

Aus der Klinik für Kinder- und Jugendmedizin I
Direktor: Prof. Dr. Martin Schrappe
im Universitätsklinikum Schleswig-Holstein, Campus Kiel
an der Christian-Albrechts-Universität zu Kiel

**Nachhaltige Implementierung von Shared Decision Making
in kompletten Versorgungszentren
mit dem SHARE TO CARE-Programm**

DISSERTATION
zur
Erlangung des akademischen Grades
Doctor rerum medicarum (Dr. rer. medic.)
der Medizinischen Fakultät
der Christian-Albrechts-Universität zu Kiel

vorgelegt von
Constanze Stolz-Klingenberg
aus **Düsseldorf**

Kiel **2024**

Referent: Prof. Dr. Dipl. Psych. Friedemann Geiger

Korreferent/in: Prof. Dr. med. Frederick Palm

Datum der Disputation: 19.11.2025

Zum Druck genehmigt, Kiel, den 10.09.2025

gez.: Prof. Dr. Franziska Theilig

(Vorsitzende/r der Prüfungskommission)

Inhaltsverzeichnis

Abkürzungsverzeichnis.....	II
Publikationsliste.....	III
Zusammenfassung	1
1. Hintergrund	1
1.1 Shared Decision Making (SDM)	1
1.2 Gründe für die Anwendung von SDM in der medizinischen Versorgung.....	1
1.3 SDM in der Neuromedizin	2
1.4 Überblick über Interventionen zur Förderung von SDM in der Neuromedizin	4
2. Das SHARE TO CARE-Programm (S2C) zur Förderung von SDM im neuromedizinischen Zentrum am Universitätsklinikum Schleswig-Holstein (UKSH) in Kiel	5
2.1 Rahmenbedingungen der Implementierung des S2C-Programms im neuromedizinischen Zentrum am UKSH in Kiel	5
2.2 Kurzbeschreibung der Intervention	5
2.3 Darstellung und übergreifende Bewertung der Forschungsergebnisse.....	6
2.4 Limitationen.....	9
3. Ausblick.....	10
4. Literaturverzeichnis	11
Erklärung des Eigenanteils an den erfolgten Publikationen.....	IV
Danksagung	VI
Eidesstattliche Versicherung	VII

Abkürzungsverzeichnis

MS = Multiple Sklerose

PD = Morbus Parkinson

SDM = Shared Decision Making

S2C = SHARE TO CARE-Programm

UKSH = Universitätsklinikum Schleswig-Holstein

Publikationsliste

Artikel 1:

Stolz-Klingenberg, C., Bünzen, C., Coors, M., Flüh, C., Stürner, K.H., Wehkamp, K., Clayman, M.L., Scheibler, F., Rüffer, J.U., Schüttig, W., Sundmacher, L., Berg, D., & Geiger, F. (2023). Comprehensive Implementation of Shared Decision Making in a Neuromedical Center Using the SHARE TO CARE Program. *Patient preference and adherence*, 17, 131-139. <https://doi.org/10.2147/PPA.S388432>

Artikel 2:

Stolz-Klingenberg, C., Bünzen, C., Coors, M., Flüh, C., Margraf, N.G., Wehkamp, K., Clayman, M.L., Scheibler, F., Wehking, F., Rüffer, J.U., Schüttig, W., Sundmacher, L., Synowitz, M., Berg, D. & Geiger, F. (2022). Sustainability of large-scale implementation of shared decision making with the SHARE TO CARE program. *Frontiers in neurology*, 13, 1037447. <https://doi.org/10.3389/fneur.2022.1037447>

Zusammenfassung

1. Hintergrund

Täglich werden in der medizinischen Versorgung von Patient*innen vielfältige Entscheidungen getroffen: Welche Diagnostik liefert die richtigen Erkenntnisse zur Therapieplanung? Welches Medikament lindert die Symptome am besten und ist zeitgleich praktikabel in der Umsetzung? Findet eine Behandlung besser stationär oder ambulant statt? Wie invasiv soll die Intervention durchgeführt werden? Um Antworten auf diese und viele weitere Fragen zu finden, existieren unterschiedliche Perspektiven, wie Entscheidungsprozesse in der medizinischen Versorgung gestaltet werden sollen und wie die betroffenen Patient*innen, Angehörigen und das medizinische Fachpersonal involviert sein sollen.

1.1 Shared Decision Making (SDM)

In den vergangenen Jahren hat der Ansatz einer gemeinsamen Entscheidungsfindung, das sogenannte Shared Decision Making (SDM), im Vergleich zum Ansatz einer informierten Einwilligung einen zunehmend höheren Stellenwert gewonnen. Im Rahmen einer informierten Einwilligung präsentieren Ärzt*innen als medizinische Expert*innen den Patient*innen die entscheidungsrelevanten Informationen, während Patient*innen zuhören, verstehen und durch ihre Zustimmung dem Entscheidungsprozess mit geringer Interaktion beiwohnen (Childress & Childress, 2020). Im Gegensatz dazu beschreibt SDM die Entscheidungsfindung zwischen Arzt*Ärztin und Patient*in als Austauschprozess von zwei Expert*innen (Coulter, 1999): Ärzt*innen steuern weiterhin als medizinische Expert*innen ihr Wissen über die Erkrankung, mögliche Symptome, verschiedene Therapieoptionen und Prognosen bei. Patient*innen agieren als Expert*innen für sich selbst, die ihre Erwartungen, Präferenzen, Sorgen, Erfahrungen mit der Erkrankung und Lebensumstände in den Entscheidungsprozess einbringen. Durch einen Austausch der beiden Expert*innen auf Augenhöhe können medizinisch vertretbare Entscheidungen getroffen werden, die bestmöglich zu den Wünschen und Lebensumständen der Patient*innen passen.

1.2 Gründe für die Anwendung von SDM in der medizinischen Versorgung

Die aktive Mitsprache von Patient*innen in die medizinische Entscheidungsfindung ist aus zahlreichen Gründen sinnvoll. SDM ist sowohl ethisch notwendig als auch

gesetzlich im Patientenrechtegesetz in Deutschland gefordert (Heesen et al., 2011; Rummer & Scheibler, 2016). Durch große Fortschritte in der medizinischen Forschung steht mittlerweile für viele Erkrankungen eine deutlich größere Auswahl an medizinisch vertretbaren Therapieoptionen zur Verfügung, die sich in ihrer Wirksamkeit, dem Profil an Nebenwirkungen und der Art der Anwendung unterscheiden (Heesen et al., 2011). Diese Vielfalt macht es unabdingbar, dass Patient*innen mitentscheiden, da die Entscheidungsgewichtung durch den*die Arzt*Ärztin ganz anders ausfallen kann als die Bewertung durch Patient*innen – es wird eine gemeinsame Gewichtung der Vor- und Nachteile der Therapieoptionen benötigt, bei der Patient*innen einordnen, welche Nachteile am ehesten für sie tragbar bzw. welche Vorteile für ihr persönliches Leben am stärksten relevant sind (Corell et al., 2021). Wenn die medizinische Versorgung auf die Wünsche, Präferenzen und Lebensumstände des betroffenen Patient*innen abgestimmt ist, berichten Patient*innen von größerer Zufriedenheit mit der Therapie, zeigen stärkere Adhärenz in der Behandlung und entwickeln ein besseres Gefühl von Selbstwirksamkeit und Kontrolle über die Erkrankung (Légaré et al., 2018; Oterhals et al., 2006; Richter et al., 2011). Zeitgleich bietet der Austausch auf Augenhöhe mit dem medizinischen Personal die Chance, dass Patient*innen ein tiefergehendes Verständnis über ihre Erkrankung und damit assoziierte Krankheitsprozesse und Symptome erlangen. Die so verbesserte Gesundheitskompetenz der Patient*innen begünstigt eine realistische Erwartung über die Wirksamkeit von Therapien (Whittle et al., 2007). Erweiternd ist ein*e gut informierte*r Patient*in befähigt, Nebenwirkungen frühzeitiger zu erkennen und präventiv zu handeln – ein Aspekt, der in der immer komplexeren medizinischen Versorgung maßgeblich zur Patientensicherheit beitragen kann (Heesen et al., 2011). Zusammenfassend kann SDM einen wichtigen Beitrag zu einer qualitativen und individualisierten medizinischen Versorgung leisten. Warum SDM vor allem im Bereich der Neuromedizin besonders relevant ist, wird nachfolgend erläutert.

1.3 SDM in der Neuromedizin

Die Neuromedizin beschäftigt sich mit allen Erkrankungen des zentralen und peripheren Nervensystems und ist aus zahlreichen Gründen prädestiniert für die Anwendung von SDM. In der Neuromedizin werden unter Anderem chronische und progressive Erkrankungen wie Multiple Sklerose (MS), Epilepsie oder Morbus

Parkinson (PD) untersucht und behandelt. Ab der Diagnose einer solchen Erkrankung begeben sich Patient*in und Arzt*Ärztin in eine langfristige Zusammenarbeit, bei der die Behandlung besonders dann gut funktioniert, wenn Patient*innen nachhaltig therapietreu im Team mit dem medizinischen Personal arbeiten (Bieber et al., 2006; Hamann et al., 2010). Mit Fortschreiten einer solchen Erkrankung zeigen sich Einflüsse auf die physische, kognitive und psychosoziale Gesundheit der Patient*innen, die individuell unterschiedlich in ihrer Schwere und Symptomatik ausgeprägt sein können (Ubbink et al., 2022). Die schwere Vorhersagbarkeit des Krankheitsverlaufes macht es zwingend notwendig, dass Patient*innen aktiv in ihrer Therapiegestaltung mitentscheiden. Insbesondere, da bei einigen chronischen Erkrankungen, wie z.B. bei der MS, die Diagnose der Erkrankung häufig bereits im jungen Erwachsenenalter erfolgt. In dieser Lebensphase werden in der Regel weitreichende Entscheidungen für das persönliche Leben getroffen, wie die Berufswahl oder Familienplanung. Im Zuge einer gemeinsamen medizinischen Entscheidungsfindung können die Lebensumstände und persönlichen Lebenspläne der Patient*innen in Bezug zu den unterschiedlichen Auswirkungen vorhandener Therapieoptionen gesetzt werden. Ergänzend steht durch den medizinischen Forschungsfortschritt mittlerweile bei vielen neurologischen Erkrankungen eine Vielzahl an Therapieoptionen zur Verfügung, die sich in ihren Nebenwirkungen, ihrer Effektivität und der Art der Anwendung unterscheiden (Colligan et al., 2017; Lapidès, 2021; Ziemssen et al., 2015). In diesen Fällen ist der Beratungs- und Austauschbedarf zwischen Patient*innen und Ärzt*innen besonders hoch, um eine individuell optimal passende Entscheidung finden zu können (Ubbink et al., 2022; van Ceuninck Capelle et al., 2017). Der Prozess kann herausfordernd sein, da Patient*in und Arzt*Ärztin häufig unterschiedliche Zielsetzungen für eine erfolgreiche Therapie haben: Während der*die Arzt*Ärztin in erster Linie den mithilfe medizinischer Diagnostik sichtbaren Krankheitsfortschritt verlangsamen möchte, liegt das Hauptaugenmerk vieler Patient*innen auf der Lebensqualität in ihrem Alltag (Col et al., 2018). Die unterschiedliche Gewichtung von Arzt*Ärztin und Patient*in unterstreicht die Notwendigkeit einer aktiven Einbindung der Patient*innen und ihrer Angehörigen. Im Rahmen progressiver Erkrankungen können kognitive Einschränkungen auftreten, durch die Angehörige für Patient*innen und für ihre Therapieentscheidungen immer relevanter werden (Nijhuis et al., 2019). Viele Angehörige fühlen sich nicht gut genug

informiert und eingebunden, um bei Therapieentscheidungen zu unterstützen bzw. stellvertretend für Patient*innen zu entscheiden (Schubart et al., 2008). Im Rahmen gemeinsamer Entscheidungen können Angehörige frühzeitig eingebunden die Präferenzen der noch entscheidungsfähigen Patient*innen kennenlernen, um später die Wünsche der Patient*innen aktiv zu vertreten.

1.4 Überblick über Interventionen zur Förderung von SDM in der Neuromedizin

Grundlegend lassen sich SDM-Interventionen hinsichtlich ihrer Zielgruppe sowie der Interventionsarten unterscheiden (Légaré et al., 2018): Die Interventionen können entweder Ärzt*innen, Patient*innen, Gesundheitsfachpersonen aus der Pflege oder eine Kombination aller drei Zielgruppen ansprechen. Die Interventionsinhalte reichen von einer Informierung über Flyer für einzelne Zielgruppen über die Erstellung von erkrankungsspezifischen Entscheidungshilfen hin zu Training von SDM-Kompetenzen in Workshops oder Coachings. In der Neuromedizin gibt es eine Bandbreite an Entscheidungshilfen, deren Aufbau von ausgedruckten Pro-Kontra-Listen über 3-D-Animationen des Gehirns bis hin zu Erklärvideos reichen (Corell et al., 2021). Die thematisierten Erkrankungen sind beispielsweise Morbus Parkinson, bösartige Hirnerkrankungen, Vestibularis Schwannom, Multiple Sklerose, Epilepsie, Schlaganfall oder Migräne. In der Neuromedizin gibt es einige wenige SDM-Trainingsprogramme für Ärzt*innen oder medizinisches Fachpersonal. Auffallend ist allerdings, dass die meisten Programme mit kleinen Stichproben und in spezialisierten Arbeitsbereichen durchgeführt wurden (Porta-Etessam et al., 2023; Takaesu et al., 2022). Zusammenfassend existieren bereits einige wenige Ansätze, um SDM in der Neuromedizin zu etablieren. Die bestehenden Ansätze werden allerdings bisher nur isoliert für einzelne Fachabteilungen, für einzelne Zielgruppen und meist mit Fokus auf die Nutzung einer Entscheidungshilfe angewendet. Dies deckt sich mit dem Befund von Légaré et al. (2018), dass bisher kaum multimodale, großflächige SDM-Interventionen für alle relevanten Zielgruppen in der klinischen Praxis implementiert wurden. Um diese Lücke zu schließen, wurde das SHARE TO CARE-Programm (S2C) entwickelt, welches im Folgenden erläutert wird.

2. Das SHARE TO CARE-Programm (S2C) zur Förderung von SDM im neuromedizinischen Zentrum am Universitätsklinikum Schleswig-Holstein (UKSH) in Kiel

Das multimodulare SHARE TO CARE-Programm (S2C) wurde im Rahmen eines Innovationsfondprojektes über 4 Jahre von 2017 bis 2021 an 17 Kliniken des Universitätsklinikums Schleswig-Holstein (UKSH) am Campus Kiel im erfolgreich implementiert (Geiger, 2023). Die vorliegende Arbeit fokussiert sich auf die Ergebnisse einer prospektiven Interventionsstudie unter Einschluss des Neurozentrums am UKSH, Campus Kiel, insbesondere auf die Auswertung der Patient*innendaten.

