Shared responsibility between general practitioners and highly specialized physicians in chronic spinal cord injury: Study protocol for a nationwide pragmatic nonrandomized interventional study

Rebecca Tomaszek a, c, 1, Dima Touhami a, b, c, *, Stefan Essig c, Armin Gemperli a, b, c

A R T I C L E   I N F O

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A B S T R A C T

Introduction: To improve the continuity of care for persons with spinal cord injury (SCI) living in peripheral areas, collaboration between general practitioners (GPs) and specialists is needed. This pragmatic nonrandomized interventional study assesses feasibility and effectiveness of a new primary care model based on this collaboration.

Methods: The intervention is medical education on SCI related topics offered by specialists to GPs practicing in rural areas. Outcomes are assessed and analyzed in physicians and patients. Group allocation of persons with SCI follows intention-to-treat principle with intervention group being those in close proximity to a participating GP.

Results: It is expected that ten GPs and sixteen specialists will take part in the study’s intervention. An average difference in “Doctor’s opinion on collaboration questionnaire” score (mean 44; SD ± 12) from baseline after two years post-intervention in the group of participating GPs is hypothesized at P-value < 0.05; meanwhile, the control group remains at an average score of 56. Of persons with SCI (n = 395), 230 are expected to take part in the study at baseline. An average modified “Spinal Cord Injury-Secondary Conditions Scale” change in score from baseline to 24 months post-intervention is expected to fall from 12.0 to 9.0 in the intervention group and to stay at 12.0 in the control group.

Conclusion: The study aims to improve patients’ outcomes and providers’ experience with delivery of care for persons with SCI, as compared to current best practice.

Trial registration: ClinicalTrials.gov, NCT04071938. Registered August 28, 2018, https://www.clinicaltrials.gov/ct2/show/NCT04071938.

1. Introduction

Medical advances, enhanced emergency medical services and availability of specialized spinal cord injury (SCI) centers have significantly improved the life of persons with SCI in Switzerland, as in most other developed countries [1]. Yet, those affected face a lifelong increased risk of secondary health problems, which may intensify their experience with disability and adversely influence different aspects of their lives [2]. Secondary conditions, such as spasticity, chronic pain, sexual dysfunction, bowel and bladder problems, often require a comprehensive array of care. Although, specialty care is considered the cornerstone to maintain health and functional abilities, the general practitioner (GP) is the main provider of health care services for persons with SCI in Switzerland and visited annually by 88% [3]. Due to the low incidence, GPs might lack the SCI-specific knowledge and the incentive to seek adequate resources to meet the complex needs of persons with SCI [4,5]. Especially, patients from rural areas and with insufficient transportation possibilities, rate access and quality of primary care, as well as SCI-related care unfavorably [6]. Persons that are required to travel long distances to utilize specialist services are willing to obtain closer...
SCI-related care from a smaller competence center [7]. Primary care services were rated of higher quality by persons residing in regions close to one of four specialized SCI centers in Switzerland, leading to the assumption that collaboration with medical specialists and transfer of knowledge might be greater in primary care and to the benefit of patients [7].

Various stakeholders and practitioners have demanded the coordination of specialized and primary care in chronic conditions. In 2016 the WHO concluded that “European health systems do not meet the needs of patients with multi-morbidity because they are ‘disease orient- ed’ and organized around single medical specialties which fragments care”, resulting in “contradictory medical advice, over-prescribing, over-hospitalization and poor patient satisfaction” [8]. In a related WHO policy brief, the collected evidence on care for persons with multi-morbidity were presented, with the conclusion that “primary care is often the most appropriate base for initiatives but must have the full cooperation of specialized care” [9]. It further denotes the “coordination of care between primary care and specialized care [to be] at the core when developing care for this patient group” [9]. However, there is no general agreement on how to achieve effective collaboration between GPs and specialists in chronic conditions. Theoretical and practical fundamentals of other care models show that building collaboration and mutual agreement of services between GPs and specialists, including clarified roles, tasks and guidelines, lead to efficient referrals and better support of complex or multi-morbid patients [10-14].

