within wards/hospitals. A clear process description is also essential for robot-assisted mobilization, according to the experts in this study. These should be accompanied by implementation science frameworks such as Consolidated Framework for Implementation Research (CFIR) or Theoretical Domains Framework (TDF) [41]. Without this, integration into daily routines is difficult, as Bertelsen also described [24] and challenges may arise in terms of end-user acceptance due to missing knowledge, attitudes and resources [27].

Defining clear responsibilities, such as forming a core team, also creates structure in the area of staff planning. Nurses in the core team should be given time off for integration, according to the experts' recommendations. This could be achieved, for example, in a manner similar to wound management in Germany. These nurses are specialized and work either across hospitals exclusively in the area of wound care or as specialists within a ward [42, 43]. it would imply an adaptation of the nursing staff structures to innovative technologies. However, specialization in robot-assisted therapy and separating these specialists from the ward team would require new thought processes and further research. Thus, there is a possibility that problematic aspects such as less mobilization due to a lack of time or acute staff shortages [15, 16] may occur to a lesser extent. Additionally, if task assignment is regulated within the ward team in the form of the core team, risks such as the lack of safe handling of robotic systems can already be reduced.

Studies have demonstrated that mobilization is performed less when it involves more physical effort [15]. Various robotic systems offer the possibility of minimizing physical effort by taking over the lifting and supporting tasks. This was also pointed out by experts from the

field, who linked the statement to more intensive training for the patient. The positive effect of robot-assisted mobilization on patient well-being also affected the motivation of the users according to the experts. Just et al. [22] were able to show positive trends in patient outcomes, but further research is needed to generalize this statement.

The development of robotic assistance systems has made considerable progress in recent years. However, there is a discrepancy between the requirements of clinical practice and the technical developments to implement and use robotics intuitively and without increased additional effort. Similarly, the clinical requirements for a medical device to be used on patients are a significant hurdle. The experts emphasized that exchanging opinions with users during the development phase is essential for this. Vermeesch et al. [44] pointed out that, in connection with robotics, certain conditions must be satisfied to allow the patients and users to rate the device as acceptable and useful. Kerssens et al. [45] found that caregivers have high expectations of robotics in home care. In the expert interviews, this was similarly confirmed for the acute inpatient sector, showing that a human-related barrier arises if the demands are not met.

Human-related barriers were also mentioned by the experts with regard to other aspects. These included, in particular, team dynamics, affinity for technology, and the motivation of the individuals. Servaty et al. [46] also described a lack of motivation as one of the biggest hurdles for implementation. Waibel et al. [47], however, could not identify any significant hurdles in this respect of their qualitative study.

Similar to the expert survey, this study also highlighted the costs of purchase and permanent financing [47]. The experts increasingly emphasized that financing of the devices for permanent implementation represents is an economic challenge. In addition to the purely monetary expenditure for the device, this also includes any measures that need to be taken structurally. Grunow et al. [48] suggested that sufficient space for robotic devices should be included in the design of patient rooms in the intensive care setting.

The rapid development in the field of robotic systems requires further research on various aspects to further optimize patient care and to provide nurses with future-oriented devices, especially the influence of various human, technical and structural factors on the success of an implementation [26].

Limitations

Due to the higher number of experts from Germany, many results refer to inpatient settings in this country and may therefore not be transferable to other settings or countries. Also, the small and heterogeneous sample might give a limited insight into the topic. Since this study dealt with integration processes into the clinical setting, only professionals had been included. The patients' point of view was disregarded, as they could only reflect unique therapy experiences and it was assumed that caregivers incorporated their patients' feedback into therapy and into their statements. Statements by a great cohort of patients would have strengthened the research and should be integrated in following research.

Implications

Many factors must be taken into account before purchasing/renting robotic devices for use in nursing practice [49]. Hospital and ward managers should consider in advance whether the conditions (such as space, floor conditions, and noise levels) on site are suitable for the robotic device and whether the costs can be covered without subsidies from health insurance companies. Technicians have to ensure that the robot meets the requirements for clinical use as part of the development. Within the integration process, it is essential that a core team of nurses is trained. These key users should be motivated and support the implementation. Moreover, standardized processes need to be developed for robot-assisted therapy. These can be ward-related or hospital-related and should be generated by or in co-operation with the ward or team management. The management must also ensure that nurses are given sufficient time off of routine work as is common in medical devices integration. Similarly, time off for training sessions is essential to ensure safe handling and becoming key user for the device. Manufacturers should provide comprehensive support and assistance during the integration process. Repeated training over time should also be offered in order to train more or newly hired nurses in addition to the core team.

Conclusion

The healthcare systems face multiple challenges like the shortage of skilled workers. If implemented well and sustainably, robotic systems offer the opportunity to provide higher frequency training for patients while relieving nurses of the physical effort. For accomplishing this, the prerequisites and the conditions of the respective hospital/ ward must be checked and adapted prior to the purchase. When integrating the device, it is recommended to involve the concerned end-users fully and provide sufficient time off to train the handling of the device. Support from the manufacturers is essential. For the future, consideration should be given to how the innovative therapy is included in standard care and funding.

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Author contributions
AW, IR, and UF made substantial contributions to the conception and the design of the work. UF and IE applied for funding. AW drafted the manuscript. The other authors critically revised the draft and contributed to the final writing of the paper. All the authors read and approved the final manuscript.

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Data availability
The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The study was approved by the Ethics Committee of the Ludwig-Maximilians University Munich, Germany (20–0883).

Consent to participate
In this study, all the methods were carried out in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Ludwig-Maximilians University Munich, Germany. All the participants signed written informed consent forms and were voluntarily enrolled in the study. Additionally, they could withdraw from the study at any time. All the participants were assured that their information would remain confidential.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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References