2.1 Rahmenbedingungen der Implementierung des S2C-Programms im neuromedizinischen Zentrum am UKSH in Kiel

Das Neurozentrum am UKSH in Kiel setzt sich aus der Klinik für Neurologie und der Klinik für Neurochirurgie zusammen. Mehrere tausend Patient*innen aller neurologischen Erkrankungen aus ganz Schleswig-Holstein, teilweise sogar aus dem gesamten Bundesgebiet werden im Neurozentrum jährlich behandelt (Universitätsklinikum Schleswig-Holstein, 2023). Die zeitgleiche Programm-Implementierung sowohl innerhalb des Neurozentrums als auch in eng zusammenarbeitenden Kliniken (z.B. Klinik für Innere Medizin I und Klinik für Innere Medizin II) ermöglicht eine interdisziplinäre Umsetzung von SDM in der Behandlung der Patient*innen.

2.2 Kurzbeschreibung der Intervention

Das SHARE TO CARE-Programm verfolgt das Ziel, die Anwendung von SDM in der medizinischen Versorgung zu vermitteln und zu fördern. Es besteht aus vier Interventionsbausteinen, deren individuelle Wirksamkeit jeweils in randomisiert-kontrollierten Studien belegt worden sind (Geiger, 2023): SDM-Training des ärztlichen Personals, Online-Entscheidungshilfen, Einbindung der Pflege und Gesundheitsfachberufe sowie Patient*innenaktivierung. Das Programm adressiert alle relevanten medizinischen Berufsgruppen und Patient*innen, um eine ganzheitliche Implementierung entlang der Behandlungspfade von Patient*innen zu ermöglichen. Nach der vollständigen Implementierung des S2C-Programms kann eine Klinik das S2C-Zertifikat als SDM-Zertifizierung erhalten.

2.3 Darstellung und übergreifende Bewertung der Forschungsergebnisse

Die beiden vorliegenden Artikel betrachten chronologisch den Verlauf der Implementierung und Aufrechterhaltung des SHARE TO CARE-Programms im Neurozentrum, eingebettet in eine großflächige Implementierung in einem Großteil der Kliniken am UKSH am Campus Kiel.

Artikel 1 fokussiert sich auf die initiale Implementierung der Intervention über eine Zeitdauer von knapp 2 Jahren, während Artikel 2 die Aufrechterhaltung und Nachhaltigkeit der Implementierung bis zu 18 Monate nach Abschluss der Initialimplementierung beleuchtet. In einem Prä-Post-Design wurden Daten einer unabhängigen Stichprobe vor der Interventionsdurchführung (t_0), unmittelbar nach der Initialimplementierung (t_1) und 6 bis 18 Monate nach der Initialimplementierung (t_2) erhoben. Beide Artikel konzentrieren sich auf den patientenzentrierten Endpunkt Patient*innenbeteiligung im Entscheidungsprozess als Indikator für SDM, gemessen über das Messinstrument PICS_{PDM} (Lerman et al., 1990). Die Ergebnisse werden um die weiteren sekundären patientenzentrierte Endpunkte Vorbereitung auf die Entscheidung (Messinstrument: PrepDM (Bennett et al., 2010)) sowie Zusammenarbeit bei der Entscheidungsfindung (Messinstrument: COLL (Forcino et al., 2018)) ergänzt.

Wie in Abschnitt 2.2 bereits beschrieben, verfolgt das S2C-Programm das Ziel, dass in der klinischen Versorgung von Patient*innen verstärkt gemeinsame Entscheidungsfindung zwischen medizinischem Personal und Patient*innen stattfindet. Mehr gemeinsame Entscheidungsfindung bedeutet eine aktive Einbindung und Beteiligung der Patient*innen. Mit den patientenzentrierten Endpunkten der Forschungsergebnisse kann sichergestellt werden, dass nicht nur das medizinische Personal den Eindruck hat, Patient*innen bei der Entscheidung ins Boot zu holen, sondern dass wirklich geprüft wird, ob Patient*innen sich als aktive Entscheidungsträger*innen wahrnehmen.

Die Forschungsergebnisse in den beiden vorliegenden Artikeln bestätigen, dass Patient*innen nach Implementierung des S2C-Programms mehr gemeinsame Entscheidungsfindung und aktive Beteiligung erleben: In Artikel 1 zeigt sich eine signifikant stärkere Beteiligung der Patient*innen nach der Initialimplementierung im Neurozentrum im Vergleich zu der Erhebung vor Implementierungsstart ($p = <.001$, Hedges $g = .49$); zeitgleich geben sie an, dass sie sich signifikant besser auf die

Entscheidung vorbereitet gefühlt haben ($p = .02$, Hedges $g = .32$) und sich die Zusammenarbeit mit dem medizinischen Personal signifikant verbessert hat ($p = .05$, Hedges $g = .26$). In Artikel 2 sind die gemessenen Effekte auf die Entscheidungsbeteiligung, die Entscheidungsvorbereitung und die Zusammenarbeit mit dem medizinischen Personal bis zu 18 Monate nach Ende der Initialimplementierung etwas schwächer, allerdings immer noch signifikant stärker im Vergleich zu den Daten vor Durchführung der Intervention (PICS_{PDM}: $p = .02$, Hedges $g = .33$; PrepDM: $p = .01$, Hedges $g = .34$; COLL: $p = .05$, Hedges $g = .26$).

Die Forschungsergebnisse der beiden vorliegenden Artikel sind aus mehreren Gründen positiv zu bewerten: In Artikel 1 wird erstens die Implementierung einer komplexen SDM-Intervention beleuchtet, die alle relevanten Personen im Behandlungsverlauf von Patient*innen einbindet. Wie in Abschnitt 1.4 beschrieben, fokussieren die meisten bisherigen Forschungsergebnisse zur Durchführbarkeit und Effektivität von SDM-Interventionen auf bestimmte Zielgruppen oder Interventionsbausteine, z.B. die Erstellung einer Entscheidungshilfe. Der ganzheitliche Ansatz des S2C-Programms ist ein Novum und ermöglicht neue Erkenntnisse zur Umsetzung von komplexen SDM-Interventionen, sodass die vorliegenden Artikel zur Bewertung und Weiterentwicklung von ganzheitlichen Ansätzen beitragen kann. Zweitens sind die Forschungsergebnisse insofern interessant, dass die SDM-Intervention am gesamten Neurozentrum des UKSHs implementiert wurde anstatt nur in spezialisierten neuromedizinischen Fachambulanzen, die gegebenenfalls bereits besonders geeignet für die Anwendung von SDM erscheinen z.B. in einer MS-Ambulanz mit relativ jungen Patient*innen. Der Großteil der Patient*innen in den Stichproben war zwischen 40 und 80 Jahren alt, sodass die Forschungsergebnisse für eine sehr große Bandbreite an Patient*innen Aussagekraft haben. Der Aspekt einer vielschichtigen Stichprobe wird durch das Vorgehen bei der Stichprobengewinnung unterstützt: Weder Patient*innen noch Ärzt*innen wussten beim Entscheidungsgespräch, dass die Patient*innen nach ihrer Entlassung zum Entscheidungsprozess befragt werden würden. Das ärztliche Team hatte keinen Einfluss auf die Auswahl der Patient*innen und waren verblindet über den Zeitraum, in dem Patient*innen rückwirkend befragt werden sollten. Dies führt dazu, dass in den Entscheidungsgesprächen der befragten Patient*innen eine realistische Gesprächsführung zu erwarten ist im Vergleich zu einer möglichen

Verzerrung durch eine besonders SDM-bemühte Gesprächsführung, wenn Kenntnis über die anschließende Befragung bestanden hätte.

Drittens ist zu beachten, dass die vorliegenden Forschungsergebnisse das Neurozentrum am UKSH eingebettet in eine Gesamtimplementierung am Großteil des Campus Kiel des UKSHs zeigen. Die Implementierung von SDM in einem so großen Setting hat bisher in Deutschland nicht stattgefunden, sodass der Erkenntniswert groß ist. Insbesondere relevant in der Neuromedizin – ein Fachbereich, bei dem Patient*innen oftmals interdisziplinär von anderen Fachbereichen wie der Inneren Medizin mitbehandelt werden. Die bereichsübergreifende Implementierung erleichtert die Zusammenarbeit und ermöglicht es Patient*innen, beständig in den verschiedenen Fachbereichen in der Rolle des aktiven Mitentscheiders agieren zu können. Am UKSH-Campus in Kiel betreut auf bestimmten Stationen ärztliches Personal aus der Neuromedizin und den internistischen Bereichen gemeinsam Patient*innen; dort ist es zwingend erforderlich, dass das gesamte ärztliche Team geschult worden ist, um eine gemeinsame Sprache und ein gemeinsames SDM-Rollenverständnis zu leben.

Artikel 2 beleuchtet die Aufrechterhaltung der S2C-Programminhalte nach der Initialimplementierung. Nachhaltigkeit ist bei Interventionen im medizinischen Kontext grundlegend immer relevant, bei so großflächigen Interventionen wie dem S2C-Programm aber besonders wichtig. Die Forschungsergebnisse aus Artikel 2 leisten einen großen Beitrag zur Frage der Nachhaltigkeit von SDM-Interventionen, da dieses Feld bisher nahezu unerforscht ist. 6 Monate in der Neurochirurgie und 18 Monate in der Neurologie nach der Erstimplementierung ist das SDM-Level leicht abgeschwächt, aber immer noch signifikant wahrnehmbar für die befragten Patient*innen. Die unterschiedlichen langen Erhebungszeiträume innerhalb des Neurozentrums lassen sich insofern erklären, dass die t_2 -Daten zeitgleich Mitte 2021 mit Ablauf der Innovationsfondförderung erhoben wurden und die Klinik für Neurologie im Projektverlauf schneller die Interventionsbausteine durchlaufen konnte mit anschließender t_1 -Erhebung im Vergleich zur Klinik für Neurochirurgie.

Das Ergebnis, dass Patient*innen sich auch Monate später weiterhin beteiligt und besser vorbereitet fühlen, ist aufgrund einer Rahmenbedingung im Zuge des Innovationsfondprojektes bemerkenswert: Die Aufrechterhaltung des S2C-Programms im Neurozentrum fiel auf die Endphase der Initialimplementierung in

anderen Klinikteilen des UKSHs im Rahmen der Projektförderung bis zum Sommer 2021, sodass der primäre Fokus des Projektteams auf dem Vervollständigen der Interventionsbausteinen in den noch nicht final implementierten Kliniken lag. Neue Mitarbeitende im Neurozentrum wurden nachgeschult, Aktivierungsmaterial und Entscheidungshilfen wurden ausgegeben; trotzdem war die Aufrechterhaltung durch die limitierten personellen Ressourcen des Projektteams weniger intensiv im Vergleich zum Vorgehen seit Sommer 2021. Seit Sommer 2021 findet eine sehr strukturierte Aufrechterhaltung der Bausteine des S2C-Programms statt: Das Neurozentrum hat ähnlich wie die Funktion eines klinikinternen Hygienebeauftragten Verantwortlichkeit für die Aufrechterhaltung der S2C-Bausteine klinikintern verteilt, sodass gemeinsam mit Ärzt*innen als SDM-Beauftragte die Aufrechterhaltung durchgeführt wird. Neue Mitarbeitende werden geschult, es finden regelmäßig SDM-Teamschulungen statt und es werden über die S2C-Bausteine hinaus SDM-Initiativen von Mitarbeitenden des Neurozentrums umgesetzt.

Dies zeigt, dass die Forschungsergebnisse aus Artikel 2 einen Effekt zeigen, der vermutlich abbildet, wieviel SDM mit geringem Aufrechterhaltungsaufwand Monate später erlebbar bleibt. Zeitgleich macht es neugierig, wie sich die deutlich intensivierte und strukturierte Aufrechterhaltung der S2C-Programmbausteine seit Sommer 2021 auf die patientenzentrierten Endpunkte im Neurozentrum auswirkt.

2.4 Limitationen

Die vorliegenden Forschungsergebnisse beschränken sich auf die patientenseitigen Effekte. Bei einer multimodalen Intervention, bei der neben den Patient*innen das ärztliche Team sowie das Gesundheitsfachpersonal adressiert werden, ist eine Evaluation des Programms aus verschiedenen Perspektiven sinnvoll. Die Erhebung der subjektiven Perspektive vom ärztlichen und pflegerischen Team sowie die objektive Auswertung der Wirksamkeit ist nicht spezifisch für das Neurozentrum, sondern für die Gesamtimplementierung am UKSH durchgeführt worden (Geiger, 2023), sodass keine spezifischen Rückschlüsse für das Neurozentrum möglich sind. Eine mögliche Verzerrung der Daten kann durch die weltweite Covid-19-Pandemie erfolgt sein. Während die Baseline-Erhebung 2018 vor der Covid-19-Pandemie durchgeführt wurde, haben die Post-Erhebungen im Neurozentrum unter Einfluss der Pandemie stattgefunden. Es lässt sich vermuten, dass im Zuge von Lock-Downs und medizinischer Notfallversorgung in Krankenhäusern weniger elektive

Entscheidungen getroffen wurden. Dies macht die Forschungsergebnisse umso bemerkenswerter, da vermeintlich weniger SDM-Situationen entstanden und trotzdem mehr Patient*innen aktiv mitentscheiden konnten.

3. Ausblick

Die vorliegenden Forschungsergebnisse geben einen ersten Einblick, wie eine multimodulare SDM-Intervention erfolgreich in einem gesamten neuromedizinischen Zentrum implementiert und nachhaltig aufrechterhalten werden kann. Die Einbindung vom gesamten medizinischen Personal und den Patient*innen sowie die übergreifende Implementierung in kooperierenden Fachbereichen zur Neuromedizin stellen mögliche Erfolgsfaktoren für die signifikante Veränderung des wahrgenommenen SDM-Level durch die Patient*innen dar. Aus den Forschungsergebnissen lassen sich einige Fragestellungen und Weiterentwicklungsmöglichkeiten für die Zukunft ableiten.

Wie in Abschnitt 2.3 bereits erläutert, findet seit Sommer 2021 nach der t₂-Erhebung eine sehr strukturierte Aufrechterhaltung der Interventionsbausteine statt. Eine weitere Datenerhebung der patientenrelevanten Endpunkte kann Aufschluss darüber geben, inwiefern sich das SDM-Level über die Zeit verändert. Einerseits lässt sich vermuten, dass die nachhaltige Aufrechterhaltung dazu führt, dass SDM stärker in das Rollenverständnis des medizinischen Personals übergegangen ist. Bei neuen Kolleg*innen gehört die SDM-Schulung im Neurozentrum zur Einarbeitung, sodass über die Dauer ein Kulturwandel hin zur selbstverständlichen Anwendung von SDM möglich sein könnte. Ein solcher Kulturwandel könnte über die Zeit auch bei geringem Aufrechterhaltungsaufwand ein konstantes SDM-Level ermöglichen, da SDM-Gespräche routiniert durchgeführt werden. Andererseits kann auch ein gewisser Gewöhnungseffekt des medizinischen Personals und der Patient*innen an SDM auftreten – während zu Beginn der Interventionsimplementierung das Aktivierungsmaterial und die Schulung neuer Input gewesen sind, kann 4 Jahre später eine Ergänzung um neue Impulse notwendig sein, um die Salienz von SDM im klinischen Alltag zu stärken.