In view of that, a pragmatic non-randomized interventional study will assess the feasibility and effectiveness of a new primary care model that embeds specialized medicine for persons with chronic SCI living in peripheral areas in Switzerland. The study aims to improve patients’ outcomes and providers’ experience with delivery of patient centered care in persons with SCI as compared to current best practice.

2. Material and methods

The Swiss Spinal Cord Injury Cohort Study (SwiSCI) Interest Group “Policy, Services and Care Perspective” endorsed the study. The protocol was later approved by the SwiSCI steering committee, representing the four SCI centers in Switzerland (Clinique Romande de Réadaptation, Sion; Swiss Paraplegic Center, Nottwil; University Clinic Balgrist, Zürich; REHAB Basel, Basel), Swiss Paraplegic Association, Swiss Paraplegic Foundation, Swiss Paraplegic Research, Para Help and representatives of persons with SCI.

2.1. Objectives

The primary objective of this study is to determine if medical education enhances shared care between GPs and specialized physicians and positively affects the morbidity, service utilization, and care experience of persons living with chronic SCI in the community. Furthermore, the study assesses feasibility of the collaboration between GPs and specialized physicians. Secondary objectives comprise 1) the assessment of first contact of care for persons with SCI and determination of reasons for encounter (RFE) and health problems managed in Swiss primary care, 2) identification of role-distributions and preferred collaboration models. The tertiary objective is to give implications for defining patient pathways and the generalizability of the model for other conditions besides SCI.

2.2. Participants and blinding

The inclusion criteria of GPs in the intervention group include 1) GP’s practice of more than 60 min vehicle driving distance to nearest specialized SCI center, 2) working in a group practice, 3) the availability of comprehensive services such as ultrasound, physio- and occupational therapy at the practice, and 4) the physical accessibility of the practice by wheelchair users. GPs, who fit the inclusion criteria but do not participate, are allocated to the control group. For persons with SCI, the inclusion criteria comprise persons 1) who previously participated in SwiSCI community survey in 2017, 2) are 16 years of age or older, 3) permanently residing in Switzerland but 4) further than 60 min vehicle driving distance from nearest specialized SCI center. The intervention group consists of persons with chronic SCI living in the region of a participating GP, irrespective if they visit these practices. The control group comprises persons with SCI who fit the inclusion criteria but live outside the catchment areas of participating GPs. The exclusion criteria comprise persons in their initial rehabilitation phase, diagnosed with acute SCI, with congenital conditions leading to paraplegia or tetraple- gia, including spina bifida, neurodegenerative disorders such as multiple sclerosis and amyotrophic lateral sclerosis, and Guillain-Barré syndrome. Neither persons with SCI, nor physicians are blinded to their group assignment.

2.3. Intervention

GPs in the intervention group receive medical education regularly on SCI related topics by specialists. The selection of topics is based on prevalent secondary health conditions in Swiss persons with SCI [15]. These topics are presented to stakeholders, who give their opinions on elements of SCI care to be delivered in primary care settings, and GPs prioritize the topics according to their interest. After the first medical education event, a specialized-nursing service, ParaHelp, visits the GP practices to train staff on topics specific to the practice environment such as transfer and mobilization of persons with SCI. Furthermore, ParaHelp provides support for complex care and social work whenever necessary. Ongoing medical education allows for networking and continuous collaboration. Specialists are anticipated to visit the GP practices and perform joint consultations on SCI related care. The intervention gives physicians the opportunity to self-determine role-distributions for an accessible shared expertise to community-dwelling persons with SCI. Subsequently, persons with SCI in the intervention group are invited to receive SCI care from the GP in their area.