1. International Agency for Research on Cancer. Cancer Tomorrow. Estimated number of new cases from 2020 to 2040, both sexes, age [0–85+]. 2020. https://gco.iarc.fr/tomorrow/en/dataviz/bars?mode=population. Accessed 8 Aug 2022.
2. Feigin VL, Stark BA, Johnson CO, et al. Global, regional, and national burden of stroke and its risk factors, 1990–2019: a systematic analysis for the global burden of Disease Study 2019. Lancet Neurol. 2021;795–820. https://doi.org/10.1016/S1474-4422(21)00252-0.
3. Malekahmadi M, Moradi Moghaddam O, Islam SMS, Tanha K, Nematy M, Pahlavani N, Firouzi S, Zali MR, Norouzy A. Evaluation of the effects of pycnogenol (French maritime pine bark extract) supplementation on inflammatory biomarkers and nutritional and clinical status in traumatic brain injury patients in an intensive care unit: A randomized clinical trial protocol 2020. doi:https://doi.org/10.1186/s13063-019-4008-x.
4. Diserens K, Moreira T, Hirt L, Faouzi M, Grujic J, Bieler G, et al. Early mobilization out of bed after ischaemic stroke reduces severe complications but not cerebral blood flow: a randomized controlled pilot trial. Clin Rehabil. 2012;26:451–9. https://doi.org/10.1177/0269215511425541.
5. Chiang LL, Wang LY, Wu CP, Wu HD, Wu YT. Effects of physical training on functional status in patients with prolonged mechanical ventilation. Phys Ther. 2006;86:1271–81. https://doi.org/10.2522/ptj.20050036.
6. Bernhardt J, Dewey H, Collier J, Thrift A, Lindley R, Moodie M, Donnan G. A very early Rehabilitation Trial (AVERT). Int J Stroke. 2006;1:169–71. https://doi.org/10.1111/j.1747-4949.2006.00044.x.
7. Beyer J, Seidel EJ. Frührehabilitation ist erstes Glied einer nahtlosen Rehabilitationskette. [Acute Care Rehabilitation is the First Link in a chain of Rehabilitation Interventions]. Rehabilitation (Stuttg). 2017;56:272–85. https://doi.org/10.1055/s-0043-112071.
8. Bein T, Bischoff M, Brückner U, Gebhardt K, Henzler D, Hermes C, et al. Kurzversion S2e-Leitlinie - "Lagerungstherapie und Frühmobilisation zur Prophylaxe oder Therapie von pulmonalen Funktionsstörungen". [Short version S2e guidelines: "Positioning therapy and early mobilization for prophylaxis or therapy of pulmonary function disorders"]. Anaesthesist. 2015;64:596–611. https://doi.org/10.1007/s00101-015-0060-4.
9. Hermans G, Van den Berghe G. Clinical review: intensive care unit acquired weakness.Crit Care. 2015.
10. Miranda Rocha AR, Martinez BP, Maldaner da Silva VZ, Forgiarini Junior LA. Early mobilization: Why, what for and how?Med Intensiva. 2017.
11. Berney S, Elliot D, Denehy L. ICU-acquired weakness - a call to arms (and legs). Crit Care Resusc. 2011.
12. Herridge MS, Tansey CM, Matté A, Tomlinson G, Diaz-Granados N, Cooper A, et al. Functional disability 5 years after acute respiratory distress syndrome. N Engl J Med. 2011;364:1293–304. https://doi.org/10.1056/NEJMoa1011802.
13. Hermans G, de Jonghe B, Bruyninckx F, van den Berghe G. Interventions for preventing critical illness polyneuropathy and critical illness myopathy. Cochrane Database Syst Rev. 2009;CD006832. https://doi.org/10.1002/14651858.CD006832.pub2.
14. Morris PE, Goad A, Thompson C, Taylor K, Harry B, Passmore L, et al. Early intensive care unit mobility therapy in the treatment of acute respiratory failure. Crit Care Med. 2008;36:2238–43. https://doi.org/10.1097/CCM.0b013e318180b90e.
15. Winkelman C, Peereboom K. Staff-perceived barriers and facilitators.Crit Care Nurse. 2010:2.
16. McWilliams DJ, Pantelides KP. Does physiotherapy led early mobilisation affect length of stay in ICU?ACPRC Journal. 2008:5–10.
17. Barber EA, Everard T, Holland AE, Tipping C, Bradley SJ, Hodgson CL. Barriers and facilitators to early mobilisation in Intensive Care: a qualitative study. Aust Crit Care. 2015;28. https://doi.org/10.1016/j.aucc.2014.11.001. 177 – 82; quiz 183.
18. Calabrò RS, Naro A, Russo M, Leo A, Balletta T, Saccà I, et al. Do post-stroke patients benefit from robotic verticalization? A pilot-study focusing on a Novel Neurophysiological Approach. Restor Neurol Neurosci. 2015. https://doi.org/10.3233/RNN-140475.
19. Villafañe JH, Taveggia G, Galeri S, Bissolotti L, Mullè C, Imperio G, Valdes K, Borboni A, Negrini S. Efficacy of Short-Term Robot-Assisted Rehabilitation in Patients With Hand Paralysis After Stroke: A Randomized Clinical Trial. Hand (N Y). 2018.
20. Taveggia G, Borboni A, Salvi L, Mulé C, Fogliaresi S, Villafañe JH, Casale R. Efficacy of robot-assisted rehabilitation for the functional recovery of the upper limb in post-stroke patients: a randomized controlled study.Eur J Phys Rehabil Med. 2016.
21. Huebner L, Schroederh I, Kraft E, Gutmann M, Biebl J, Klamt A, Frey J, Warmbein A, Rathgeber I, Eberl I, Fischer U, Scharf C, Schaller S, Zoller M. Frühmobilisation auf der Intensivstation – Sind robotergestützte Systeme die Zukunft? Anaesthesiologie 2022. doi:https://doi.org/10.1007/s00101-022-01130-x.
22. Just IA, Fries D, Loewe S, Falk V, Cesarovic N, Edelmann F, Feuerstein A, Haufe FL, Xiloyannis M, Riener R, Schoenrath F. Movement therapy in advanced heart failure assisted by a lightweight wearable robot: a feasibility pilot study. ESC Heart Fail. 2022. https://doi.org/10.1002/ehf2.13903.
23. Klamt AC, Schmidbauer L, Warmbein A, Rathgeber I, Fischer U, Eberl I. Very early Robot-Assisted mobilization of Intensive Care Patients - A Scoping Review. Stud Health Technol Inform. 2021. https://doi.org/10.3233/SHTI210350.
24. Bertelsen AS, Storm A, Minet L, Ryg J. Use of robot technology in passive mobilization of acute hospitalized geriatric medicine patients: a pilot test and feasibility study.Pilot Feasibility Stud. 2020.

25. Shaw J, Agarwal P, Desveaux L, Palma DC, Stamenova V, Jamieson T, et al. Beyond "implementation": digital health innovation and service design. NPJ Digit Med. 2018;1:48. https://doi.org/10.1038/s41746-018-0059-8.
26. Greenhalgh T, Wherton J, Papoutsi C, Lynch J, Hughes G, A'Court C, et al. Beyond adoption: a New Framework for Theorizing and evaluating nonadoption, abandonment, and Challenges to the Scale-Up, Spread, and sustainability of Health and Care Technologies. J Med Internet Res. 2017;19:e367. https://doi.org/10.2196/jmir.8775.
27. Zerth J, Jaensch P, Müller S, Technik.Pflegeinnovation und Implementierungsbedingungen:157–72. doi:https://doi.org/10.1007/978-3-662-63107-2_11.
28. Fernandez ME, Hoor GA ten, van Lieshout S, Rodriguez SA, Beidas RS, Parcel G et al. Implementation Mapping: Using Intervention Mapping to Develop Implementation Strategies. Front Public Health. 2019;7:158. doi:https://doi.org/10.3389/fpubh.2019.00158.
29. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions:: Following considerable development in the field since 2006, MRC and NIHR have jointly commissioned an update of this guidance to be published in 2019. 2019. https://www.mrc.ac.uk/documents/pdf/complex-interventions-guidance/.
30. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups.International J Qual Health Care. 2007.
31. Bogner A, Littig B, Menz W. Das Experteninterview. Theorie, Methode, Anwendung; 2005.
32. DePoy E, Gitlin LN. Introduction to research: understanding and applying multiple strategies. St. Louis, Missouri: Elsevier; 2016.
33. VERBI – Software. Consult. Sozialforschung. GmbH. MAXQDA 2022. www.maxqda.de.
34. Bengtsson M. How to plan and perform a qualitative study using content analysis. NursingPlus Open. 2016;2:8–14. https://doi.org/10.1016/j.npls.2016.01.001.
35. Creswell JW, Plano Clark VL. Designing and conducting mixed methods research. 3rd ed. Thousand Oaks, CA: SAGE; 2018.
36. Kvale S. Interviews: an introduction to qualitative research interviewing. California: Thousand Oaks; 1996.
37. Flick U. Gütekriterien qualitativer Sozialforschung. In: Baur N, Blasius J, editors. Handbuch Methoden der empirischen Sozialforschung: Band 1. 2nd ed. Wiesbaden: Springer VS; 2019. pp. 473–88. https://doi.org/10.1007/978-3-658-21308-4_33.
38. Flick U, von Kardorff E, Steinke I, editors. Qualitative Forschung: Ein Handbuch. Hamburg: Rowohlt Taschenbuch Verlag; 2009.
39. Speziale HS, Streubert HJ, Carpenter DR. Qualitative research in nursing: advancing the humanistic imperative. 5th ed. Lippincott Williams & Wilkins; 2011.
40. Polit DF, Beck CT. Nursing research: generating and assessing evidence for nursing practice. 10th ed. Philadelphia: Lippincott Williams & Wilkins; 2016.
41. Birken SA, Powell BJ, Presseau J, Kirk MA, Lorencatto F, Gould NJ, et al. Combined use of the Consolidated Framework for implementation research (CFIR) and the theoretical domains Framework (TDF): a systematic review. Implement Sci. 2017;12:2. https://doi.org/10.1186/s13012-016-0534-z.
42. Hübner U. Pflegeinformatik: Mehrwert für die Patientenversorgung. Dtsch Ärzteblatt. 2010;107:134–6.
43. Daumann S. Wundmanagement und Wunddokumentation. 5th ed. Stuttgart: Kohlhammer; 2018.
44. Vermeersch P, Sampsel DD, Kleman C. Acceptability and usability of a telepresence robot for geriatric primary care: A pilot. 2018;Geriatric nursing.
45. Kerssens C, Kumar R, Adams AE, Knott CC, Matalenas L, Sanford JA, Rogers WA, Kerssens C, Kumar R, Adams AE, Knott CC, Matalenas L, Sanford JA, Rogers WA. Personalized technology to. Personalized technology to support older adults with and without cognitive impairment living at home. American journal of Alzheimer's disease and other dementias 2015. doi:https://doi.org/10.1177/1533317514568338.
46. Servaty R, Möhler R, Kersten A, Brukamp K, Müller M. Barriers and facilitators of implementing robotic systems in nursing care. In: Pflegeinnovationszentrum, editor. Clusterkonferenz 2018; 2018.
47. Waibel AK, Holl F, Swoboda W, Fotteler M. Chances and Risks of Using Robotic Assistance Systems in Early Neurological Rehabilitation: A Qualitative Analysis. Studies in Health Technology and Informatics. 2022.
48. Grunow JJ, Nydahl P, Schaller SJ. Mobilisation auf Intensivstationen: Intensivpflegezimmer und Medizintechnik können helfen. [Mobilization of Intensive Care Unit Patients: how can the ICU rooms and Modern Medical Equipment help?]. Anaesthesiol Intensivmed Notfallmed Schmerzther. 2022;57:41–51.
49. Warmbein A, Schroeder I, Mehler-Klamt A, Rathgeber I, Huber J, Scharf C, et al. Robot-assisted early mobilization of intensive care patients: a feasibility study protocol. Pilot and Feasibility Studies. 2022;8:236. https://doi.org/10.1186/s40814-022-01191-0.