Ergänzend ist eine Weiterentwicklung der digitalen Entscheidungshilfen im Neurozentrum denkbar. Die multimediale Gestaltung bietet bereits viele Nutzungsmöglichkeiten, allerdings beschränken sie sich auf die deutsche Sprache. Eine Übersetzung ins Englische und weitere Sprachen könnte den Zugang zu

medizinischen Informationen für mehr Menschen ermöglichen. Zusätzlich könnte die Bereitstellung von entscheidungsrelevanten Informationen in einem analogen Format gerade ältere Patient*innen unterstützen, die bei der Nutzung der digitalen Entscheidungshilfen überfordert sind. Ziel sollte es sein, möglichst vielen Patient*innen die Rahmenbedingungen zu ermöglichen, um aktiv in ihrer Behandlung mitzuwirken und sich an am Entscheidungsprozess zu beteiligen.

4. Literaturverzeichnis

- Bennett, C., Graham, I. D., Kristjansson, E., Kearing, S. A., Clay, K. F. & O'Connor, A. M. (2010). Validation of a preparation for decision making scale. *Patient education and counseling*, 78(1), 130–133.
<https://doi.org/10.1016/j.pec.2009.05.012>
- Bieber, C., Müller, K. G., Blumenstiel, K., Schneider, A., Richter, A., Wilke, S., Hartmann, M. & Eich, W. (2006). Long-term effects of a shared decision-making intervention on physician-patient interaction and outcome in fibromyalgia. A qualitative and quantitative 1 year follow-up of a randomized controlled trial. *Patient education and counseling*, 63(3), 357–366.
<https://doi.org/10.1016/j.pec.2006.05.003>
- Childress, J. F. & Childress, M. D. (2020). What Does the Evolution From Informed Consent to Shared Decision Making Teach Us About Authority in Health Care? *AMA journal of ethics*, 22(5), E423-429.
<https://doi.org/10.1001/amajethics.2020.423>
- Col, N. F., Solomon, A. J., Springmann, V., Garbin, C. P., Ionete, C., Pbert, L., Alvarez, E., Tierman, B., Hopson, A., Kutz, C., Berrios Morales, I., Griffin, C., Phillips, G. & Ngo, L. H. (2018). Whose Preferences Matter? A Patient-Centered Approach for Eliciting Treatment Goals. *Medical decision making: an international journal of the Society for Medical Decision Making*, 38(1), 44–55.
<https://doi.org/10.1371/journal.pone.0164862>
- Colligan, E., Metzler, A. & Tiryaki, E. (2017). Shared decision-making in multiple sclerosis. *Multiple sclerosis (Houndmills, Basingstoke, England)*, 23(2), 185–190. <https://doi.org/10.1177/1352458516671204>
- Corell, A., Guo, A., Vecchio, T. G., Ozanne, A. & Jakola, A. S. (2021). Shared decision-making in neurosurgery: a scoping review. *Acta neurochirurgica*, 163(9), 2371–2382. <https://doi.org/10.21037/apm.2017.06.11>

- Coulter, A. (1999). Paternalism or partnership? Patients have grown up-and there's no going back. *BMJ (Clinical research ed.)*, 319(7212), 719–720.
<https://doi.org/10.1136/bmj.319.7212.719>
- Forcino, R. C., Barr, P. J., O'Malley, A. J., Arend, R., Castaldo, M. G., Ozanne, E. M., Percac-Lima, S., Stults, C. D., Tai-Seale, M., Thompson, R. & Elwyn, G. (2018). Using CollaboRATE, a brief patient-reported measure of shared decision making: Results from three clinical settings in the United States. *Health expectations: an international journal of public participation in health care and health policy*, 21(1), 82–89. <https://doi.org/10.1111/hex.12588>
- Geiger, F. (2023). Ergebnisbericht. Vollimplementierung von Shared Decision Making im Krankenhaus. https://innovationsfonds.g-ba.de/downloads/beschluss-dokumente/374/2023-02-23_MAKING-SDM-A-REALITY_Ergebnisbericht.pdf [Zugriff: 02.01.2024]
- Hamann, J., Mendel, R., Schebitz, M., Reiter, S., Bühner, M., Cohen, R., Berthele, A. & Kissling, W. (2010). Can psychiatrists and neurologists predict their patients' participation preferences? *The Journal of nervous and mental disease*, 198(4), 309–311. <https://doi.org/10.1097/NMD.0b013e3181d6128c>
- Heesen, C., Solari, A., Giordano, A., Kasper, J. & Köpke, S. (2011). Decisions on multiple sclerosis immunotherapy: new treatment complexities urge patient engagement. *Journal of the neurological sciences*, 306(1-2), 192–197.
<https://doi.org/10.1016/j.jns.2010.09.012>
- Lapides, D. A. (2021). Shared Decision-making in Autoimmune Neurology: Making Decisions in the Face of Uncertainty. *Neurology. Clinical practice*, 11(2), 141–146. <https://doi.org/10.1212/CPJ.0000000000000796>
- Légaré, F., Adekpedjou, R., Stacey, D., Turcotte, S., Kryworuchko, J., Graham, I. D., Lyddiatt, A., Politi, M. C., Thomson, R., Elwyn, G. & Donner-Banzhoff, N. (2018). Interventions for increasing the use of shared decision making by healthcare professionals. *The Cochrane database of systematic reviews*, 7(7), CD006732. <https://doi.org/10.1002/14651858.CD006732.pub4>.
- Lerman, C. E., Brody, D. S., Caputo, G. C., Smith, D. G., Lazaro, C. G. & Wolfson, H. G. (1990). Patients' Perceived Involvement in Care Scale: relationship to attitudes about illness and medical care. *Journal of general internal medicine*, 5(1), 29–33. <https://doi.org/10.1007/BF02602306>

- Nijhuis, F. A. P., van den Heuvel, L., Bloem, B. R., Post, B. & Meinders, M. J. (2019). The Patient's Perspective on Shared Decision-Making in Advanced Parkinson's Disease: A Cross-Sectional Survey Study. *Frontiers in neurology*, 10, 896. <https://doi.org/10.1186/s40814-018-0286-4>
- Oterhals, K., Hanestad, B. R., Eide, G. E. & Hanssen, T. A. (2006). The relationship between in-hospital information and patient satisfaction after acute myocardial infarction. *European journal of cardiovascular nursing*, 5(4), 303–310. <https://doi.org/10.1016/j.ejcnurse.2006.01.004>
- Porta-Etessam, J., Santos-Lasaosa, S., Rodríguez-Vico, J., Núñez, M., Ciudad, A., Díaz-Cerezo, S., Comellas, M., Pérez-Sádaba, F. J., Lizán, L. & Guerrero-Peral, A. L. (2023). Evaluating the Impact of a Training Program in Shared Decision-Making for Neurologists Treating People with Migraine. *Neurology and therapy*, 12(4), 1319–1334. <https://doi.org/10.1007/s40120-023-00495-4>
- Richter, M., Schmid-Ott, G., Leicht, R. & Muthny, F. A. (2011). Wahrgenommene Informationsvermittlung und Partizipation von Patienten in der kardiologischen Rehabilitation – Ausprägung und Zusammenhänge mit Reha-Outcome und Selbstwirksamkeit. *Physikalische Medizin Rehabilitationsmedizin Kurortmedizin* (21), 126–130. <https://doi.org/10.1055/s-0031-1277143>
- Rummer, A. & Scheibler, F. (2016). Patientenrechte: Informierte Entscheidung als patientenrelevanter Endpunkt. *Deutsches Ärzteblatt*, 113(8).
- Schubart, J. R., Kinzie, M. B. & Farace, E. (2008). Caring for the brain tumor patient: family caregiver burden and unmet needs. *Neuro-oncology*, 10(1), 61–72. <https://doi.org/10.1215/15228517-2007-040>
- Takaesu, Y., Aoki, Y., Tomo, Y., Tsuboi, T., Ishii, M., Imamura, Y., Tachimori, H. & Watanabe, K. (2022). Implementation of a shared decision-making training program for clinicians based on the major depressive disorder guidelines in Japan: A multi-center cluster randomized trial. *Frontiers in psychiatry*, 13, 967750. <https://doi.org/10.3389/fpsy.2022.967750>
- Ubbink, D. T., Damman, O. C. & Jong, B. A. de (2022). Shared decision-making in patients with multiple sclerosis. *Frontiers in neurology*, 13, 1063904. <https://doi.org/10.1177/0272989X21996342>
- Universitätsklinikum Schleswig-Holstein. (2023). Campus Kiel I Klinik für Neurologie: Unsere Klinik. <https://www.uksh.de/neurologie-kiel/Unsere+Klinik.html> [Zugriff: 02.01.2024]

- van Ceuninck Capelle, A. de, van der Meide, H., Vosman, F. J. H. & Visser, L. H. (2017). A qualitative study assessing patient perspectives in the process of decision-making on disease modifying therapies (DMT's) in multiple sclerosis (MS). *PLoS ONE*, 12(8), e0182806. <https://doi.org/10.1136/medethics-2016-103791>
- Whittle, J., Conigliaro, J., Good, C. B., Kelley, M. E. & Skanderson, M. (2007). Understanding of the benefits of coronary revascularization procedures among patients who are offered such procedures. *American heart journal*, 154(4), 662–668. <https://doi.org/10.1016/j.ahj.2007.04.065>
- Ziemssen, T., Stefano, N. de, Sormani, M. P., van Wijmeersch, B., Wiendl, H. & Kieseier, B. C. (2015). Optimizing therapy early in multiple sclerosis: An evidence-based view. *Multiple sclerosis and related disorders*, 4(5), 460–469. <https://doi.org/10.1016/j.msard.2015.07.007>

Comprehensive Implementation of Shared Decision Making in a Neuromedical Center Using the SHARE TO CARE Program

Constanze Stolz-Klingenberg¹, Claudia Bünzen¹, Marie Coors², Charlotte Flüh³, Klarissa Hanja Stürner⁴, Kai Wehkamp^{5,6}, Marla L Clayman^{7,8}, Fueloep Scheibler^{9,10}, Jens Ulrich Rüffer^{9,10}, Wiebke Schüttig², Leonie Sundmacher², Daniela Berg⁴, Friedemann Geiger^{1,9,11}

¹National Competency Center for Shared Decision Making, University Hospital Schleswig-Holstein, Kiel, Germany; ²Chair of Health Economics, Technical University of Munich, Munich, Germany; ³Department of Neurosurgery, University Hospital Schleswig-Holstein, Kiel, Germany; ⁴Department of Neurology, University Hospital Schleswig-Holstein, Kiel, Germany; ⁵Department of Internal Medicine I, University Hospital Schleswig-Holstein, Kiel, Germany; ⁶Department of Medical Management, MSH Medical School Hamburg, Hamburg, Germany; ⁷Center for Healthcare Organization and Implementation Research (CHOIR), Veterans Administration, Bedford, MA, USA; ⁸Department of Population and Quantitative Health Sciences, University of Massachusetts Chan Medical School, Worcester, MA, USA; ⁹SHARE TO CARE Patientenzentrierte Versorgung GmbH, Cologne, Germany; ¹⁰TakePart Media+Science GmbH, Cologne, Germany; ¹¹Department of Psychology, MSH Medical School Hamburg, Hamburg, Germany

Correspondence: Constanze Stolz-Klingenberg, Universitätsklinikum Schleswig-Holstein, Campus Kiel, Arnold-Heller-Straße 3, Haus 9, Kiel, 24105, Germany, Tel +49 431 500 20208; +49 151 17271928, Email Constanze.Stolz-Klingenberg@uksh.de

Purpose: SHARE TO CARE (S2C) is a comprehensive, multi-module implementation program for shared decision making (SDM). It is currently applied at the University Hospital Schleswig-Holstein in Kiel, Germany, and among general practitioners at the Federal State of Bremen. This study examines the results of the full implementation of S2C in terms of effectiveness within the Kiel Neuromedical Center comprising the departments of neurology and neurosurgery.

Method and Design: The S2C program consists of four combined intervention modules: 1) multimodal training of physicians; 2) a patient activation campaign including the ASK-3 method; 3) digital evidence-based patient decision aids; and 4) SDM support by nurses, e.g., as decision coaches. The SDM level before and immediately after implementation was retrospectively assessed in consecutively selected patients on the subscale “Patient Decision Making” of the Perceived Involvement in Care Scale (PICS_{PDM}). Mean scores were compared with t-tests.

Results: Eighty-nine percent of all physicians (N = 56) completed the SDM training. We developed a total of 12 evidence-based digital decision aids in the center, educated two decision coaches to support patients’ decision processes by using decision aids. Physicians adjusted patients’ pathways to incorporate the use of decision aids. Patients (n = 261) reported a significant increase in participation ($p < 0.001$; Hedges’ $g = 0.49$) in medical decision making.

Conclusion: The S2C program has been successfully implemented within the entire Neuromedical Center. Patients reported a medium to small increase of perceived involvement in decision making demonstrating the effectiveness of the implementation. For future research, it might be interesting to investigate the sustainability of the effects of S2C. In addition, it seems useful to complement the patient-based evaluation with observer-based data.