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Robot-assisted early mobilization for intensive care unit patients: Feasibility and first-time clinical use

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ABSTRACT

Background: Early mobilization is only carried out to a limited extent in the intensive care unit. To address this issue, the robotic assistance system VEMOTION® was developed to facilitate (early) mobilization measures more easily. This paper describes the first integration of robotic assistance systems in acute clinical intensive care units.
Objective: Feasibility test of robotic assistance in early mobilization of intensive care patients in routine clinical practice.
Setting: Two intensive care units guided by anesthesiology at a German university hospital.
Participants: Patients who underwent elective surgery with postoperative treatment in the intensive care unit and had an estimated ventilation time over 48 h.
Methods: Participants underwent robot-assisted mobilization, scheduled for twenty-minute sessions twice a day, ten times or one week, conducted by nursing staff under actual operational conditions on the units. No randomization or blinding took place. We assessed data regarding feasible cutoff points (in brackets): the possibility of enrollment ($x \geq 50$ %), duration (pre- and post-setup ($x \leq 25$ min), therapy duration ($x = 20$ min), and intervention-related parameters (number of mobilizing professionals ($x \leq 2$), intensity of training, events that led to adverse events, errors or discontinuation). Mobilizing professionals rated each mobilization regarding their physical stress ($x \leq 3$) and feasibility ($x \geq 4$) on a 7 Point Likert Scale. An estimated sample size of at least twenty patients was calculated. We analyzed the data descriptively.
Results: Within 6 months, we screened thirty-two patients for enrollment. 23 patients were included in the study and 16 underwent mobilization using robotic assistance, 7 dropped out (enrollment eligibility = 69 %). On average, 1.9 nurses were involved per therapy unit. Participants received 5.6 robot-assisted mobilizations in mean. Pre- and post-setup had a mean duration of 18 min, therapy a mean of 21 min. The robot-assisted mobilization was started after a median of 18 h after admission to the intensive care unit. We documented two adverse events (pain), twelve errors in handling, and seven unexpected events that led to interruptions or discontinuation. No serious adverse events occurred. The mobilizing nurses rated their physical stress as low (mean 2.0 ± 1.3) and the intervention as feasible (mean 5.3 ± 1.6).
Conclusions: Robot-assisted mobilization was feasible, but specific safety measures should be implemented to prevent errors. Robotic-assisted mobilization requires process adjustments and consideration of unit staffing levels, as the intervention does not save staff resources or time.
Registration: clinicaltrials.org TRN: NCT05071248; Date: 2021/10/08; URL https://clinicaltrials.gov/ct2/show/NCT05071248.
Tweetable abstract: Robot-assisted early mobilization in intensive care patients is feasible and no adverse event occurred.

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What is already known

- Early mobilization has positive effects on intensive care patients like preventing the loss of muscle strength.
- Manual early mobilization in intensive care patients represents a high physical strain for mobilizing professionals.
- Robotic assistance systems for mobilization are increasingly being developed, but studies focus mainly on patient outcomes and safety.

What this paper adds

- This study addressed the feasibility of robot-assisted early mobilization in critically ill patients and the implementability in settings such as intensive care units.
- Robot-assisted early mobilization has a comparable risk profile to conventional early mobilization, with an adverse event rate of 1.8 %.
- The load on the mobilizing staff was appropriate, but introduction of robotics cannot counteract intensive staff retention and is time consuming.

1. Background

Early mobilization might have positive effects on the cognitive and functional health of patients in the intensive care unit (ICU) (Thomsen et al., 2008; Bailey et al., 2007; Morris et al., 2008; Burtin et al., 2009; Schweickert et al., 2009; Connolly et al., 2016; Reid et al., 2018; Beyer and Seidel, 2017; Luca et al., 2022). Mobilization helps to prevent the loss of muscle strength (Burtin et al., 2009) and can prevent functional disorders (Thomsen et al., 2008; Bailey et al., 2007; Fichtner et al., 2017; Fuest and Schaller, 2019). Patients in the intensive care setting may benefit from mobilization, in terms of shorter hospitalization (Morris et al., 2008; Schweickert et al., 2009) or faster recovery (Eggmann et al., 2018).

In most cases, nurses or physical therapists in intensive care units carry out mobilization therapy manually. Usually, at least two specialists are involved for the duration of the intervention (Bein et al., 2015), so the therapy is staff-intensive. In this context, it is problematic that the current shortage of qualified staff, especially nurses, also affects intensive care in Germany. According to the S2e guideline ("Positioning therapy and early mobilization for prophylaxis or therapy of pulmonary dysfunctions") (Bein et al., 2015), patients with pulmonary disease should undergo the first early mobilization 72 h after admission to the intensive care unit at the latest, if there is no medical reason indicating otherwise (Fichtner et al., 2017; Kumpf et al., 2018). Regarding the guideline, mobilization should be performed twice daily for 20 min. The recently revised iteration, embodied in the S3 guideline (Deutsche Gesellschaft für Anästhesie und Intensivmedizin, 2023), softened these criteria, emphasizing the central role of the patient's condition in determining the extent and frequency of mobilization. If patients are still sedated or ventilated (Barber et al., 2015), they lack the muscle tone to cooperate during mobilization therapy. Consequently, there is an increased physical and time burden on the mobilizing professionals, which can lead to the widely prevalent problem of back pain (Gilchrist and Pokorná, 2021) and other musculoskeletal disorders (Da Costa and Vieira, 2010; Ellapen and Narsigan, 2014) due to the heavy lifting work. In daily practice, this can result in reduced or less intensive mobilization (Hodgson et al., 2015).

Over the past few years, technology and robotics developers have addressed this issue (Yakub et al., 2014). Currently, there are several robotic assistance systems that can support (early) mobilization (Huebner et al., 2022; Klamt et al., 2021) and can physically relieve nurses (Bohlen et al., 2020; Brinkmann et al., 2022; Hegewald et al., 2018). These systems, which are technically adapted to the patient population, are already being tested and implemented in some hospitals (Dieterich et al., 2022; Calabrò et al., 2015; Charite University, n.d.; Peper et al., 2022). Studies have focused more on safe handling and feasibility concerning patient outcomes (Just et al., 2022), and less on implementation and feasibility in the context of intensive care units concerning aspects such as staff retention or time and effort.

For this purpose, a three-year research project was initiated. Prior to that, a comprehensive preliminary study was carried out, which focused on the current state of early mobilization in intensive care units and the experience gained to date with the implementation of robotic systems (Huebner et al., 2022; Klamt et al., 2021; Warmbein et al., 2023; Mehler-Klamt et al., 2022a).

The aim of this study was to investigate whether robotic assistance systems are feasible for mobilization of surgical patients in the intensive care unit. For this purpose, we examined to what extent robot-assisted early mobilization can be carried out in a homogenous patient population, whether patient safety incidents[1] (Larizgoitia et al., 2013) occur that cause harm (ICH Harmonised Tripartite, 1994), interruption or discontinuation, and how mobilizing nursing professionals assess this form of mobilization.

2. Methods

2.1. Study design and setting

This was a monocentric feasibility study with standardized observations (Thierbach and Petschick, 2019). The evaluation was part of a multi-thematic study design within the MobiStaR (mobilization of intensive care patients by a new standard in adaptive robotics) project (Warmbein et al., 2022). The overall study represented the first implementation of the robotic system VEMOTION® into the practical setting of acute clinical intensive care units. It included three study arms, which deal with feasibility, the experience of the mobilizing professionals (Mehler-Klamt et al., 2022b), and the effects on patient outcomes. Since these data were collected using various assessment methods and time points from different institutions, this article solely presents the thematic focus of the feasibility. Based on the development model of complex interventions of the Medical Research Council (Craig et al., 2019), the study took place in the feasibility phase. The study was registered on clinicaltrials.org (TRN: NCT05071248; Date: 2021/10/08). Reactive Robotics GmbH, Munich, Germany, developed the VEMOTION® system, which is CE certified and approved for intensive care patients. This was the only robot used in this study.

The study was conducted in two interdisciplinary intensive care units, guided by anesthesiology, at the university hospital in Munich, Germany. There were up to sixty nurses working in each ICU, so there was high staff rotation from shift to shift and between the caretaking of individual patients. The intervention took place from September 2021 to March 2022 during a peak phase of the COVID-19 pandemic, which restricted conditions during the study. Since the conventional mobilization therapy carried out in the two ICUs differed significantly from the planned robot-assisted intervention in terms of frequencies, durations, and intensity, no comparison was made in this study.

2.2. Participants

Robot-assisted mobilization was performed with adult patients who underwent scheduled surgery and planned postoperative treatment in an interdisciplinary ICU. The patients had given informed written consent to the study physicians prior to the procedure (ICH Harmonised Guideline Integrated Addendum to ICH E6(R1), n.d.). Postoperative treatment included an expected ventilation time of more than 48 h. As prerequisites for VEMOTION® training, patients had to weigh between 45 and 135 kg and be between 1.50 and 1.95 m tall. These criteria primarily applied to patients requiring a (lung) transplant operation. During the transplantation

[1] A Patient Safety Incident is defined as "an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. A patient safety incident can be a reportable circumstance, a near miss, a no harm incident or a harmful incident (adverse event)" (Larizgoitia et al., 2013).

informed consent discussion, the study physicians approached them regarding their potential participation in the study. Patients were excluded if they were chronically ventilated or bedridden, had a clinical frailty scale score of ≥7 (Tipping, 2016), were at risk for or had elevated intracranial pressure, had a recent cerebral hemorrhage, or had pre-existing neuromuscular disease resulting in chronic limitation of strength and performance. An estimated sample size of at least 20 patients had been calculated, which can be found in the study protocol (Warmbein et al., 2022; Tabachnick and Fidell, 2014; Kinney et al., 2020).

Nursing professionals had to work in an anesthesiology intensive care unit and be trained in robot-assisted mobilization on this specific device. Nurses got detailed information about the study and its evaluation as part of the training (see Fig. 1). Participation in the study was voluntary. Since no personal data were collected, no additional written consent was obtained in this study arm besides that of the study arm evaluating behavior and experiences (Warmbein et al., 2022).

2.3. Description of materials

For enrollment eligibility, data was collected on the number of patients meeting the inclusion criteria, the number of patients included, and the number of dropouts. Regarding interventions, data collection included the frequency of robot-assisted and conventional mobilization in each shift. This involved documenting the duration, pre- and post-preparation time, and the number of personnel involved in mobilization. For robot-assisted mobilization, we recorded the degree of verticalization, duration at the highest level of verticalization, step count per minute, and total step count. We also documented all kind of patient safety incidents (Larizgoitia et al., 2013) that led to any kind of harm, f. e. adverse events (AEs) (ICH Harmonised Tripartite, 1994), or reasons for discontinuation. After completing robot-assisted mobilization, the performing nurses were asked to rate the feasibility and physical exertion of the mobilization on a Likert scale ranging from 0 to 7. The data collection forms were discussed with the mobilizing nurses. During the discussion, the target values for assessing the overall feasibility (≥4.0) and physical stress (≤3) were jointly established.

2.4. Clear descriptions of all processes, interventions, comparisons

The study covered the period of robot-assisted early mobilization of patients who met the inclusion criteria. The intervention was planned for twice a day for 20 min, for at least 10 times or for 7 days, beginning in the first 72 h after admission to the ICU (Bein et al., 2015). Data collection took place every day during the morning and afternoon shifts, if it was deemed safe following the recommendations and criteria of the Consensus Conference, decided by the responsible unit physicians and nurses (Hodgson et al., 2014). Recommendations followed the traffic light system (Rocca et al., 2016). In order to implement the intervention in the unit, a new process for the robot-assisted mobilization was established, and 10–12 nurses per unit were instructed on the use. During training sessions lasting 1.5 h, a manufacturer trainer instructed 3–4 nurses at a time in the device. The training followed the manufacturer's best practice training regimen, which encompassed not only the fundamental application, but also demonstrated modifications based on patients' needs and included emergency training. To facilitate the learning process, a healthy volunteer would lie in the patient bed, and the nurses would learn the procedure through hands-on practice. Follow-up training sessions were held as real mobilizations of patients. Once nurses were confident in using the robot, they were authorized to instruct other nurses.

After surgery, included patients were placed in special study beds that were compatible with the adaptive robotic system. For the intervention, the patient was secured in the study bed; the robotic system was connected to the bed and the patient with a belt system. The device moved the legs according to gait patterns and offered the possibility to raise the patient up to 70°, allowing passive and passive-assistive walking in bed.

Fig. 1. Training session with the robotic system.

After regaining consciousness, patients could determine the intensity of motion and verticalization of the bed. If the patient was not conscious, nurses performed mobilization carefully and with lower intensity. During the intervention as well as pre- and post-processing, members of the research team were present to support the nurses and collect data. The technical developers were available for additional training and refresher sessions in the introductory phase, and spontaneous requests for assistance during mobilizations were answered throughout the whole integration.

2.5. Statistical analysis

Data were collected on standardized forms and managed using Research Electronic Data Capture (REDCap) tools (Harris et al., 2009; Harris et al., 2019), maintained and secured by IT specialists. REDCap is a secure web-based software platform designed to support data capture for research studies. The data were pseudonymized using randomly assigned three-digit IDs and analyzed descriptively using R software (*R: A Language and Environment for Statistical Computing*, 2022). We described continuous variables as median and minimum/maximum values or mean and standard deviation, as appropriate. Categorical variables were described as frequency and percentage. In this study, robot-assisted mobilization was rated as feasible when a minimum amount of such mobilizations (i.e., 50 %) could be performed, no serious adverse events occurred, and it was judged acceptable by the users.

2.6. Enrollment eligibility

Every patient who met the inclusion criteria was included in the assessment of enrollment eligibility, which is where the potential of the intervention should be derived. We recorded the number of screened patients who were not included in the study. It was determined that at least 50 % of the patients should be included to consider the enrollment eligibility feasible, and the retention rate (number of patients who discontinued the intervention or had AEs) should be below 10 %.

2.7. Negative incidents and reasons for discontinuation

We systematically documented all patient safety incidents (Larizgoitia et al., 2013) or reasons for discontinuation within robot-assisted mobilization. These were categorized as follows:

(1) Serious adverse events (SAEs) ("any untoward medical occurrence that at any dose results in death or is life-threatening" (ICH Harmonised Tripartite, 1994)), adverse events (AEs) ("unfavorable changes in health, including abnormal laboratory findings, that occur in trial participants during the clinical trial or within a specified period following the trial" (ICH Harmonised Tripartite, 1994; U.S. National Libary of Medicine, n.d.).
(2) errors ("a broader term referring to any act of commission (doing something wrong) or omission (failing to do the right thing) that exposes patients to a potentially hazardous situation" (Patient Safety Network, 2019))

Furthermore, we created a classification for events that led to interruptions and discontinuations of the intervention but did not result in a (serious) adverse event or harm, nor occurred due to an error.

(3) unexpected events or experiences/organizational issues that did not result in any (potential) harm but led to an interruption or discontinuation of the intervention.

2.8. Intervention-related feasibility

To assess intervention-related feasibility, the duration and setup time should both be less than a mean of 25 min. To assess staff retention, the number of mobilizing professionals had to be less than two (compared with the recommendation of two professionals in the S2e guideline (Bein et al., 2015)). We also documented the degree of verticalization, minutes at the highest degree of verticalization, steps per minute, and total minutes of intervention (mean of 20 min). The mobilizing professionals rated their own physical stress (target value: a maximum mean of 3) and feasibility (target value: a minimum mean of 4) of every robot-assisted mobilization on a 7-point Likert scale.

2.9. Ethics approval and consent to participate

The study was approved by the Ethics Committee of Ludwig-Maximilians-University, Munich, Germany (21-0355). Patients consented to participate in written form.