Keywords: shared decision making intervention, decision aids, physician training, patient activation, neurology, neurosurgery, SDM

Introduction

Shared decision making (SDM) describes the process of information exchange between patients and physicians based on the best available evidence about different treatment options and patient’s preferences aiming for an informed and shared decision.¹ In Germany, participation of patients in their medical decision making is mandated by law.² Additionally, several advantages support implementation of SDM compared to the use of informed consent only in medical decision making: there is evidence that a large number of complaints occur because of patients’ lack of participation in decision processes and

a resulting lack of understanding of potential benefits and harms. That is, patients receive information about potential risks of the treatment choice but do not necessarily understand individual consequences for their life when side-effects occur.³ SDM offers a chance to fill this information gap as the exchange between physician and patient focuses on patient's preferences and life circumstances, which fosters the patient's deeper understanding of different therapy options, their benefits and harms, and probability of occurrence.⁴ As a result, patients are better informed, feel more satisfied with their treatment choice, show greater treatment adherence and self-efficacy during conduction of therapy.^{4,5} Furthermore, patients feel more trust in treatment and experience greater satisfaction with their physician, and their care in general.⁶ In addition, patient's deep understanding leads to a more realistic expectation of treatment outcomes⁷ and in consequence to less complaints and decisional regret.⁸ In sum, SDM meets patients' needs for better information and involvement in medical decision making at an individual level. Furthermore, SDM can improve health care regarding safety and cost-effectiveness.⁹

These issues lead to the question of how to successfully implement SDM in healthcare. Several programs aiming to foster SDM in medical decision making either focus on patient information using decision aids or training of health care professionals. In addition, many programs are limited to specific populations or healthcare sectors. Légaré et al (2018) give an overview about different methods and starting points on how to increase SDM in health care summing up that only few programs follow a holistic approach of combining information and training involving patients, physicians and other medical staff.⁴ The aim of the present study was to examine the feasibility of the multicomponent and holistic SHARE TO CARE program (S2C) and its effectiveness regarding the increase of the SDM level in hospitals.¹⁰ The S2C program involved physicians, health care professionals and patients and was implemented in a large-scale, hospital-wide setting including 22 departments of the University Hospital Schleswig Holstein (UKSH) in Kiel, Germany. To address the complexity of the intervention, the program implementation and evaluation was designed as a triangulated qualitative and quantitative evaluation based on CFIR as framework. In this paper, we focus on the effectiveness from a patient perspective and present the quantitative patient reported outcome measures at the Neuromedical Center of UKSH.¹⁰

Methods

Design and Setting

To examine effectiveness of the S2C-program we collected data at the Neuromedical Center (Department of Neurology and Department of Neurosurgery) at University Hospital Schleswig Holstein (UKSH), Campus Kiel, in 2018 prior to (baseline t_0) and in 2020 immediately after implementation of the S2C program (t_1) as part of the hospital-wide implementation. The baseline survey was conducted at a time when neither medical staff nor patients had been informed about the upcoming SDM implementation. At t_1 , medical staff was informed that the S2C program would be evaluated. However, they were not aware of evaluation measures, the sampling period and, hence, the patients to be included as patients received questionnaires only after their discharge. They had no influence on inclusion of patients as the data for patient inclusion was provided by the hospital management independently of the individual departments. During their consultations, neither medical staff nor patients were aware that they might be invited to participate in a survey about SDM later.

Participants

We included adults (age 18 and older) who recently had a consultation at the Neuromedical Center at the UKSH in Kiel. During their hospital treatment potential participants signed informed consent to be contacted for medical research. After their discharge, patients were contacted by mail to fill out a questionnaire. Both outpatients and inpatients were covered by the intervention modules and covered by the evaluation. There were no a priori exclusion criteria regarding the diagnosis. The questionnaire can be found in [Appendix A](#). The study was approved by the Ethics Committee of the Faculty of Medicine at Kiel University (reference number A111/18).

Intervention

The multicomponent S2C program consists of four intervention modules addressing physicians, medical staff and patients. Each module had been separately tested previously in randomised controlled trials and shown effectiveness and feasibility.¹⁰

1) A minimum of 80% of all physicians within each clinical department ought to complete a multimodal training composed of an online-training¹¹ and two individual feedback sessions based on videotaped patient consultations: The online training (one hour approx.) provided basic SDM knowledge and several simulations of physician-patient-interactions to demonstrate Dos and Don'ts in SDM. Subsequently, physicians received an individual SDM coaching session in a peer group setting (2–5 participants) based on their own videotaped patient consultations. Interaction of increased self-reflection through video excerpts and feedback from colleagues and experienced SDM coaches aimed to create an encouraging and constructive learning atmosphere. Later, physicians recorded another consultation and participated in a second small group training to further increase and consolidate their SDM skills. After successful training completion, physicians received a certificate and education credits by the Physicians Chamber of the Federal State of Schleswig-Holstein.

2) To increase patients' participation and involvement in medical decision making, every patient received information why and how to actively take part in their physician-patient interaction. By distributing various material inside the Neuromedical Center (e.g., SDM clips on screens, roll ups, posters, flyers, promotional items, SDM content on the department websites, paper postcards and screen-based messages and media) we encouraged patients to ask more questions during their consultation to gain deeper understanding of their treatment opportunities. The core element of this campaign was the ASK-3 approach.¹²

3) To foster patients' understanding of their condition and treatment opportunities indication-specific digital evidence-based Patient Decision Aids (EbPDA) were implemented. They were developed in cooperation with local physicians following the International Patient Decision Aids Standards.^{13,14} Experts for evidence-based medicine within the study group conducted a systematic review of best available evidence for all treatment options. They also performed needs assessment interviews with patients to align with needs and preferences of patients in the specific decision situations. Methods were based on the German guidelines for evidence-based patient information and the methods of systematic reviews in patient information.^{15,16} Conceptualizing EbPDA as a user-oriented interface, we enhanced text information with graphics and video clips featuring the local clinical experts explaining interventions as well as patients who shared their experience facing the same decision as the EbPDA user. Each EbPDA underwent external review. More information regarding structure of the EbPDA can be found in [Appendix B](#).

Decision Aids cannot cover all decisions that are regularly made in a university hospital. Therefore, we selected topics together with clinical experts in the departments based on frequency of their occurrence and the physicians' appraisal of the expected benefit in daily clinical practice. We expected a spill-over effect from the decisions made with the help of decision aids to others, where no EbPDA is available.

4) We educated at least 80% of all nurses by a videoclip how to integrate SDM in patient care and how to support patients and physicians to apply the abovementioned modules. Additionally, selected nurses (or physiotherapists, study nurses etc.) were trained as decision coaches to facilitate patients' decision processes with physicians. The training is designed in a similar way as physicians' face-to-face feedback sessions: During 2 workshop days, healthcare professionals gained further knowledge about SDM, deep insight in the DAs of their specific department or section and skills to support patients' decision making. Accompanied by the S2C trainer team, nurses completed decision coach training by recording coaching conversations with a patient twice and received individual feedback. Decision coaches function as emotional assistance to sensitize patients to unanswered questions and treatment preferences. The decision aids could be filled out either at home or in the company of a decision coach at the hospital in preparation for an improved physician-patient-consultation.

By completing all four modules a department meets the criteria to be awarded with the S2C certificate.

Data Collection and Outcome Measures

Outcome data was collected in a pre-post-design using mailed patient questionnaires before (t_0) and after (t_1) intervention. Baseline measurement was conducted from July until September 2018 at the Department of Neurology and from August until October 2018 at the Department of Neurosurgery. Post intervention measurement (t_1) took place from January until March 2020 at the Department of Neurology and from November 2020 until January 2021 at the Department of Neurosurgery. Patients received up to two mailed reminders if they failed to answer within 4 weeks. Post intervention measurement was launched as soon as the four intervention modules were completed.

Sampling was performed as a retrospective and consecutive sample at a certain key date. The overall sample size within the hospital-wide SDM implementation was prescribed by the study protocol ($N > 1,600$ pre and post each).¹⁰ The sample size within each of the 22 included departments was determined by its proportion of cases compared to the overall hospital, with a minimum of $N > 30$ per measurement and department. This resulted in a minimum of $N > 60$ in this study in the Neuromedical Center (2/22 departments).

The primary outcome was the “Patient Decision Making” (PICS_{PDM}) subscale of the Perceived Involvement in Care Scale (PICS), a patient-reported outcome instrument translated and validated in Germany.^{17,18} The SDM level was measured on a scale from 1 = ‘do not agree at all’ to 4 = ‘totally agree’. PICS_{PDM} can be seen as a key indicator of SDM-based physician-patient interaction and has proven applicable in retrospective studies by mail.¹⁹

As secondary outcome, SDM level was assessed using the patient questionnaire collaboRATE (COLL; 3 items; 5 point scale).²⁰ The Preparation for Decision Making Scale (PrepDM; 10 items; 5 point scale) was used as an indicator of decision-specific health literacy.²¹ In addition, data of the other two subscales of PICS, doctor facilitation scale (PICS_{DFS}) and patient information scale (PICS_{PIS}), were collected.

Statistical Analyses

For descriptive purposes, data are expressed as mean with standard deviation (SD) and/or 95% confidence interval (CI), unless stated otherwise. Analysis was conducted as an intention-to-treat approach. A questionnaire was declared evaluable if all questions of the respective subscale were answered. Missing data mechanism was assumed to be missing not at random (MNAR). To avoid possibly biased and misleading results using multiple imputation under the MNAR assumption, a complete case analysis has been performed. We used Z-score normalization before pooling the two departments. An independent two-sided *t*-test was used to determine if there were significant differences between t_0 -baseline and t_1 -post-intervention data for PICS_{PDM}, COLL and PrepDM. Effect size was judged using Hedge’s *g*.

To analyse sociodemographic factors as potential effect modifiers, we performed a multiple regression analysis examining the effect of age, education gender and the intervention itself on PICS_{PDM}.

To conduct a responder analysis, a threshold value of > 2.5 points on the PICS_{PDM}, which ranges from 1 to 4 points, was set a priori as an indicator of SDM. Associations between and among baseline and post-intervention groups and PICS_{PDM} threshold value of < 2.5 were assessed using chi-square-test. A score above 2.5 indicated a good level of SDM. All analyses were performed using STATA 16.1 with a *p*-value < 0.05 considered to indicate statistical significance.

Results

Feasibility of the Intervention

The 4 modules of S2C were successfully implemented at the Neuromedical Center: when the t_1 -post intervention measurement was initiated, a total of 89% of all physicians completed training ($N = 56$) and 12 decision aids had been developed (topics e.g., epilepsy medication, advanced Parkinson disease, neuropathic pain, severe tremor, vestibular schwannoma) and were in use. A current list of all DA-topics of the program can be found at (<https://share-to-care.de>). We approached the whole nursing staff by an education video and reached $> 80\%$. We educated 2 decision coaches, and launched the patient activation campaign as planned within the entire center. Implementation took approximately 1.5 years in Neurology and 2 years in Neurosurgery where it was temporarily interrupted by the COVID19 pandemic. Further measures of feasibility (e.g., a qualitative evaluation) will be reported elsewhere.

Patients’ Characteristics

During the previously defined sampling period, 109 of 182 all contacted patients at t_0 mailed back a survey (response rate: 60.5%). At t_1 due to organizational reasons 267 patients were contacted. One hundred fifty two of them (56.9%) sent back their questionnaire. Therefore, both response rates were close to the predefined range as described in the study protocol (60–70%).¹⁰

Details of patients’ characteristics are shown in Table 1.

Table 1 Sample Description

	t₀		t₁		Total
	n	%	n	%	
Number of patients	109		152		261
Age					
Total responses	107		152		259
18–40 years	6	5.6%	22	14.5%	
41–60 years	40	37.4%	54	35.5%	
61–80 years	53	49.5%	66	43.4%	
Over 80 years	8	7.5%	10	6.6%	
Gender					
Total responses	99		147		246
Female	45	45.5%	74	50.3%	
Male	54	54.5%	73	49.7%	
Education					
Total responses	102		152		254
Lower than secondary school certificate	38	37.3%	46	30.3%	
Secondary school certificate	32	31.3%	53	34.8%	
Higher education entrance qualification	28	27.4%	48	31.6%	
Other school qualification	4	4.0%	5	3.3%	

Effectiveness

The perceived SDM level increased significantly after the intervention (z-score standardized PICS_{PDM}: $M_{t_0} = -0.29$ (SD = 1.10); $M_{t_1} = 0.19$ (SD = 0.88); $p < 0.001$; see Table 2). The effect size Hedges' $g = 0.49$ indicates a medium effect.²²

Patients reported significantly increased health literacy in preparation for treatment decisions (PrepDM: $M_{t_0} = -0.19$ (SD=1.04); $M_{t_1} = 0.13$ (SD = 0.95); $p = 0.002$; Hedges' $g = 0.32$) and reported a greater collaboration with physicians (Coll: $M_{t_0} = -0.15$ (SD= 0.97); $M_{t_1} = 0.11$ (SD = 1.01); $p = 0.005$; Hedges' $g = 0.26$). Following Cohen (1977), effect sizes vary from medium to small effects.²²

To examine potential influence of age, gender or education on the primary endpoint PICS_{PDM}, we performed a multiple regression analysis. Results indicated that apart from the intervention itself ($p < 0.001$), no other variable had a significant impact (see Table 3).

In the responder analysis at t_0 , 58% of all consultations exceeded 2.5 (our pre-defined cutpoint for PICS_{PDM} for “good SDM”); at t_1 , the quota of conversation with high SDM level was enhanced to 77% ($p = 0.001$). The two additional subscales PICS_{DFS} and PICS_{PIS} had descriptively positive, nonsignificant results (data not reported).

Table 2 Endpoints Before and After Implementation (z-Score Standardized Values)

	Original Values				z-Score Standardized Values					
	t ₀		t ₁		t ₀		t ₁			
	M	SD	M	SD	M	SD	M	SD	p	Hedges' g
PICS _{PDM}	2.65	0.92	3.06	0.75	−0.29	1.10	0.19	0.88	<0.001	0.49
COLL	3.63	1.12	3.93	1.18	−0.15	0.99	0.11	1.01	0.05	0.26
PrepDM	3.15	1.29	3.55	1.19	−0.19	1.04	0.13	0.95	0.02	0.32

Table 3 Multiple Linear Regression Analysis of the Effect of Time Point of Measurement, Age, Sex and Educational Level on the Primary Endpoint “Patient Participation in Decision Making” (PICS_{PDM})

	Regression Coefficient	SD	95% CI
Time point of measurement Baseline t_0 (reference group) Post intervention t_1	0.43**	0.13	0.15 to 0.67
Age (years) 18–40 (reference group) 41–60 Over 60	–0.20 –0.37	0.23 0.22	–0.57 to 0.30 –0.73 to 0.12
Sex Female (reference group) Male	–0.04	0.13	–0.29 to 0.21
Highest educational level attained Lower than secondary school certificate (reference group) Secondary school certificate Higher education entrance qualification	0.21 0.15	0.16 0.16	–0.08 to 0.53 –0.13 to 0.49
Regression constant	–0.09	0.25	–0.63 to 0.33
R²	0.08		
R² adj.	0.05		
n (t_0)	85		
n (t_1)	140		

Note: ** $p < 0.01$.

Discussion and Conclusion

To our knowledge this is the first study exploring the center-wide implementation of SDM in Neuromedicine. Results from the Neuromedical Center in Kiel indicate that the multicomponent S2C program significantly increases SDM from the patients' point of view according to both PICS_{PDM} and CollaboRATE. Patients also report being better informed and prepared for their medical decisions. As patient participation plays an important role in medical encounters regarding patient's adherence, trust and collaboration between physician and patient,^{23,24} and satisfaction with the decision itself,⁶ these are promising results for the improvement of healthcare quality in general. There is no evidence in our data that the program works better – or solely – for patients with certain sociodemographic characteristics, namely age, gender or educational level. This is an important finding as it is sometimes argued that SDM is not applicable to poorly educated or elderly patients.²⁵

The high number of trained physicians (89%) is a strong indication for good feasibility and acceptance of the intervention. To the best of our knowledge, there is no other large-scale SDM implementation program with comparable values. The high level of training participation was positively influenced by various factors: On the one hand, the implementation was supported by SDM motivated chief and senior physicians, who themselves completed the training and acted as role models. One physician in each department was designated as the central key figure and contact person for all physicians and health care professionals for the topic of SDM. On the other hand, structural support was provided so that physicians completed the training in paid working hours whenever possible. In addition, the simultaneous implementation of S2C program not only in the Neuromedical Center but in many other departments of the UKSH led to the fact that SDM could also be applied in interdisciplinary patient cases e.g., in the development of decision aids. In this context, it is important to stress that there were no strong incentives for physicians and patients to be part of the program.

Across the whole hospital, we intended to train approximately 150 nurses. In the end, we were only able to train significantly fewer (2 at the Neuromedical Center). This can be explained by the shortage of nursing staff in Germany that was even exacerbated by the COVID pandemic so that there were not enough resources available to enable nurses to receive further training as decision coach. There is further research needed to create a better framework for decision coaching in a hospital-wide implementation of SDM.

The validity of our findings might be limited by the lack of a randomization. However, as we enrolled the entire center with an organization-focused implementation program, an analysis randomizing physicians or patients to different experimental arms was not applicable. Due to the size of the departments, a cluster-randomized study was neither affordable nor implementable. Hence, a consecutive cohort study provided the best experimental quality. As we obtained the data through the hospital administration, the organizational burden for prospective data collection was too high, so that a larger recall bias may have resulted from the retrospective survey. Because of the consistent survey process, we expect a similar recall bias at both survey time points. Therefore, the effect measured should only minimally be biased. However, data protection regulation did not allow us to capture the exact times of discharge and survey administration for each patient separately. Representativity might be reduced by self-selection of consenting and of responding patients. However, response rates of around 60% are to be viewed rather high. Even more, neither physicians nor the study group had any influence on the selection of patients enrolled in the study or were aware of the sampling period and the evaluation measures. Restrictively, it might be added that we assumed an independent sample as the probability that a patient was included twice in the survey is very low, but never excluded. As another possible limitation, all outcome data on effectiveness reflect the patient's point of view using PICS and CollaboRATE as retrospective patient-reported outcome instruments. It is indisputable, that the patient's experience is of major importance, especially when other patient-related variable like adherence are discussed. Nevertheless, the evaluation within other departments at the UKSH in Kiel also includes observer-based analyses of videotaped consultations using MAPPIN'SDM^{26,27} and data on costs and quality of care as a result of the SDM implementation.¹⁰ With those future findings, it will be possible to further underscore the conclusions from the current study.

Due to pre-post design of the study the results may be biased by the COVID19 pandemic – pre-intervention data collection took place in regular operation of the Neuromedical Center whereas post-intervention data was collected in the first year of the pandemic. The survey period in the Department of Neurosurgery coincided with an increased number of COVID infections and hospitalized patients during winter season. As a consequence, elective treatments and surgeries were postponed such that our sample of patients might differ from pre- to post-intervention survey. However, with a reduction of elective treatments at t_1 , the proportion of decisions qualified for SDM is lower. Therefore, if all patients are included in a consecutive sample under these conditions, regardless of whether they come as emergency treatment or as a planned procedure, the measured SDM level after the intervention t_1 can rather be regarded as underestimated.

Furthermore due to the pre post design of the study a general effect of time might have biased the results. Our 10 year experience in observative studies with PICS did not find strong trends in perceived involvement.¹⁹ Therefore, a bias by time in 2.5 years seems to be rather small.

For future research it might be interesting to evaluate qualitative and quantitative data from additional departments of UKSH Kiel to gain a more comprehensive insight in a hospital-wide implementation. In addition, another post-intervention measurement at Neuromedical Center is scheduled at least 6 months after t_1 so that we can judge the sustainability of the S2C intervention.

In conclusion, this study provided convincing evidence for an increase of perceived involvement of patients in their medical decision making from a center-wide multi-module implementation of SDM in neuromedicine. Future studies on the application of the multicomponent S2C program in other departments in Kiel as well as in other hospitals beyond Kiel will show if the S2C program will live up to the expectations of being a universally applicable program for large-scale implementation of SDM.

Abbreviations

SDM, Shared decision making; UKSH, University Hospital Schleswig Holstein; EbPDA, evidence-based Patient Decision Aids.

Ethics Statement

The study was approved by the Ethics Committee of the Faculty of Medicine at Kiel University (reference number A111/18). The study is aligned with the Helsinki declaration.

Funding

The SHARE TO CARE project was funded by the German Innovation Fund of the Federal Joint Committee (NVF17009) and the Medical Faculty of the Kiel University.

Disclosure

FG, FS and KW are co-founders, JUR is CEO and co-founder of SHARE TO CARE Patientenzentrierte Versorgung GmbH (Cologne/Germany). JUR is also CEO of TakePart Media + Science GmbH, Cologne, Germany. KHS reports personal fees from Hoffmann La-Roche AG, Sanofi Genzyme, Merck KGaA, Biogen Idec, Bayer AG, and Bristol-Meyer-Squibb. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

References

1. Stigglebout AM, van der Weijden T, Wit MPT, et al. Shared decision making: really putting patients at the centre of healthcare. *BMJ*. 2012;344:e256. doi:10.1136/bmj.e256
2. Rummer A, Scheibler F. Patientenrechte: informierte Entscheidung als patientenrelevanter Endpunkt. *Deutsches Ärzteblatt*. 2016;113(8):A322.
3. Posner KL, Severson J, Domino KB. The role of informed consent in patient complaints: reducing hidden health system costs and improving patient engagement through shared decision making. *J Healthc Risk Manag*. 2015;35(2):38–45. doi:10.1002/jhrm.21200
4. Légaré F, Adekpedjou R, Stacey D, et al. Interventions for increasing the use of shared decision making by healthcare professionals. *Cochrane Database Syst Rev*. 2018;7:19–22. doi:10.1002/14651858.CD006732.pub4
5. Richter M, Schmid-Ott G, Leicht R, Muthny FA. Wahrgenommene Informationsvermittlung und Partizipation von Patienten in der kardiologischen Rehabilitation – ausprägung und Zusammenhänge mit Reha-Outcome und Selbstwirksamkeit. *Physikalische Medizin Rehabilitationsmedizin Kurortmedizin*. 2011;1(21):126–130. doi:10.1055/s-0031-1277143
6. Clayman ML, Bylund CL, Chewning B, Makoul G. The impact of patient participation in health decisions within medical encounters: a systematic review. *Med Decis Making*. 2016;36(4):427–452. doi:10.1177/0272989X15613530
7. Whittle J, Conigliaro J, Good CB, Kelley ME, Skanderson M. Understanding of the benefits of coronary revascularization procedures among patients who are offered such procedures. *Am Heart J*. 2007;154(4):662–668. doi:10.1016/j.ahj.2007.04.065
8. Davison BJ, Goldenberg SL. Decisional regret and quality of life after participating in medical decision-making for early-stage prostate cancer. *BJU Int*. 2003;91(1):14–17. doi:10.1046/j.1464-410x.2003.04005.x
9. Elwyn G, Frosch DL, Kobrin S. Implementing shared decision-making: consider all the consequences. *Implement Sci*. 2016;11:114. doi:10.1186/s13012-016-0480-9
10. Danner M, Geiger F, Wehkamp K, et al. Making shared decision-making (SDM) a reality: protocol of a large-scale long-term SDM implementation programme at a Northern German University Hospital. *BMJ Open*. 2020;10(10):e037575. doi:10.1136/bmjopen-2020-037575
11. Geiger F, Hacke C, Potthoff J, et al. The effect of a scalable online training module for shared decision making based on flawed video examples - a randomized controlled trial. *Patient Educ Couns*. 2021;104(7):1568–1574. doi:10.1016/j.pec.2020.11.033
12. Shepherd HL, Barratt A, Jones A, et al. Can consumers learn to ask three questions to improve shared decision making? A feasibility study of the ASK (AskShareKnow) Patient-Clinician Communication Model(®) intervention in a primary health-care setting. *Health Expect*. 2016;19(5):1160–1168. doi:10.1111/hex.12409
13. Elwyn G, O'Connor A, Stacey D, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ*. 2006;333(7565):417. doi:10.1136/bmj.38926.629329.AE
14. Holmes-Rovner M. International Patient Decision Aid Standards (IPDAS): beyond decision aids to usual design of patient education materials. *Health Expect*. 2007;10(2):103–107. doi:10.1111/j.1369-7625.2007.00445.x
15. Lühnen J, Albrecht M, Mühlhauser I, Steckelberg A. Leitlinie evidenzbasierte Gesundheitsinformation. Available from: <https://www.leitlinie-gesundheitsinformation.de/>. Accessed November 14, 2022.
16. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Allgemeine Methoden (Version 5.0). Available from: https://www.iqwig.de/papierkorb/general-methods_version-5-0_alt.pdf?rev=194835. Accessed November 14, 2022.
17. Fülöp S, Freise D, Pfaff H. Die Einbeziehung von Patienten in die Behandlung - Validierung der deutschen PICS Skalen. *J Public Health*. 2004;1(12):199–209.
18. Lerman CE, Brody DS, Caputo GC, Smith DG, Lazaro CG, Wolfson HG. Patients' Perceived Involvement in Care Scale: relationship to attitudes about illness and medical care. *J Gen Intern Med*. 1990;5(1):29–33. doi:10.1007/BF02602306
19. Scheibler F, Pfaff H, Kowalski C, Ansmann L. Shared Decision Making in Brustzentren in NRW: Ergebnisse einer 10-Jahres-Trendanalyse. *Z Evid Fortbild Qual Gesundhwes*. 2019;147-148:97–102. doi:10.1016/j.zefq.2019.09.003
20. Forcino RC, Barr PJ, O'Malley AJ, et al. Using CollaboRATE, a brief patient-reported measure of shared decision making: results from three clinical settings in the United States. *Health Expect*. 2018;21(1):82–89. doi:10.1111/hex.12588
21. Bennett C, Graham ID, Kristjansson E, Kearing SA, Clay KF, O'Connor AM. Validation of a preparation for decision making scale. *Patient Educ Couns*. 2010;78(1):130–133. doi:10.1016/j.pec.2009.05.012

22. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Routledge; 1977.
23. Ommen O, Wirtz M, Janssen C, et al. Psychometric evaluation of an instrument to assess patient-reported psychosocial care by physicians': a structural equation modeling approach. *Int J Qual Health Care*. 2009;21(3):190–197. doi:10.1093/intqhc/mzp010
24. Deinzer A, Veelken R, Kohnen R, Schmieder RE. Is a shared decision-making approach effective in improving hypertension management? *J Clin Hypertens*. 2009;11(5):266–270. doi:10.1111/j.1751-7176.2009.00112.x
25. Légaré F, Thompson-Leduc P. Twelve myths about shared decision making. *Patient Educ Couns*. 2014;96(3):281–286. doi:10.1016/j.pec.2014.06.014
26. Kasper J, Hoffmann F, Heesen C, Köpke S, Geiger F. MAPPIN'SDM - The Multifocal Approach to Sharing in Shared Decision Making. *PLoS One*. 2012;7(4):e34849. doi:10.1371/journal.pone.0034849
27. Kasper J, Liethmann K, Heesen C, Reissmann DR, Geiger F. Training doctors briefly and in situ to involve their patients in making medical decisions-Preliminary testing of a newly developed module. *Health Expect*. 2017;20(6):1254–1263. doi:10.1111/hex.12565

Patient Preference and Adherence

Dovepress

Publish your work in this journal

Patient Preference and Adherence is an international, peer-reviewed, open access journal that focusing on the growing importance of patient preference and adherence throughout the therapeutic continuum. Patient satisfaction, acceptability, quality of life, compliance, persistence and their role in developing new therapeutic modalities and compounds to optimize clinical outcomes for existing disease states are major areas of interest for the journal. This journal has been accepted for indexing on PubMed Central. The manuscript management system is completely online and includes a very quick and fair peer-review system, which is all easy to use. Visit <http://www.dovepress.com/testimonials.php> to read real quotes from published authors.

Submit your manuscript here: <https://www.dovepress.com/patient-preference-and-adherence-journal>

Supplementary Data

Appendix A

Questionnaire „Making SDM a reality” project

	Do not agree at all	Rather do not agree	Rather agree	Fully agree
PICS – Doctor facilitation scale (DFS)				
My doctor asked me whether I agree with his/her decisions.	☐	☐	☐	☐
My doctor gave me a complete explanation for my medical symptoms or treatment	☐	☐	☐	☐
My doctor asked me what I believe is causing my medical symptoms	☐	☐	☐	☐
My doctor encouraged me to talk about personal concerns related to my medical symptom	☐	☐	☐	☐
My doctor encouraged me to give my opinion about my medical treatment	☐	☐	☐	☐
PICS – Patient Information Scale (PIS)				
I asked my doctor to explain the treatment or procedure to me in greater detail	☐	☐	☐	☐
I asked my doctor for recommendations about my medical symptoms	☐	☐	☐	☐
I went into great detail about my medical symptoms	☐	☐	☐	☐
I asked my doctor a lot of questions about my medical symptoms	☐	☐	☐	☐
PICS – Patient Decision Making Scale (PDM)				
I expressed my needs and concerns that I had about the treatment.	☐	☐	☐	☐
I gave my opinion on the test or treatment I would prefer for my condition	☐	☐	☐	☐
I discussed certain tests or treatment again with my doctor	☐	☐	☐	☐

I gave my opinion on the treatments and tests that the doctor wanted to perform

☐☐☐☐

I have participated in important decisions regarding my diagnosis and treatment

☐☐☐☐

collaboRATE

Some questions about the support you received from your doctor during your consultation

Thinking about your consultation at the University hospital named above...

1. ... How much effort was made to help you understand your health issues?

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

No effort
made

Every effort
was made

2. ... How much effort was made to listen to the things that matter most to you about your health issues?

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

No effort
made

Every effort
was made

3. ... How much effort was made to include what matters most to you in choosing what to do next?

0	1	2	3	4	5	6	7	8	9
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

No effort
made

Every effort
was made

Preparation for Decision Making Scale (PrepDM)

Some questions about your preparation on the decision making

Please indicate how helpful you found the information you received in the run-up to the above-mentioned decision-making at the University Hospital (UKSH).

Did the information you received at the university hospital...