3. Results

3.1. Enrollment eligibility

During the recruitment period, 525 patients were treated in the two ICUs. Thirty-two patients met the prerequisites for participation in the study and were screened for enrollment (see Fig. 2). Because of the restrictions imposed by the COVID-19 pandemic, there has been a reduction in the number of elective procedures performed. Consequently, this has led to a decrease in the pool of eligible patients available for screening, as emergency patients were unable to give informed consent. Nine eligible patients could not be enrolled for logistic reasons (e.g., patient

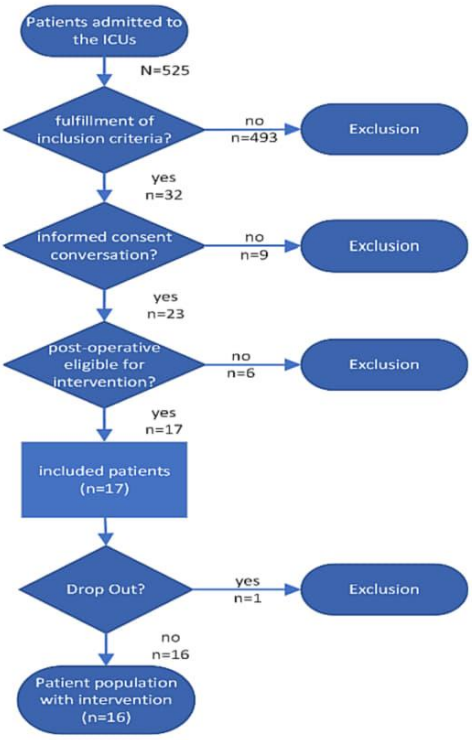

Fig. 2. Selection and inclusion/exclusion process of the study population.

Table 1
Overview of patient characteristics. Normally distributed data are shown as mean ± SD and non-normally distributed data as median (IQR). Categorical data are summarized as frequency (percentage). SD = standard deviation, IQR = interquartile range.

	All (n = 23)	Intervention (n = 16)	Dropout (n = 7)
Male sex	12 (52 %)	8 (50 %)	4 (57 %)
Age in years	58 ± 8.8	58 ± 8.4	56 ± 10.3
Height in cm	170 ± 6.9	169 ± 7.1	172 ± 6.2
Weight in kg	66 ± 11.1	67 ± 11.9	67 ± 9.8
BMI[a] in kg/m^2	23 ± 4.2	23 ± 4.3	22 ± 4.2
Length of ICU stay in days	14 (25)	14 (19)	23 (21)
Length of invasive ventilation (in h)	191 (653)	126 (501)	524 (435)
No. robot-assisted mobilizations	–	6 (4.5)	–
Pre-op. FSS ICU[b]	35 (0)	35 (0)	35 (0)
SAPS II[c] (Day 0)	40 ± 10.3	38 ± 8.6	47 ± 12.3
RASS[d] (Day 1)	−5 (0)	−5 (1)	−5 (0)
SOFA[e] (Day 1)	8 ± 3.3	7 ± 2.5	12 ± 2.1

[a] BMI = body mass index.
[b] Pre-op. FSS ICU = pre-operative Functional Status Score for the Intensive Care Unit.
[c] SAPS II = Simplified Acute Physiology Score II.
[d] RASS = Richmond Agitation Sedation Scale.
[e] SOFA = sepsis-related organ failure assessment score.

not available for information and consent preoperatively). The study physicians invited twenty-three patients to participate and were fully informed. All patients consented in writing to participate in the study. Within the study period, one patient withdrew consent postoperatively. The predefined target criterion of study participation of at least 50 % of the potential patients was met, with 69 % (16/23). Of the 23 patients included, 7 patients (30 %) were not able to undergo the intervention due to extracorporeal membrane oxygenation (ECMO) treatment and hemodynamic instability (n = 6) or withdrawal of consent (n = 1). The patient population is described in Table 1.

In total, the nurses carried out 90 robot-assisted mobilizations with 16 patients. In 161 instances, mobilization could not be performed. Medical contraindications (e.g., ECMO therapy) were a factor in sixty-nine cases, organizational reasons such as staffing shortages were mentioned in forty-two cases, patients expressed different preferences in thirty cases, and mobilization was prevented in twenty cases due to (planned) medical treatment (see supplemental material). Using robotic assistance, 70 % of the patients were mobilized. All patients also underwent standard mobilization therapy.

On average, mobilization began after 18 h. Fifteen of the sixteen patients (94 %) were mobilized within the first 72 h from ICU admission. The first robot-assisted mobilization started on average after 26 h. One patient was first mobilized after 115 h (see Fig. 3).

On average, the patients were mobilized using robotic assistance 5.6 (±2.9) times within the one-week period. The number of mobilizations varied between 2 and 10 units. The setup time varied from 9 to 45 min and post-processing time from 3 to 20 min (mean 8 min). With a mean setup time of 18 min and mobilization time of 21 min, the target time of a maximum 25 min was met. There was no observed decrease in setup times throughout the duration of the study.

3.2. Reasons for discontinuation and patient safety incidents

Within the study period, eight discontinuations of the intervention occurred (see Table 2). One discontinuation was due to the indication of pain by the patient. Additionally, one intervention was prematurely terminated due to a user error. These two events present the most important reasons for discontinuation, corresponding to 1.8 % of all interventions. In four cases, patients discontinued the intervention due to short-term exhaustion, wherein one event was classified as patient safety incident. Two discontinuations were unrelated to the intervention (attributed to medical treatment and bowel movement). In summary, there were no serious adverse events and three interruptions with one pain, one exhaustion and one incorrect utilization of the therapy device. Five interruptions were non-critical events such as bowel movement, exhaustion and interruption for medical treatment.

Throughout the entire study period, the researchers documented twenty-two events that posed an impairment factor in the context of the intervention. Among these, fourteen events (64 %) were resolved during the intervention, enabling the completion of the intervention. This included one AE with pain, which the attending nurse successfully addressed with medication administration, and the patient agreed to complete the intervention.

The most frequent events were errors related to robotics handling, such as misses in connecting the adaptive robot to the study bed or entrapment of infusion cables in the robot's fixation system. These events caused no harm but were considered avoidable. No serious adverse event occurred; one incidence of pain was categorized as adverse event.

3.3. Staff deployment and evaluation

Across all mobilizations, the mean number of professionals performing the therapy was 1.9. Thus, the target criterion of <2 individuals was met, but the number could not be reduced to 1. The number of mobilizing

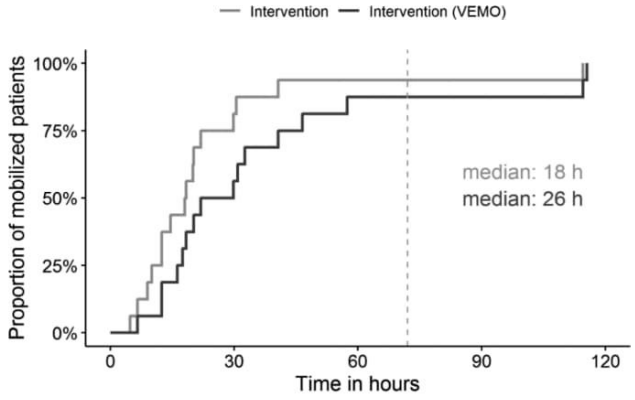

Fig. 3. Kaplan–Meier curve for time to first mobilization. Light gray curve shows time to first mobilization of any type and dark gray curve shows time to first robot-assisted mobilization. Dashed gray line shows 72 h since ICU admission.

Table 2
Reasons for discontinuations and patient safety incidents in robot-assisted mobilization.

	Category	Description	Number (total)	Discontinuations	
				In patient safety incidents	In uncritical events
Patient safety Incidents	SAE[a]	–	–	–	–
	AE[b]	Pain	2	1	–
	Errors	Incorrect utilization of the therapy device	10	1	–
		Lack of workplace monitoring	1	–	–
		Software update error	1	–	–
Other events	Organizational issue	Medical treatment	1	–	1
	Unexpected events/experiences	Bowel movement	2	–	1
		Exhaustion	4	1	3
		Maximum force shutdown of robot by the patient	1	–	–
	TOTAL			3	5
			22	8	

[a] SAE = serious adverse event.
[b] AE = adverse event.

specialists varied between one and four for the individual therapy units (one person, 19 %; two persons, 65 %; three persons, 11 %; four persons, 1 %). This number did not vary in the course of therapy for individual patients.

After each mobilization, the nurses responsible for the mobilization assessed their own physical stress and the feasibility of the training session. On average, physical stress was rated as 2.0 (±1.3) on a scale from 0 (no stress) to 7 (very high stress). The target criterion value of ≤3 was achieved. The assessed physical stress varied according to the number of mobilizations the individual patient received. The mean rating that was above the target criterion was exceeded in five of ten mobilizations (see supplemental material). As a result, the overall physical stress can be considered appropriate, but a general relief of the physical burden could not be confirmed due to the outliers.