		Not at all	A little	some- what	Quite a bit	A great deal
1	make you recognize decision needs to be made	☐	☐	☐	☐	☐
2	prepare you to make a better decision	☐	☐	☐	☐	☐
3	make you think about pros and cons of each option	☐	☐	☐	☐	☐
4	help you think about which pros and cons are most important	☐	☐	☐	☐	☐
5	help you know that decision depends on what matters most to you	☐	☐	☐	☐	☐
6	organize your own thoughts about decision	☐	☐	☐	☐	☐
7	help you to think about how involved you want to be in decision	☐	☐	☐	☐	☐
8	help you identify questions you want to ask	☐	☐	☐	☐	☐
9	prepare you to talk to your doctor about what matters most	☐	☐	☐	☐	☐
10	prepare you for a follow up visit with your doctor	☐	☐	☐	☐	☐

Appendix B

Link to 3 demo versions of decision aids of the project

<https://demo.share-to-care.de/>

Benutzername: T01-demouser-1022

Passwort: qiG2JZpc



OPEN ACCESS

EDITED BY

Christoph Heesen,
University Medical Center
Hamburg-Eppendorf, Germany

REVIEWED BY

Alessandra Solari,
IRCCS Carlo Besta Neurological
Institute Foundation, Italy
Alba Corell,
University of Gothenburg, Sweden

*CORRESPONDENCE

Constanze Stolz-Klingenberg
Constanze.Stolz-Klingenberg@uksh.de

SPECIALTY SECTION

This article was submitted to
Neuroepidemiology,
a section of the journal
Frontiers in Neurology

RECEIVED 05 September 2022

ACCEPTED 01 November 2022

PUBLISHED 23 November 2022

CITATION

Stolz-Klingenberg C, Bünzen C,
Coors M, Flüh C, Margraf NG,
Wehkamp K, Clayman ML, Scheibler F,
Wehking F, Ruffer JU, Schüttig W,
Sundmacher L, Synowitz M, Berg D
and Geiger F (2022) Sustainability of
large-scale implementation of shared
decision making with the SHARE TO
CARE program.
Front. Neurol. 13:1037447.
doi: 10.3389/fneur.2022.1037447

COPYRIGHT

© 2022 Stolz-Klingenberg, Bünzen,
Coors, Flüh, Margraf, Wehkamp,
Clayman, Scheibler, Wehking, Ruffer,
Schüttig, Sundmacher, Synowitz, Berg
and Geiger. This is an open-access
article distributed under the terms of
the [Creative Commons Attribution
License \(CC BY\)](https://creativecommons.org/licenses/by/4.0/). The use, distribution
or reproduction in other forums is
permitted, provided the original
author(s) and the copyright owner(s)
are credited and that the original
publication in this journal is cited, in
accordance with accepted academic
practice. No use, distribution or
reproduction is permitted which does
not comply with these terms.

Sustainability of large-scale implementation of shared decision making with the SHARE TO CARE program

Constanze Stolz-Klingenberg^{1*}, Claudia Bünzen¹,
Marie Coors², Charlotte Flüh³, Nils G. Margraf⁴,
Kai Wehkamp^{5,6}, Marla L. Clayman^{7,8}, Fueleop Scheibler¹,
Felix Wehking⁹, Jens Ulrich Ruffer¹⁰, Wiebke Schüttig²,
Leonie Sundmacher², Michael Synowitz³, Daniela Berg⁴ and
Friedemann Geiger^{1,11}

¹National Competency Center for Shared Decision Making, University Hospital Schleswig-Holstein, Kiel, Germany, ²Chair of Health Economics, Technical University of Munich, Munich, Germany, ³Department of Neurosurgery, University Hospital Schleswig-Holstein, Kiel, Germany, ⁴Department of Neurology, University Hospital Schleswig-Holstein, Kiel, Germany, ⁵Department of Internal Medicine I, University Hospital Schleswig-Holstein, Kiel, Germany, ⁶Department of Medical Management, MSH Medical School Hamburg, Hamburg, Germany, ⁷Center for Healthcare Organization and Implementation Research (CHOIR), Veterans Administration, Bedford, MA, United States, ⁸Department of Population and Quantitative Health Sciences, University of Massachusetts Chan Medical School, Worcester, MA, United States, ⁹Department of Emergency Medicine, University Hospital Jena, Jena, Germany, ¹⁰TakePart Media + Science GmbH, Cologne, Germany, ¹¹Department of Psychology, MSH Medical School Hamburg, Hamburg, Germany

Introduction: SHARE TO CARE (S2C) is a comprehensive implementation program for shared decision making (SDM). It is run at the University Hospital Schleswig-Holstein (UKSH) in Kiel, Germany, and consists of four combined intervention modules addressing healthcare professionals and patients: (1) multimodal training of physicians (2) patient activation campaign including the ASK3 method, (3) online evidence-based patient decision aids (4) SDM support by nurses. This study examines the sustainability of the hospital wide SDM implementation by means of the Neuromedical Center comprising the Departments of Neurology and Neurosurgery.

Methods: Between 2018 and 2020, the S2C program was applied initially within the Neuromedical Center: We implemented the patient activation campaign, trained 89% of physicians ($N = 56$), developed 12 patient decision aids and educated two decision coaches. Physicians adjusted the patients' pathways to facilitate the use of decision aids. To maintain the initial implementation, the departments took care that new staff members received training and decision aids were updated. The patient activation campaign was continued. To determine the sustainability of the initial intervention, the SDM level after a maintenance phase of 6–18 months was compared to the baseline level before implementation. Therefore, in- and outpatients received a questionnaire via mail after discharge. The primary endpoint was the "Patient Decision Making" subscale of the Perceived Involvement in Care Scale (PICS_{PDM}). Secondary endpoints were an additional scale measuring SDM (CollaborATE), and the PrepDM scale, which determines patients' perceived health literacy while

preparing for decision making. Mean scale scores were compared using *t*-tests.

Results: Patients reported a significantly increased SDM level (PICS_{SDM} $p = 0.02$; Hedges' $g = 0.33$; CollaboRATE $p = 0.05$; Hedges' $g = 0.26$) and improved preparation for decision making (PrepDM $p = 0.001$; Hedges' $g = 0.34$) 6–18 months after initial implementation of S2C.

Discussion: The S2C program demonstrated its sustainability within the Neuromedical Center at UKSH Kiel in terms of increased SDM and health literacy. Maintaining the SDM implementation required a fraction of the initial intensity. The departments took on the responsibility for maintenance. Meanwhile, an additional health insurance-based reimbursement for S2C secures the continued application of the program.

Conclusion: SHARE TO CARE promises to be suitable for long-lasting implementation of SDM in hospitals.

KEYWORDS

shared decision making (SDM), sustainability, SDM implementation, decision aids, training of physicians, patient activation

Introduction

Patients' satisfaction, successful treatment of diseases and cost-effectiveness are three of the main goals in healthcare, which in some cases are difficult to reconcile. Shared decision making (SDM) as a process of information exchange and negotiation can contribute as an essential lever to achieve these ambitious goals simultaneously (1). To successfully reach a shared decision, a positive and productive collaboration between physician and patient is needed (2). Physicians act as medical experts with their expertise in causes of disease, symptoms, treatment options with possible advantages and disadvantages. Based on the best available evidence they provide the information base for a meaningful physician-patient-conversation (3). The patient acts as an expert on himself, his preferences and his personal circumstances. Patients enrich the information exchange with their thoughts, experiences of disease, risk behavior and expectations—information that is not evident from any medical record (1). The active participation of both leads to a shared decision that is medically justifiable and provides the best fit for the individual patient. Such an exchange on equal terms meets patients need for better information, understanding and involvement in their medical decision making (4–6). In a study with more than 1,500 cancer patients in Germany over 80% of the participants preferred to take a collaborative or active role in decision making underlying the need for increased SDM-practice (7).

In addition to the arguments from the patient's point of view, SDM also offers advantages for physicians as well as the healthcare system: SDM strengthens patients' self-responsibility

and knowledge of their disease, so that well-informed patients more rapidly recognize and communicate side-effects. This can be a protective factor against serious treatment complications, especially in complex decision-making situations with a multitude of treatment options, such as in the treatment of multiple sclerosis in neurology (8). Complementary, patients perceive themselves as more self-efficacious (6). In particular through the application of SDM, patients develop more realistic outcome expectations leading to increased patient satisfaction, greater treatment adherence, less decisional regret and less complaints (9–12).

In sum, there are many arguments in favor of SDM. This raises the question: How can SDM be successfully implemented in the hospital initially, and how can it be maintained so that SDM remains a matter of course in daily healthcare?

Only a limited number of SDM-interventions follow a comprehensive approach involving all relevant stakeholders, i.e., patients, physicians, nurses and other healthcare professionals (12). The SHARE TO CARE program (S2C) addresses each of these groups with a dedicated intervention module. Integrating four modules into a comprehensive implementation strategy, the S2C program aims to implement SDM within entire hospitals. The four S2C modules are:

(1) *Training of all physicians.* A minimum of 80% of physicians within each clinical department has to complete a multimodal training composed of an online-training session (13) and two individual feedback sessions based on videotaped patient consultations. Physicians first complete a 1-h online session presenting basic SDM knowledge and several simulations of physician-patient-interactions to demonstrate

Do's and Don'ts in SDM. Subsequently, physicians take part in an individual SDM coaching session in a peer group setting (2–5 participants) based on their own videotaped patient consultations. Interaction of increased self-reflection through video excerpts and feedback from colleagues and experienced SDM coaches shall create an encouraging and constructive learning atmosphere. Later, physicians record another consultation and participate in a second small group training to further increase and consolidate their SDM skills. After successful training completion, physicians receive a certificate and education credits by the Physicians Chamber of the Federal State of Schleswig-Holstein.

(2) *Activation of patients.* To increase patients' participation and involvement in medical decision making, every patient receives information how to actively take part in their physician-patient consultations using the ASK-3 approach (14). By distributing various promotion/information material (e.g., SDM video clips on screens, roll ups, posters, flyers, promotional items, SDM web page, paper postcards and screen-based messages and media) inside each department, patients are encouraged to ask specific questions during their consultation to gain deeper understanding of their treatment opportunities.

(3) *Implementation of evidence-based decision aids.* Fostering patients' understanding of their condition and treatment opportunities is also done through online evidence-based Patient Decision Aids (EbPDA). These are developed within each department based on a literature and guideline review, in cooperation with physicians and patients. The evidence research team conducts a systematic review of best available evidence for all treatment opportunities available at the hospital. They also perform needs assessment interviews with patients to align with needs and preferences of patients in the specific decision situations. Methods are based on the German Standard of evidence-based patient information and the methods of evidence generation in patient information (15, 16). Considering EbPDA as a user-oriented interface, text information is complemented with video clips featuring local physicians explaining interventions and local patients who share their experience facing the same decision as the DA user. The process of DA development follows the International Patient Decision Aids Standards (17–19). Each EbPDA undergoes external review. The process of EbPDA development for the S2C program is described in detail elsewhere (20).

As decision aids will never cover every relevant decision within a hospital, clinical experts are to choose topics that are of relevance from a clinical perspective, preference-sensitive as well as sufficiently frequent. These topics are expected to induce a spill-over effect to decisions where no EbPDA is available in terms of a systematic consideration of benefits and harms of each treatment as well as the patient's preferences.

(4) *Integration of nurses as SDM supporters.* At least 80% of the nurses are educated how to integrate SDM within their own work and how to support patients and physicians

regarding the application of the abovementioned modules. Beyond this, selected nurses (or physiotherapists, study nurses etc.) are trained as decision coaches to facilitate patients' decision processes with physicians. Training is designed in a similar way as physicians' coaching sessions: During 2 workshop days, healthcare professionals gain further knowledge about SDM, deep insight in the DAs of their specific department or section, and skills to support patients' decision making. Accompanied by the S2C trainer team, nurses complete decision coach training by recording coaching conversations with a patient twice and receiving individual feedback. Decision coaches function as emotional assistance to sensitize patients to unanswered questions and treatment preferences improving the physician-patient-consultation.

By completing all four modules, a department meets the criteria to be awarded with the S2C certificate. The fulfillment of the criteria is reviewed annually.

Initial findings from the hospital-wide implementation of SDM at the UKSH in Kiel indicate that the S2C program is feasible and effective (21).

Beyond the short-term effectiveness of SDM interventions, it is crucial that the effects are long-lasting, or can be maintained with reasonable effort. However, there is very limited research on the sustainability of SDM interventions. In a sample of patients with fibromyalgia, Bieber et al. (2) were able to show a diminished but still significantly enhanced SDM level 1 year after their SDM intervention. In a review by Martinez-Gonzalez et al. (22), only outcome parameters related to SDM—but not the SDM level itself—were reported, e.g., knowledge or perceived information level. No study was found with long-term effects (>3 months). Another study in outpatient asthma practices included data 1 year after implementation, but with poor comparability due to lack of a baseline survey (23).

In summary, there is no conclusive evidence on the sustainability of hospital wide implemented SDM interventions such as the S2C program. Although—given the substantial effort required for large-scale implementation of SDM—such evidence is particularly relevant as only a long-term effective intervention is cost-effective and reasonable for a hospital. To fill this research gap, the aim of this study was to examine the sustainability of the large-scale implementation of SDM with the S2C program at the UKSH in Kiel (24).

Methods

Design and setting

To assess the sustainability of the S2C program in terms of a long-lasting increase of the SDM level, we collected data at the Neuromedical Center (Department of Neurology and Department of Neurosurgery) at UKSH in Kiel. Patients were included in 2018 prior to the SDM implementation (baseline t_0),

in 2020 immediately after the implementation (t_1) and in 2021 at the end of the funding period of the implementation project, i.e., 6–18 months after implementation (t_2). In this study, data from t_2 and t_0 were compared.

The baseline survey was conducted at a time when neither medical staff nor patients had been informed about the upcoming SDM implementation. At t_1 and t_2 , medical staff was informed that the S2C program would be evaluated. However, they were not aware of evaluation measures, the sampling period and, hence, the patients to be included. They had no influence on inclusion of patients. During their consultations, patients were not aware that they might be invited to participate in a study about SDM later.

Participants

We included adult patients (age 18 and older) who recently had a consultation at the Neuromedical Center at the UKSH in Kiel (inpatients and outpatients). After their discharge, patients were contacted by mail to fill out a questionnaire (see Section 2.4 for details). The study was approved by the Ethics Committee of Faculty of Medicine of Kiel University (reference number A111/18).

Intervention

Initial implementation

Between 2018 and 2020, the S2C program had been applied successfully within the Neuromedical Center: The patient activation campaign had been rolled out, 89% of physicians ($N=56$) had completed SDM training, 12 patient decision aids had been developed, 2 decision coaches had been educated. Patients' pathways had been adjusted to facilitate the use of decision aids. Implementation took ca. 1.5 years in Neurology and 2 years in Neurosurgery where it was temporarily interrupted by the Covid19 pandemic. Both departments were awarded the S2C certificate indicating full SDM implementation, which is valid 12 months. At t_1 immediately after implementation, the SDM level had significantly increased, as reported elsewhere (21).

Maintenance of the implementation

After successful initial implementation, step by step the departments were asked to take on the responsibility for maintenance of the SDM implementation: New physicians should be consecutively trained, and all physicians should participate in further SDM education (twice a year). Other healthcare professionals should be regularly educated. The decision aids should be kept up to date and the patient activation campaign be continued.

Data collection and outcome measures

Outcome data was collected in a pre-post-design *via* mailed patient questionnaires before (t_0), immediately after (t_1) intervention and at follow-up 6–18 months after (t_2) intervention. Baseline measurements were conducted from July until September 2018 at the Department of Neurology and from August until October 2018 at the Department of Neurosurgery. Long-term post intervention data collection (t_2) took place from May until July 2021 for both departments, shortly before the end of the funding period to cover the longest possible follow up-period. This explains the different time periods between t_1 and t_2 at the Department of Neurology vs. the Department of Neurosurgery. Patients received two mailed reminders if they failed to answer within 4 weeks.

Both inpatients and outpatients were included without exclusion criteria regarding diagnosis or other parameters. Sampling was done as a retrospective and consecutive sample at a certain key date. The overall sample size within the hospital-wide SDM implementation was prescribed by the study protocol ($N > 1.600$ pre and post each) (24). The sample size within each of the 22 departments included within the hospital-wide implementation was determined by its proportion of cases compared to the overall hospital, with a minimum of $N > 30$ per measurement and department. This resulted in a minimum of $N > 60$ in this study in the Neuromedical Center with its two constituting departments.

The primary outcome was the “Patient Decision Making” (PICSPDM) subscale of the Perceived Involvement in Care Scale (PICS), a patient reported outcome instrument translated and validated in German (25, 26). It was measured on a scale from 1 = “do not agree at all” to 4 = “totally agree”. PICSPDM can be seen as a key indicator of SDM-based physician-patient interaction and has proven applicable in retrospective studies by mail (27). As secondary outcome, SDM level was assessed using the patient questionnaire collaboRATE (28) (COLL; 3 items; 5 point scale). The Preparation for Decision Making Scale (29) (PrepDM; 10 items; 5 point scale) was used as an indicator of decision-specific health literacy.

In addition, the process of maintaining the SDM implementation was monitored and documented.

Statistical analyses

For descriptive purposes, data are expressed as mean with standard deviation (SD) and/or 95% confidence interval (CI), unless stated otherwise. A questionnaire was declared evaluable if all questions of the respective subscale were answered. We used z -score normalization before pooling the two departments. t_0 -baseline and t_2 -post-intervention data were compared using independent two-sided t -test to examine whether there were significant differences in PICSPDM, PrepDM, and COLL. In

addition, we performed a multiple regression analysis testing the effect of age, education and gender on PICS_{SDM}, PrepDM, and COLL. Effect size was reported using Hedges' g . All analyses were performed using STATA 16.1 with a p -value < 0.05 considered to indicate statistical significance.

Results

Patients' characteristics

During the previously defined sampling period, 109 (63%) of all eligible patients at t_0 mailed back a survey. The sampling period at t_2 happened to contain more eligible patients. 142 of them (59%) sent back their questionnaire. Therefore, both response rates were in the predefined range as described in the study protocol (24).

Details of patients' characteristics are shown in Table 1.

Transfer to "maintenance mode"

The Neuromedical Center successfully switched into "maintenance mode" regarding the four S2C modules: Until submission of this manuscript, 17 additional physicians completed training and 14 more physicians have entered the training process. Each ward management conducted internal SDM education for nurses at least annually. As a complement to the continued patient activation campaign *via* ASK 3 (flyers, posters, cards), a short video encouraging patients to engage in decision making was made available on the screen at the patient's bedside. The decision aids were regularly reviewed by clinical experts which led to an update of the decision aid for Parkinson's disease.

Beyond the maintenance of the standard S2C modules, the Neuromedical Center proactively expanded its SDM activity: an additional SDM consultation service by specifically trained staff was introduced at the epilepsy outpatient ward. Complementary, the Center engaged in scientific and public relations activity featuring the patient-centeredness as proven by the certified SDM implementation.

Sustained effects

The newly obtained long-term data from this study revealed a significant increase of the SDM level 6–18 months after the intervention [z -score standardized PICS_{SDM}: $M_{t0} = -0.19$ (SD = 1.04); $M_{t2} = 0.14$ (SD = 0.95); $p = 0.02$]. The effect size Hedges' $g = 0.33$ indicates a small effect (30).

Patients reported an improved preparation for their treatment decision [PrepDM: $M_{t0} = -0.20$ (SD = 1.00); $M_{t2} = 0.14$ (SD = 0.96); $p = 0.001$; Hedges' $g = 0.34$]. In addition,

patients experienced a better collaboration with physicians [Coll: $M_{t0} = -0.15$ (SD = 0.98); $M_{t2} = 0.11$ (SD = 1.00); $p = 0.05$; Hedges' $g = 0.26$] (see Table 2).

To examine potential influence of age, gender or education on the primary endpoint PICS_{SDM}, we performed a multiple regression analysis. Results indicated that apart from the intervention itself ($p = 0.05$), younger patients reported significantly higher levels of SDM (see Table 3). Table 3 displays results of additional multiple regression analysis on the potential impact of age, gender and educational level on the secondary endpoints COLL and PrepDM.

Discussion and conclusion

It had already been shown that the S2C program is feasible and can have positive effects on the SDM level right after full implementation: Immediately after the end of implementation, patients felt significantly more involved and better informed and prepared for decision-making (21). At that time, the healthcare professionals were trained recently and the learning content was fresh in their minds, the decision aids had been newly developed with a great deal of commitment from physicians, and patient activation had just been set up. In short, SDM was on everyone's agenda.

This new study is the first exploring the sustainability of a full S2C implementation in a hospital. The question was, how does the SDM level evolve months after the end of the initial implementation? Do departments deliberately invest resources to maintain the implementation, and does the effect on patient-reported SDM level and health literacy persist?

The results of this study show: Even 6–18 months after the end of the initial implementation of the S2C intervention, i.e., 2.5–3 years after the first physician has been trained, the SDM level is still significantly increased. Patients continue to perceive themselves as significantly more involved than before the intervention as indicated coherently by two different SDM measures, PICS and CollaboRATE. In addition, patients reported a higher health literacy while preparing for a decision. As patients were recruited regardless of their diagnosis, from acute and aftercare, from inpatient and outpatient care, in neurology and neurosurgery, these results seem exceptionally representative.

The sustained intervention effects can be attributed to at least two factors. On the one hand, it may be assumed that the effects from the initial intervention in terms of skills and attitudes have persisted among the healthcare professionals, and that they adhered to the procedures and pathways that were adapted to allow for SDM. In line with Légaré et al. (12), the comprehensiveness and intensity of a multifaceted program like S2C in combination with the fact that nearly all departments at the hospital in Kiel were transformed into SDM clinics simultaneously is supposed to have had enough

TABLE 1 Sample description.

	t_0		t_2		Overall
	<i>n</i>	%	<i>n</i>	%	
Number of patients	109		142		251
Age					
Total responses	107		142		249
18–40 years	6	5.6%	17	12.0%	
41–60 years	40	37.4%	46	32.4%	
61–80 years	53	49.5%	69	48.6%	
Over 80 years	8	7.5%	10	7.0%	
Gender					
Total responses	99		126		225
Female	45	45.5%	74	58.7%	
Male	54	54.5%	52	41.3%	
Education					
Total responses	102		140		242
Lower than secondary school certificate	38	37.3%	42	30.0%	
Secondary school certificate	32	31.3%	52	37.2%	
Higher education entrance qualification	28	27.4%	44	31.4%	
Other school qualification	4	4.0%	2	1.4%	

TABLE 2 Endpoints before and after implementation (original and z-score standardized values).

	Original values				z-score standardized values				<i>p</i>	Hedges' <i>g</i>
	<i>t</i> ₀		<i>t</i> ₂		<i>t</i> ₀		<i>t</i> ₂			
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>		
PICS _{PDM}	2.65	0.92	2.92	0.85	−0.19	1.04	0.14	0.95	0.02	0.33
COLL	3.15	1.29	3.59	1.26	−0.15	0.98	0.11	1.00	0.05	0.26
PrepDM	3.63	1.12	3.92	1.16	−0.20	1.00	0.13	0.96	0.01	0.34

impact to stimulate a cultural change that is more robust than a rather superficial adoption of SDM-related communication skills. On the other hand, the maintenance activity from the Neuromedical Center is regarded as important to secure sustainability. Within every hospital, let alone a university hospital, the turnover within the healthcare personnel requires constant introduction of new colleagues. The decision by the departments to continuously invest resources into SDM training and education, updates of decision aids etc. is both an important factor and a sign of appreciation of SDM. The intrinsic motivation to maintain SDM is further illustrated by the activities within the departments that exceeded the basic criteria required to renew the S2C certificate, such as ongoing scientific activity and public communication in cooperation with the National Competency Center for Shared Decision Making as well as the development of additional support models for patients regarding decision making.

Apart from the efforts within the hospital, an additional factor was established on the system level. In collaboration with the largest health insurance company in Germany, the Techniker Krankenkasse (TK), we managed to put in place a reimbursement scheme triggering an additional fee for every patient case within a department that is awarded with the S2C certificate at University Hospital Schleswig-Holstein. The motivation of the TK was to increase patient safety through enhancement of SDM, as it is recommended by the WHO (31). The reimbursement partly covers the costs for the professional SDM trainers, the updates of the decision aids etc. It is important to know that currently the departments have no financial benefits from this reimbursement; on the contrary, they invest own resources in terms of working hours of their staff. This corroborates their intrinsic motivation to maintain SDM by continuation of the S2C program. The amount of time needed to maintain SDM on a level that is sufficient for regular

TABLE 3 Multiple linear regression analysis of the effect of time point of measurement, age, sex, and educational level on the primary endpoint “patient participation in decision making” (PICS_{SDM}) and on secondary endpoints CollaboRATE and PrepDM.

	Dependent variables		
	PICS _{SDM}	COLL	PrepDM
	Regression coefficient (SD)	Regression coefficient (SD)	Regression coefficient (SD)
Time point of measurement			
Baseline t_0 (reference group)			
Follow up t_2	0.29* (0.14)	0.26 (0.14)	0.39** (0.15)
Age (years)			
18–40 (reference group)			
41–60	−0.62* (0.25)	−0.61* (0.25)	−0.50 (0.26)
Over 60	−0.62** (0.24)	−0.43 (0.24)	−0.38 (0.25)
Sex			
Female (reference group)			
Male	−0.11 (0.14)	−0.14 (0.14)	−0.07 (0.15)
Highest educational level attained			
Lower than secondary school certificate (reference group)			
Secondary school certificate	0.09 (0.17)	−0.10 (0.16)	−0.10 (0.18)
Higher education entrance qualification	−0.05 (0.17)	−0.15 (0.18)	−0.22 (0.18)
Regression constant	0.44 (0.26)	0.42 (0.27)	0.26 (0.28)
R^2	0.08	0.06	0.07
R^2 adj.	0.05	0.04	0.04
$n(t_0)$	85	88	83
$n(t_1)$	112	115	110

* $p < 0.05$; ** $p < 0.01$.

recertification is, however, much smaller than during the initial implementation phase.

Some possible limitations of this study have to be discussed. Firstly, the question may arise whether the results sustainability within two departments are sufficiently representative for the entire hospital. On the one hand, the Neuromedical Center is a large-volume center within the hospital, with a broad variety of diseases, treatments and patient characteristics. On the other hand, the S2C program has been successfully implemented in 15 other departments at the University Hospital Schleswig-Holstein simultaneously also using the standardized S2C approach (publications in preparation). There were no cues indicating that the implementation process in the Neuromedical Center was considerably different compared to the other

departments. The reason the Neuromedical Center was chosen for examination of sustainability is that it was the first entire center that had started and fully completed the intervention. This allowed for the longest follow-up period during the overarching implementation project (24). Hence, it seems justified to interpret the results as proof of the sustainability of the S2C program in general. However, future results from other departments, and from other hospitals, should be gathered to underscore this conclusion.

Secondly, data might be biased by self-selection of responding patients. However, response rates of around 60% are to be viewed as comparably high indicating a rather low risk of selection bias. In addition, neither physicians nor the study group had any influence on the selection of patients enrolled in this study.

Thirdly, all outcome data on sustainability reflect the patients' point of view using PICS, PrepDM, and CollaboRATE as retrospective patient reported outcome instruments. It is indisputable, that the patient's experience is of major importance, especially when other patient-related variables like e.g., adherence are discussed. Nevertheless, the evaluation within other departments at the UKSH in Kiel also includes observer-based analyses of videotaped consultations using MAPPIN'SDM (32) and data on costs and quality of care as a result of the SDM implementation (24). With those future findings available, it will be possible to further corroborate the conclusions drawn from the current study.

Fourthly, data might also be biased by the occurrence of the Covid-19 pandemic. While the pre-intervention data (t_0) were collected during regular hospital operation, the long-term (t_2) data collection took place from May 2021 on, immediately after a multi-week lockdown for the majority of the German population. During this period, elective procedures and treatments were restricted or postponed, so that the patient sample must be expected to be different from the pre-intervention sample. However, a reduction of elective treatments at t_2 should result in a *lower* level of perceived SDM, not a higher one. Therefore, the positive effect in this study can hardly be explained by the influence of the pandemic. On the contrary, the pandemic in general made it even harder for all departments to adhere to the intervention program. Nevertheless, in view of the major influence of the pandemic on all levels of healthcare, post-pandemic replications of these findings are welcome.

Fifthly, in subsequent analyses of this study, we found a potential impact of age on both indicators of the SDM level indicating a smaller long-term effect among older patients. However, the size of some of the compared subgroups is very small. As such effects had not been found in previous data from the same population (21), the slightly differential effect among the subgroups should be interpreted cautiously until more long-term data are available.

In conclusion, this study is valuable as it provides long-term results from a hospital wide SDM implementation effort. It shows that the comprehensive, multifaceted S2C program

has significant long-term effects on patient reported SDM and health literacy by inducing sustained intervention effects and the willingness among health professionals to actively maintain the SDM implementation. Future results from the ongoing S2C program in Kiel and in other hospitals will further broaden the knowledge on the sustainability of the program.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The study was approved by the Ethics Committee of Faculty of Medicine of Kiel University (reference number A111/18).

Author contributions

FG, KW, FS, JR, LS, and MLC contributed to conception and design of the study. CS-K and CB organized the database. LS, MC, and WS performed the statistical analysis. CS-K wrote the first draft of the manuscript. FG, FS, CB, and CS-K wrote sections of the manuscript. All authors contributed to manuscript revision, read, and approved the submitted version.