General feasibility was assessed by the mobilizing nurses on a scale from 0 (not feasible) to 7 (very feasible). Overall, with an average rating of 5.3 (±1.6), the target criterion of 4.0 was met. Therefore, the mobilizing nurses rated the robotic assistance as feasible. Assessing the different stages of mobilization units, no changes were found (see supplementary material).

3.4. Intervention-related overview

The robot-assisted mobilization parameters were assessed as part of the evaluation. The verticalization of the patient ranged between 14 and 54° (31.0 ± 8.6). For the most part, patients indicated that they did not want further verticalization. The maximum of 70° was not used within the patient cohort. On average, the patients remained at the highest degree of verticalization for 13.3 (±5.2) minutes. With a median of 20 steps per minute (IQR = 0) a range of between 270 and 682 steps (median 407.0, IQR = 38) was documented. The movement of the legs was quite feasible, but the verticalization was used cautiously.

4. Discussion

This study represents the first use of VEMOTION® in early mobilization of critical care patients in acute care hospitals. In here, a 1.8 % rate of adverse events with robotic-assisted mobilization underscores the comparable safety risk of this approach compared to conventional methods, which reported a 2.6 % rate (Nydahl et al., 2017). The contrast becomes even more significant considering that standard care interventions show a 50 % incidence of serious adverse events (Decormeille et al., 2021) while no serious adverse event occurred in our six months trial period. Despite the documented benefits of any kind of mobilization (Burtin et al., 2009) for patient populations such as lung transplant patients (Renner et al., 2023), the observed mobilization rates in other studies remain at 16 % (Hodgson et al., 2015) or range from 8 % to 53 % (Nydahl et al., 2013; Alqahtani et al., 2022). This highlights the need for careful consideration of mobilizing critically ill patients and the importance of transparent communication about potential risks.

Especially in innovations like robotics, detailed examinations about benefits and risks are essential. Calabrò et al. (2015) assessed the acceptability and the risks in patients with aneurysmal subarachnoid hemorrhage using a comparable mobilization robot, Erigo. This robot is very similar to the one used in our study, except for the need to transfer the patient from the bed to the training device. The authors reported no adverse events or discontinuations in this vulnerable patient population. Our study revealed two adverse events in the form of pain, one of which led to discontinuation of the intervention. This reaction was not desirable, but was deemed tolerable due to its short-term occurrence and as an expected risk in view of the temporal proximity to the transplantation procedure (Wickerson et al., 2016). Also exhaustion (or fatigue) has been shown to be a normal response to surgery after less invasive procedures, such as day surgery (Donadello and Gottin, 2020; Mendy et al., 2020). Patients who have undergone lung transplantation continue to experience fatigue one year after surgery (Reinsma et al., 2006). Since the exhaustion experienced by the patients had no influence on patient parameters, condition or medication, it can also be regarded as an undesirable, but tolerable side effect of the training. This contrasts with the case study by Dieterich et al. (2022), in which a patient was successfully guided through the weaning process using the VEMOTION® system, with no mobilization-related incidents reported.

In addition to Serious Adverse Events and Adverse Events, we also focused on all events that interrupted or even led to discontinuation of the intervention, as robotics is a highly complex technology that requires accurate and precise handling (Servaty et al., 2020). Using the robotic system in daily clinical practice during a peak period of the COVID-19 pandemic, characterized by increasing staff shortages and complex patient treatment protocols, was challenging and the goal of ten mobilizations per patient was rarely achieved. In this context, user errors or lapses in attention at the workstation led to longer setup times or discontinuations. Even though these user errors, in their present state, did not result in adverse events, they carried the risk for delays or patient discomfort. The ongoing demand for the designated nurses' presence (Bertelsen et al., 2020) disturbed the nurses' everyday routine, as they typically had to provide care for two patients. These were rarely placed in the same room, requiring the involvement of an additional nurse to assess the condition of the other patient during the intervention. This, coupled with the alignment of setup times with therapy duration (Waibel et al., 2022), occasionally led to the substitution of robotic assistance for more time-efficient conventional mobilization. This differs from other trials in which either nurses or physiotherapists were explicitly assigned to perform the intervention, or the safety of the intervention was tested in feasibility studies (Bertelsen et al., 2020; Gandolfi et al., 2017). To make robot-assisted mobilization an intervention that saves human resources, two other factors should be taken into account: the training of core teams within a unit, indicated in our preliminary

research (Warmbein et al., 2023) as well as the need to develop technology that is easy to use in practice, highlighted by Bertelsen et al. (2020).

However, Brinkmann et al. (2022) observed that the implementation of robotic systems for manual patient handling can alleviate physical workload and musculoskeletal strain for nurses. According to the current S3 guideline (Deutsche Gesellschaft für Anästhesie und Intensivmedizin, 2023), two specialists should be involved in the mobilization. In our study, the average number of people using the robotic system was 1.9, which can be regarded as a positive result when considering the overall staff resources. This presents a chance to provide a health-promoting intervention for nurses by reducing physically demanding tasks (Dieterich et al., 2022), and an opportunity to provide physical support to nurses.

Another study (Grunow et al., 2022) also described a lack of space for handling and storage as a barrier to implementing new robot-assisted therapies. The typically limited space in intensive care units was not a critical issue in our study, although the structural conditions were not designed for the use and storage of mobile robotics.

5. Limitations

The study only focused on the mobilization robot VEMOTION® so the results might vary with other models. While conducting the evaluation, the COVID-19 pandemic was a great burden for the staff in ICUs and influenced the frequency and length of robot-assisted mobilization. Another limitation is that procedures in the interdisciplinary intensive care unit are not schedulable. A comparison with conventional early mobilization could not be implemented, as patients were primarily passively conventionally mobilized. The cutoff points for assessing feasibility and self-perceived physical stress by the users were jointly determined with the nurses to provide a practical assessment. It should be noted that these cut-off points may vary in other healthcare institutions. Real-life conditions are described, but their transferability to other settings is restricted.

6. Conclusions

Robot-assisted early mobilization in ICUs is feasible for nurses mobilizing a pre-defined patient population. However, the study highlighted the need for more comprehensive support and training to reduce errors. Notably, no serious harm to patients was observed during this study, but incorrect usage increases the potential for harm. At the same time, the introduction of robotics cannot counteract intensive staff retention and is time consuming. Further research, in form of a larger randomized trial, is needed on the long-term implementation of robotics and related processes in the ICU setting. Since challenges such as nursing shortages cannot be solved in the near future, increased efforts should be made to support nurses with new technologies such as robotics.

Consent for publication

Not applicable.

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CRediT authorship contribution statement

Angelika Warmbein: Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Lucas Hübner:** Writing – review & editing, Writing – original draft, Methodology, Investigation. **Ivanka Rathgeber:** Writing – review & editing, Resources, Methodology, Investigation, Conceptualization. **Amrei Christin Mehler-Klamt:** Writing – review & editing, Methodology, Investigation. **Jana Huber:** Writing – review & editing, Methodology, Investigation. **Ines Schroeder:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Christina Scharf:** Writing – review & editing, Methodology, Investigation. **Marcus Gutmann:** Writing – review & editing, Methodology, Investigation. **Johanna Biebl:** Writing – review & editing, Methodology, Investigation. **Kirsi Manz:** Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Formal analysis. **Eduard Kraft:** Writing – review & editing, Funding acquisition, Conceptualization. **Inge Eberl:** Writing – review & editing, Project administration, Methodology, Funding acquisition, Formal analysis, Conceptualization. **Michael Zoller:** Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Uli Fischer:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Project administration, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization.

Data availability

The datasets generated or analyzed during the current study are not publicly available but will be available from the study directors upon reasonable request.

Declaration of Competing Interest

The authors declare that they have no competing interests. The company that manufactures the VEMOTION® system is part of the overall study consortium. However, it was not part of the clinical study or the analysis team.

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Appendix A. Supplementary data

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References

Alqahtani, J., Alahamri, M., Alqahtani, A., et al., 2022. Early mobilization of mechanically ventilated ICU patients in Saudi Arabia: results of an ICU-wide national survey. Heart Lung 56, 167–174. https://doi.org/10.1016/j.hrtlng.2022.07.010.

Bailey, P., Thomsen, G.E., Spuhler, V.J., et al., 2007. Early activity is feasible and safe in respiratory failure patients. Crit. Care Med. 35 (1), 139–145. https://doi.org/10.1097/01.CCM.0000251130.69568.87 (PMID: 17133183).