References

- Coulter A. Paternalism or partnership? Patients have grown up-and there's no going back. *BMJ*. (1999) 319:719–20. doi: 10.1136/bmj.319.7212.719
- Bieber C, Müller KG, Blumenstiel K, Schneider A, Richter A, Wilke S, et al. Long-term effects of a shared decision-making intervention on physician-patient interaction and outcome in fibromyalgia. A qualitative and quantitative 1 year follow-up of a randomized controlled trial. *Patient Educ Counsel*. (2006) 63:357–66. doi: 10.1016/j.pec.2006.05.003
- Stiggelbout AM, van der Weijden T, de Wit MPT, Frosch D, Légaré F, Montori VM, et al. Shared decision making: really putting patients at the centre of healthcare. *BMJ*. (2012) 344:e256. doi: 10.1136/bmj.e256
- Timmins F, Kalischer M. Information needs of myocardial infarction patients. *Eur J Cardiovasc Nurs*. (2003) 2:57–65. doi: 10.1016/S1474-5151(02)00089-0
- Oterhals K, Hanestad BR, Eide GE, Hanssen TA. The relationship between in-hospital information and patient satisfaction after acute myocardial infarction. *Eur J Cardiovasc Nurs*. (2006) 5:303–10. doi: 10.1016/j.ejcnurse.2006.01.004
- Richter M, Schmid-Ott G, Leicht R, Muthny FA. Wahrgenommene Informationsvermittlung und partizipation von patienten in der kardiologischen rehabilitation: ausprägung und zusammenhänge mit reha-outcome und selbstwirksamkeit. *Physikalische Medizin Rehabilitationsmedizin Kurortmedizin*. (2011) 21:126–30. doi: 10.1055/s-0031-1277143
- Grabbe P, Gschwendtner KM, Gaiser A, Kludt E, Wild B, Eich W, et al. Preferred and perceived participation roles of oncological patients in medical decision-making: results of a survey among users of the German cancer information service. *Zeitschrift für Evidenz Fortbildung und Qualität im Gesundheitswesen*. (2022) 172:40–8. doi: 10.1016/j.zefq.2022.04.026
- Heesen C, Solari A, Giordano A, Kasper J, Köpke S. Decisions on multiple sclerosis immunotherapy: new treatment complexities urge patient engagement. *J Neurol Sci*. (2011) 306:192–7. doi: 10.1016/j.jns.2010.09.012
- Davison BJ, Goldenberg SL. Decisional regret and quality of life after participating in medical decision-making for early-stage prostate cancer. *BJU Int*. (2003) 91:14–7. doi: 10.1046/j.1464-410X.2003.04005.x
- Whittle J, Conigliaro J, Good CB, Kelley ME, Skanderson M. Understanding of the benefits of coronary revascularization procedures among patients who are offered such procedures. *Am Heart J*. (2007) 154:662–8. doi: 10.1016/j.ahj.2007.04.065
- Clayman ML, Bylund CL, Chewing B, Makoul G. The impact of patient participation in health decisions within medical encounters: a systematic review. *Med Dec Mak Int J Soc Med Dec Mak*. (2016) 36:427–52. doi: 10.1177/0272989X15613530
- Légaré F, Adekpedjou R, Stacey D, Turcotte S, Kryworuchko J, Graham ID, et al. Interventions for increasing the use of shared decision making by healthcare professionals. *Cochrane Database Syst Rev*. (2018) 7:19–22. doi: 10.1002/14651858.CD006732.pub4
- Geiger F, Hacke C, Potthoff J, Scheibler F, Rueffer JU, Kuch C, et al. The effect of a scalable online training module for shared decision making based on flawed video examples: a randomized controlled trial. *Patient Educ Counsel*. (2021) 104:1568–74. doi: 10.1016/j.pec.2020.11.033
- Shepherd HL, Barratt A, Jones A, Bateson D, Carey K, Trevena LJ, et al. Can consumers learn to ask three questions to improve shared decision making? A feasibility study of the ASK (AskShareKnow) patient-clinician communication model[®] intervention in a primary health-care setting. *Health Exp Int J Public Part Health Care Health Policy*. (2016) 19:1160–1168. doi: 10.1111/hex.12409

Funding

The SHARE TO CARE project was funded by the German Innovation Fund of the Federal Joint Committee (NVF170009) and the Medical Faculty of the Kiel University.

Conflict of interest

FG and FS are co-founders, JR is CEO and co-funder of SHARE TO CARE Patientenzentrierte Versorgung GmbH (Cologne/Germany). JR is CEO of TakePart Media + Science GmbH, Cologne, Germany.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

15. Lühnen J, Albrecht M, Mühlhauser I, Steckelberg A. *Leitlinienreport zur: Leitlinie evidenzbasierte Gesundheitsinformation*. Hamburg (2017). Available online at: <http://www.leitlinie-gesundheitsinformation.de> (accessed August 24, 2021).
16. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. *Allgemeine Methoden (Version 5.0)*. Köln: Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (2017). Available online at: https://www.iqwig.de/papierkorb/general-methods_version-5-0_alt.pdf?rev=194835zuletztgeprüftam (accessed August 24, 2021).
17. Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ*. (2006) 333:417. doi: 10.1136/bmj.38926.629329.AE
18. Holmes-Rovner M. International patient decision aid standards (IPDAS): beyond decision aids to usual design of patient education materials. *Health Exp Int J Public Part Health Care Health Policy*. (2007) 10:103–107. doi: 10.1111/j.1369-7625.2007.00445.x
19. Stacey D, Volk RJ. The international patient decision aid standards (IPDAS) collaboration: evidence update 2.0. *Med Dec Mak Int J Soc Med Dec Mak*. (2021) 41:729–33. doi: 10.1177/0272989X211035681
20. Danner M, Debruwe M, Rummer A, Wehkamp K, Rüffer JU, Geiger F, et al. A scattered landscape: assessment of the evidence base for 71 patient decision aids developed in a hospital setting. *BMC Med Inform Dec Mak*. (2022) 22:44. doi: 10.1186/s12911-022-01777-x
21. Geiger F, Novelli A, Berg D, Hacke C, Sundmacher L, Kopeleva O, et al. The hospital-wide implementation of shared decision-making: initial findings of the Kiel SHARE TO CARE program. *Deutsches Arzteblatt Int*. (2021) 118:225–6. doi: 10.3238/arztebl.m2021.0144
22. Martinez-Gonzalez NA, Plate A, Markun S, Senn O, Rosemann T, Neuner-Jehle S. Shared decision making for men facing prostate cancer treatment: a systematic review of randomized controlled trials. *Patient Prefer Adheren*. (2019) 13:1153–74. doi: 10.2147/PPA.S202034
23. Tapp H, Kuhn L, Alkhazraji T, Steuerwald M, Ludden T, Wilson S, et al. Adapting community based participatory research (CBPR) methods to the implementation of an asthma shared decision making intervention in ambulatory practices. *J Asthma Off J Assoc Care Asthma*. (2014) 51:380–90. doi: 10.3109/02770903.2013.876430
24. Danner M, Geiger F, Wehkamp K, Rueffer JU, Kuch C, Sundmacher L, et al. Making shared decision-making (SDM) a reality: protocol of a large-scale long-term SDM implementation programme at a Northern German University Hospital. *BMJ Open*. (2020) 10:e037575. doi: 10.1136/bmjopen-2020-037575
25. Scheibler F, Freise D, Pfaff H. Die einbeziehung von patienten in die behandlung: validierung der deutschen PICS skalen. *Patient Educ Counsel*. (2004) 12:199–209. doi: 10.1007/s10389-004-0034-5
26. Lerman CE, Brody DS, Caputo GC, Smith DG, Lazaro CG, Wolfson HG. Patients' perceived involvement in care scale: relationship to attitudes about illness and medical care. *J Gen Intern Med*. (1990) 5:29–33. doi: 10.1007/BF02602306
27. Scheibler F, Pfaff H, Kowalski C, Ansmann L. Shared decision making in brustzentren in NRW: ergebnisse einer 10-jahres-trendanalyse. *Zeitschrift für Evidenz Fortbildung und Qualität im Gesundheitswesen*. (2019) 147–8:97–102. doi: 10.1016/j.zefq.2019.09.003
28. Forcino RC, Barr PJ, O'Malley AJ, Arend R, Castaldo MG, Ozanne EM, et al. Using CollaboRATE, a brief patient-reported measure of shared decision making: results from three clinical settings in the United States. *Health Exp Int J Public Part Health Care Health Policy*. (2018) 21:82–89. doi: 10.1111/hex.12588
29. Bennett C, Graham ID, Kristjansson E, Kearing SA, Clay KF, O'Connor AM. Validation of a preparation for decision making scale. *Patient Educ Counsel*. (2010) 78:130–3. doi: 10.1016/j.pec.2009.05.012
30. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. New York, NY: Routledge (1977).
31. World Health Organization. *Global Patient Safety Action Plan 2021–2030: Towards Eliminating Avoidable Harm in Health Care*. Geneva: World Health Organization (2021). Available online at: <https://apps.who.int/iris/rest/bitstreams/1360307/retrieve> (accessed June 12, 2022).
32. Kasper J, Hoffmann F, Heesen C, Köpke S, Geiger F. MAPPIN'SDM: the multifocal approach to sharing in shared decision making. *PLoS ONE*. (2012) 7:e34849. doi: 10.1371/annotation/3e489f03-e7e7-4b41-827e-caa85bb06466

Erklärung des Eigenanteils an den erfolgten Publikationen

Constanze Stolz-Klingenberg hatte folgenden Anteil an den folgenden Publikationen:

Publikation 1: Constanze Stolz-Klingenberg, Claudia Bünzen, Marie Coors, Charlotte Flüh, Klarissa Hanja Stürner, Kai Wehkamp, Marla L. Clayman, Fülöp Scheibler, Jens Ulrich Rüffer, Wiebke Schüttig, Leonie Sundmacher, Daniela Berg, Friedemann Geiger, Comprehensive Implementation of Shared Decision Making in a Neuromedical Center Using the SHARE TO CARE Program, Patient Preference and Adherence, 2023

Beitrag zur Publikation im Einzelnen: Das Studienkonzept und -design wurde von Herrn Geiger, Frau Bünzen, Herrn Scheibler und Herrn Rüffer entworfen. Mein Eigenanteil an der Publikation erstreckt sich auf die Durchführung wesentlicher Teile der Intervention, die Erhebung der Daten sowie die Aufbereitung und Auswertung des Datensatzes (gemeinsam mit Frau Bünzen). Ich habe den ersten Manuskript-Entwurf inklusive Literaturrecherche, Ergebnisdarstellung, Ergebnisinterpretation, Diskussion, Tabellen und Anhängen erstellt. Gemeinsam mit Herrn Geiger, Herrn Scheibler und Frau Bünzen habe ich den Manuskript-Entwurf überarbeitet und finalisiert. Alle Autoren haben den finalen Manuskript-Entwurf geprüft und um Verbesserungsvorschläge ergänzt. Ich habe das Manuskript eingereicht und das Peer Review-Verfahren bis zur Veröffentlichung bearbeitet (unterstützt von Herrn Scheibler).

Publikation 2: Constanze Stolz-Klingenberg, Claudia Bünzen, Marie Coors, Charlotte Flüh, Nils G. Margraf, Kai Wehkamp, Marla L. Clayman, Fülöp Scheibler, Felix Wehking, Jens Ulrich Rüffer, Wiebke Schüttig, Leonie Sundmacher, Michael Synowitz, Daniela Berg, Friedemann Geiger, Sustainability of large-scale implementation of shared decision making with the SHARE TO CARE program, Frontiers in Neurology, 2022

Beitrag zur Publikation im Einzelnen: Das Studienkonzept und -design wurde von Herrn Geiger, Frau Bünzen, Herrn Scheibler und Herrn Rüffer entworfen. Mein Eigenanteil an der Publikation erstreckt sich auf die Durchführung wesentlicher Teile der Intervention, die Erhebung der Daten sowie die Aufbereitung und Auswertung des Datensatzes (gemeinsam mit Frau Bünzen). Ich habe den ersten Manuskript-Entwurf inklusive Literaturrecherche, Ergebnisdarstellung, Ergebnisinterpretation, Diskussion, Tabellen und Anhängen erstellt. Gemeinsam mit Herrn Geiger, Herrn Scheibler und

Frau Bünzen habe ich den Manuskript-Entwurf überarbeitet und finalisiert. Alle Autoren haben den finalen Manuskript-Entwurf geprüft und um Verbesserungsvorschläge ergänzt. Ich habe das Manuskript eingereicht und das Peer Review-Verfahren bis zur Veröffentlichung bearbeitet (unterstützt von Herrn Geiger).

Die vorliegende Einschätzung über die erbrachte Eigenleistung wurde mit den am Artikel beteiligten Ko-Autoren/Ko-Autorinnen einvernehmlich abgestimmt.

Datum, Unterschrift Doktorandin

Datum, Unterschrift Betreuer

Danksagung

An dieser Stelle möchte ich allen Menschen danken, die mich bei der Anfertigung meiner Doktorarbeit begleitet und unterstützt haben.

Mein besonderer Dank gilt meinem Doktorvater Herrn Prof. Dr. Geiger für die großartige Unterstützung von Anfang bis Ende der gesamten Arbeit – seine Motivation im Endspurt eines Publikationsprozesses ist ansteckend!

Des Weiteren möchte ich meinen Kolleg*innen des SDM-Teams Danke sagen – sie haben mich mit Rat und Tat sowie lieben Worten begleitet.

Ich danke Herrn Prof. Dr. Schrappe und der Klinik für Kinder- und Jugendmedizin I für die Möglichkeit, im Rahmen meiner Tätigkeit am UKSH meine wissenschaftlichen Fähigkeiten zu erweitern und die Doktorarbeit anzufertigen.

Zudem möchte ich mich bei der CAU Kiel bedanken für die finanzielle Unterstützung im Rahmen des Stipendiums des Promotionsprogramms Medizininformatik – das Stipendium hat mir bereichernden Austausch mit internationalen Wissenschaftler*innen bei Fachtagungen ermöglicht.

Meiner Familie, besonders meinen Eltern und Dackel Anton, sowie meinen Freunden danke ich für die anhaltende Zuversicht und Ermutigung.

Abschließend gilt ein besonderer Dank meinem Mann – er hat mich in allen Phasen dieser Doktorarbeit unterstützt, motiviert und gestärkt.

Eidesstattliche Versicherung

Ich versichere hiermit an Eides Statt, dass meine Dissertation, abgesehen von Ratschlägen meines Betreuers und meiner sonstigen akademischen Lehrer, nach Form und Inhalt meine eigene Arbeit ist, dass ich keine anderen als die in der Arbeit aufgeführten Quellen und Hilfsmittel benutzt habe, und dass meine Arbeit bisher keiner anderen akademischen Stelle als Dissertation vorgelegen hat, weder ganz noch in Teilen.

07.05.2024 C. Sz. Klingenberg

Datum, Unterschrift Doktorandin