Barber, E.A., Everard, T., Holland, A.E., Tipping, C., Bradley, S.J., Hodgson, C.L., 2015. Barriers and facilitators to early mobilisation in intensive care: a qualitative study. Aust. Crit. Care 28 (4), 177–182. https://doi.org/10.1016/j.aucc.2014.11.001 (quiz 183. PMID: 25533868).

Bein, T., Bischoff, M., Brückner, U., et al., 2015. Kurzversion S2e-leitlinie – "lagerungstherapie und frühmobilisation zur prophylaxe oder therapie von pulmonalen funktionsstörungen". Anaesthesist 64 (8), 596–611. https://doi.org/10.1007/s00101-015-0060-4 (PMID: 26260196).

Bertelsen, A.S., Storm, A., Minet, L., Ryg, J., 2020. Use of robot technology in passive mobilization of acute hospitalized geriatric medicine patients: a pilot test and feasibility study. Pilot Feasibility Stud. 6 (1).

Beyer, J., Seidel, E.J., 2017. Frührehabilitation ist erstes Glied einer nahtlosen Rehabilitationskette. Rehabilitation (Stuttg) 56 (4), 272–285. https://doi.org/10.1055/s-0043-112071 (PMID: 28838026).

Bohlen, C.F., Brinkmann, A., Kowalski, C., Meyer, O., Hellmers, S., Hein, A., 2020. Reducing caregiver's physical strain in manual patient transfer with robot support. Reducing Caregiver's Physical Strain in Manual Patient Transfer With Robot Support, pp. 189–194.

Brinkmann, A., Böhlen, C.F., Kowalski, C., et al., 2022. Providing physical relief for nurses by collaborative robotics. Sci. Rep. 12 (1), 8644. https://doi.org/10.1038/s41598-022-12632-4 (PMID: 35606375).

Burtin, C., Clerckx, B., Robbeets, C., Ferdinande, P., Langer, D., Troosters, T., et al., 2009. Early exercise in critically ill patients enhances short-term functional recovery. Crit. Care Med. 37 (9), 2499–2505. https://doi.org/10.1097/CCM.0b013e3181a38937 (PMID: 19623052).

Calabrò, R.S., Naro, A., Russo, M., et al., 2015. Do post-stroke patients benefit from robotic verticalization? A pilot-study focusing on a novel neurophysiological approach. Restor. Neurol. Neurosci. 33 (5), 671–681. https://doi.org/10.3233/RNN-140475 (PMID: 26410207).

Charite University, d. Reactive robotics GmbH robotic assisted early mobilization in ventilated ICU patients. [cited 2022 July 19] Available from: URL: https://clinicaltrials.gov/show/NCT04423796.

Connolly, B., O'Neill, B., Salisbury, L., Blackwood, B., 2016. Physical rehabilitation interventions for adult patients during critical illness: an overview of systematic reviews. Thorax 71 (10), 881–890. https://doi.org/10.1136/thoraxjnl-2015-208273 (PMID: 27220357).

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., Petticrew, M., 2019. Developing and Evaluating Complex Interventions:: Following Considerable Development in the Field Since 2006, MRC and NIHR Have Jointly Commissioned An Update of This Guidance to be Published in 2019. Medical Research Council Available from: URL: https://www.mrc.ac.uk/documents/pdf/complex-interventions-guidance/.

Da Costa, B.R., Vieira, E.R., 2010. Risk factors for work-related musculoskeletal disorders: a systematic review of recent longitudinal studies. Am. J. Ind. Med. 53 (3), 285–323. https://doi.org/10.1002/ajim.20750 (PMID: 19753591).

Decormeille, G., Maurer-Maouchi, V., Mercier, G., et al., 2021. Adverse events in intensive care and continuing care units during bed-bath procedures: the prospective observational NURSIng during critical carE (NURSIE) study. Crit. Care Med. 49 (1), e20–e30. https://doi.org/10.1097/ccm.0000000000004745 (PMID: 33177361).

Deutsche Gesellschaft für Anästhesie und Intensivmedizin, 2023. S3 Leitlinie 001-015: lagerungstherapie und mobilisation von kritisch erkrankten auf intensivstationen. Available from: URL: https://register.awmf.org/assets/guidelines/001-015l_S3_Lagerungstherapie-Mobilisation-von-kritisch-Erkrankten-auf-Intensivstationen_2023-07.pdf.

Dieterich, F., Perras, J., Popp, W., Ahrens, M., Wirth, S., 2022. Mobilisationsrobotik für eine qualitativ hochwertige mobilisation bei einem COVID-19-patienten mit ECMO-therapie. Die Anaesthesiologie 71 (12), 959–964. https://doi.org/10.1007/s00101-022-01205-9 (PMID: 36149467).

Donadello, K., Gottin, L., 2020. Why are you so tired after surgery? Minerva Anestesiol. 86 (12), 1259–1262. https://doi.org/10.23736/S0375-9393.20.15247-7 (PMID: 33174411).

Eggmann, S., Verra, M.L., Luder, G., Takala, J., Jakob, S.M., 2018. Effects of early, combined endurance and resistance training in mechanically ventilated, critically ill patients: a randomised controlled trial. PLoS One 13 (11), e0207428.

Ellapen, T.J., Narsigan, S., 2014. Work related musculoskeletal disorders among nurses: systematic review. J. Ergonomics 4 (S4-003).

Fichtner, F., Mörer, O., Laudi, S., Weber-Carstens, S., Kaisers, U., 2017. S3-leitlinie invasive beatmung und einsatz extrakorporaler verfahren bei akuter respiratorischer insuffizienz. DIVI 4, 154–163.

Fuest, K., Schaller, S.J., 2019. Frühmobilisation auf der intensivstation: wie ist die evidenz? Med. Klin. Intensivmed. Notfmed. 114 (8), 759–764. https://doi.org/10.1007/s00063-019-0605-4 (PMID: 31428799).

Gandolfi, M., Geroin, C., Tomelleri, C., et al., 2017. Feasibility and safety of early lower limb robot-assisted training in sub-acute stroke patients: a pilot study. Eur. J. Phys. Rehabil. Med. 53 (6), 870–882. https://doi.org/10.23736/S1973-9087.17.04468-9 (PMID: 28084064).

Gilchrist, A., Pokorná, A., 2021. Prevalence of musculoskeletal low back pain among registered nurses: results of an online survey. J. Clin. Nurs. 30 (11–12), 1675–1683. https://doi.org/10.1111/jocn.15722 (PMID: 33616265).

Grunow, J.J., Nydahl, P., Schaller, S.J., 2022. Mobilisation auf Intensivstationen: intensivpflegezimmer und Medizintechnik können helfen. Anaesthesiol Intensivmed Notfallmed Schmerzther 57 (01), 41–51.

Harris, P.A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., Conde, J.G., 2009. Research electronic data capture (REDCap) – a metadata-driven methodology and workflow process for providing translational research informatics support. J. Biomed. Inform. 42 (2), 377–381.

Harris, P.A., Taylor, R., Minor, B.L., et al., 2019. The REDCap consortium: building an international community of software platform partners. J. Biomed. Inform. 95, 103208. https://doi.org/10.1016/j.jbi.2019.103208 (PMID: 31078660).

Hegewald, J., Berge, W., Heinrich, P., et al., 2018. Do technical aids for patient handling prevent musculoskeletal complaints in health care workers? --a systematic review of intervention studies. Int. J. Environ. Res. Public Health 15 (3), 476.

Hodgson, C.L., et al., 2014. Expert consensus and recommendations on safety criteria for active mobilization of mechanically ventilated critically ill adults. Crit. Care Med. 18 (6), 658.

Hodgson, C., Bellomo, R., Berney, S., et al., 2015. Early mobilization and recovery in mechanically ventilated patients in the ICU: a bi-national, multi-centre, prospective cohort study. Crit. Care Med. 19 (1), 81. https://doi.org/10.1186/s13054-015-0765-4 (PMID: 25715872).

Huebner, L., Schroeder, I., Kraft, E., et al., 2022. Frühmobilisation auf der intensivstation – sind robotergestützte systeme die zukunft? Anaesthesiologie 71 (10), 795–800. https://doi.org/10.1007/s00101-022-01130-x (PMID: 35925160).

ICH Harmonised Guideline Integrated Addendum to ICH E6(R1), d. Guideline for good clinical practice ICH E6(R2) ICH Consensus Guideline: Aktuelle E6(R2) Addendum Stufe 4 version. [cited 2020 November 9] Available from: URL: https://ichgcp.net/de.

ICH Harmonised Tripartite (Ed.), 1994. Clinical Safety Data Management: Definitions and Standards for Expedited Reporting E2A.

Just, I.A., Fries, D., Loewe, S., et al., 2022. Movement therapy in advanced heart failure assisted by a lightweight wearable robot: a feasibility pilot study. ESC Heart Fail. 9 (3), 1643–1650. https://doi.org/10.1002/ehf2.13903 (PMID: 35320878).

Kinney, A.R., Eakman, A.M., Graham, J.E., 2020. Novel effect size interpretation guidelines and an evaluation of statistical power in rehabilitation research. Arch. Phys. Med. Rehabil. 101 (12), 2219–2226.

Klamt, A.C., Schmidbauer, L., Warmbein, A., Rathgeber, I., Fischer, U., Eberl, I., 2021. Very early robot-assisted mobilization of intensive care patients – a scoping review. Stud. Health Technol. Inform. 281, 1073–1074. https://doi.org/10.3233/SHTI210350.

Kumpf, O., Braun, J.P., Brinkmann, A., Bause, H., Bellgardt, M., Bloos, F., et al., 2018. Intensivmedizinische qualitätsindikatoren 2017. Anästhesiol. Intensivmed. 59, 326–349.

Larizgoitia, I., Bouesseau, M.-C., Kelley, E., 2013. WHO efforts to promote reporting of adverse events and global learning. J. Public Health Res. 2 (3), e29. https://doi.org/10.4081/jphr.2013.e29 (PMID: 25170500).

Luca, R. de, Bonanno, M., Vermiglio, G., et al., 2022. Robotic verticalization plus music therapy in chronic disorders of consciousness: promising results from a pilot study. Brain Sci. 12 (8). https://doi.org/10.3390/brainsci12081045 (PMID: 36009107).

Mehler-Klamt, A., Huber, J., Warmbein, A., Rathgeber, I., Ohneberg, C., Hübner, L., Scharf, C., Schroeder, I., Zoller, M., Gutmann, M., Biebl, J., Kraft, E., Fischer, U., Eberl, I., 2022a. Frühmobilisation von intensivpatient*innen: eine qualitative analyse mit mobilisierendem fachpersonal an einem deutschen universitätsklinikum zur gestaltung, zum verständnis und zu den einflussfaktoren der frühmobilisation. QuPuG 2, 94–103.

Mehler-Klamt, A., Huber, J., Köstler, N., et al., 2022b. Robotische Frühmobilisation auf der Intensivstation - Kann ein Robotisches System zur Frühmobilisation Mobilisierendes Fachpersonal Entlasten?

Mendy, N., Moriceau, J., Sacuto, Y., et al., 2020. Postoperative fatigue after day surgery: prevalence and risk factors. A prospective observational study. Minerva Anestesiol. 86 (12), 1269–1276. https://doi.org/10.23736/S0375-9393.20.14358-X (PMID: 32755085).

Morris, P.E., Goad, A., Thompson, C., et al., 2008. Early intensive care unit mobility therapy in the treatment of acute respiratory failure. Crit. Care Med. 36 (8), 2238–2243. https://doi.org/10.1097/CCM.0b013e318180b90e (PMID: 18596631).

Nydahl, P., Ruhl, A.P., Bartoszek, G., et al., 2013. Early mobilization of mechanically ventilated patients: a 1-day point-prevalence study in Germany. Crit. Care Med., 42 https://doi.org/10.1097/CCM.0000000000000149.

Nydahl, P., Sricharoenchai, T., Chandra, S., et al., 2017. Safety of patient mobilization and rehabilitation in the intensive care unit. Systematic review with meta-analysis. Ann. Am. Thorac. Soc. 14 (5), 766–777. https://doi.org/10.1513/AnnalsATS.201611-843SR (PMID: 28231030).

Patient Safety Network, 2019. Adverse events, near miss, and errors. [cited 2023 August 8] Available from: URL: https://psnet.ahrq.gov/primer/adverse-events-near-misses-and-errors.

Peper, K.K., Zardykhan, D., Egger, M., et al., 2022. Testing robot-based assist-as-needed therapy for improving active participation of a patient during early neurorehabilitation: a case study. International Conference on Rehabilitation Robotics (ICORR). 2022, pp. 1–6. https://doi.org/10.1109/ICORR55369.2022.9896495 (PMID: 36176105).

R: A Language and Environment for Statistical Computing. R Foundation for Statistical Computing, Vienna, Austria Available from: URL: https://www.R-project.org/.

Reid, J., Unger, J., McCaskell, D., Childerhose, L., Zorko, D.J., Kho, M.E., 2018. Physical rehabilitation interventions in the intensive care unit: a scoping review of 117 prospective studies. J. Intensive Care 6 (8), 1–12.

Reinsma, G.D., ten Hacken, N.H.T., Grevink, R.G., van der Bij, W., Koëter, G.H., van Weert, E., 2006. Limiting factors of exercise performance 1 year after lung transplantation. J. Heart Lung Transplant. 25 (11), 1310–1316. https://doi.org/10.1016/j.healun.2006.08.008 (PMID: 17097494).

Renner, C., Jeitziner, M.-M., Albert, M., et al., 2023. Guideline on multimodal rehabilitation for patients with post-intensive care syndrome. Crit. Care, 27 https://doi.org/10.1186/s13054-023-04569-5.

Rocca, A., Pignat, J.-M., Berney, L., et al., 2016. Sympathetic activity and early mobilization in patients in intensive and intermediate care with severe brain injuries: a preliminary prospective randomized study. BMC Neurol. 16 (1), 169. https://doi.org/10.1186/s12883-016-0684-2 (PMID: 27619015).

Schweickert, W.D., Pohlman, M.C., Pohlman, A.S., et al., 2009. Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial. Lancet 373 (9678), 1874–1882. https://doi.org/10.1016/S0140-6736(09)60658-9 (PMID: 19446324).

Servaty, R., Kersten, A., Brukamp, K., Möhler, R., Mueller, M., 2020. Implementation of robotic devices in nursing care. Barriers and facilitators: an integrative review. BMJ Open 10 (9), e038650. https://doi.org/10.1136/bmjopen-2020-038650 (PMID: 32958491).

Tabachnick, B.G., Fidell, L.S., 2014. Using Multivariate Statistics. 6th ed. Pearson, Boston.

Thierbach, C., Petschick, G., 2019. Beobachtung. In: Baur, N.B.J. (Ed.), Handbuch Methoden der empirischen Sozialforschung, 2nd ed. Springer VS, Wiesbaden, pp. 1165–1181.

Thomsen, G.E., Snow, G.L., Rodriguez, L., Hopkins, R.O., 2008. Patients with respiratory failure increase ambulation after transfer to an intensive care unit where early activity is a priority. Crit. Care Med. 36 (4), 1119–1124. https://doi.org/10.1097/CCM.0b013e318168f986 (PMID: 18379236).

Tipping, C. ea, 2016. The ICU mobility scale has construct and predictive validty and is responsive: a multicenter observational study. Ann. Am. Thorac. Soc. 13 (6), 887–893.

U.S. National Libary of Medicine, d. Help - adverse events: clinicaltrials.org. [cited 2023 August 8] Available from: URL: https://classic.clinicaltrials.gov/ct2/help/adverse_events_desc.

Waibel, A.K., Holl, F., Swoboda, W., Fotteler, M., 2022. Chances and risks of using robotic assistance systems in early neurological rehabilitation: a qualitative analysis. Stud. Health Technol. Inform. 295, 434–437.

Warmbein, A., Schroeder, I., Mehler-Klamt, A., et al., 2022. Robot-assisted early mobilization of intensive care patients: a feasibility study protocol. Pilot Feasibility Stud. 8 (1), 236. https://doi.org/10.1186/s40814-022-01191-0 (PMID: 36333746).

Warmbein, A., Rathgeber, I., Seif, J., et al., 2023. Barriers and facilitators in the implementation of mobilization robots in hospitals from the perspective of clinical experts and developers. BMC Nurs. 22 (1), 45. https://doi.org/10.1186/s12912-023-01202-2 (PMID: 36797701).

Wickerson, L., Rozenberg, D., Janaudis-Ferreira, T., et al., 2016. Physical rehabilitation for lung transplant candidates and recipients: an evidence-informed clinical approach. World J. Transplant. 6 (3), 517–531. https://doi.org/10.5500/wjt.v6.i3.517 (PMID: 27683630).

Yakub, F., Md Khudzari, A.Z., Mori, Y., 2014. Recent trends for practical rehabilitation robotics, current challenges and the future. Int. J. Rehabil. Res. 37 (1), 9–21.