2.4. Physician outcome measures

The primary endpoint is the assessment of collaboration among physicians, based on the “ Doctors’ opinions on collaboration” (DOC) questionnaire. The DOC is a validated questionnaire and comprises 20 items to measure five dimensions: organization, communication, professional expertise, image, and knowing each other [16]. The English version was translated independently into German by two researchers (AG, RT) and a preliminary German version is agreed upon. It was translated back to English and differences from the original English DOC are discussed for relevance. Subsequently, a final German version is developed and tested in a third researcher (SE). The same process was done for the French and Italian versions of the questionnaire. The DOC gives implications on the collaboration between GPs and specialists and between intervention and control GPs. Answer distributions between the different groups of physicians are compared per item in each dimension. The DOC is documented in GPs and specialists at baseline and after two years post the intervention. Satisfaction with collaboration is assessed among physicians as a secondary endpoint. It is based on a Likert scale rating (1-5) and measured at the start and after two years post the intervention. Semi-structured interviews with physicians in the intervention group are conducted at baseline to explore 1) experiences with collaboration, 2) the current role-distribution, and 3) potential improvement possibilities to achieve shared care.
2.5. Patient outcome measures

The primary outcome measure for persons with SCI is the “modified Spinal Cord Injury Secondary Conditions Scale” (SCI-SCS) score as composite endpoint (N = 14 conditions). Study participants between and within intervention and control groups are evaluated for difference in change from baseline for the endpoint using a 4-point rating on severity and treatment during the last 3 months, after one year and two years post intervention. Secondary outcome measures comprise SCI-SCS sub-score on pressure sores and urinary tract infections, modified SCI-SCS composite score per-protocol analysis, the number of in-patient hospitalizations during the last 6 and 12 months, and the number of visits to a specialist or a SCI center during the last 6 months. It additionally includes satisfaction with health care provision in the living region and with primary care provider. Exploratory endpoints include SCI-SCS sub scores for other health conditions, length of inpatient stays during the last 6 or 12 months, quality of life and mental health according to SF-36 MH/Vitality scale [17]. Additional exploratory endpoints comprise first point of contact for health problems, having a personal GP and the number of visits to GP and specialists during the last 6 or 12 months.

2.6. Implementation and time schedule

The study starts in summer 2020 and ends in summer 2022, with a duration of 24 months and a total of four endpoints measurements (see Table 1). Table 2 summarizes the implementation and time schedule of the study.

2.7. Sample size/recruitment

Specialized physicians are recruited from the four specialized SCI centers in Switzerland: Rehab Basel, Clinic for neuro-rehabilitation and paraplegia, Basel; The Spinal Cord Injury Center at Balgrist University Hospital, Zürich; Clinique Romande de réadaptation, Sion and the Swiss Paraplegic Center, Nottwil. Four specialists per center are anticipated to join the study (n = 16). Eligible GPs (n = 120) are initially identified based on their practice location using an assessment of residency and health care utilization patterns in persons with SCI, as performed by Ronca et al. [6,18]. For an informed decision to participate, members of the research team visit interested GPs to provide details on the study objectives, design and responsibilities of GPs participating in the study. When agreeing to participate, these GPs (n = 10) are assigned to the intervention group. Eligible GPs who do not wish to participate in the intervention are contacted and allocated to the control group, if they agree to participate in the outcome measurement (n = 20). Additionally, we will document the reasons for not participating to identify barriers that can be addressed in the future. Persons with SCI (n = 395) who previously participated in SwiSCI community survey 2017 and met the eligibility criteria, are invited to take part in the study. Fig. 1a and b presents the recruitment process for physicians and persons with SCI respectively.

Table 1
Overview of outcome measures and intervention.

| Year | 2017 | 2020 | 2021 | 2022 |
|------|------|------|------|------|
| Time point | T₁ | T₂ “Before intervention” | T₁ “12 months post intervention” | T₂ “24 months post intervention” |

**Intervention component**

- Medical education once a year
- Parallel visits
- Collaboration with specialists (joint consultation, enhanced communication)
- Patients receive invitation letter to visit participating GP
- Modified SCI-SCS score: composite score and per health condition
- SCI-SCS sub-scores: pressure scores, urinary tract infection
- SCI-SCS sub-scores: other conditions
- In-patient hospitalization during the last 6 and 12 months
- Length of inpatient stays during last 6 and 12 months
- Satisfaction with health care provision
- SF-36 MH/Vitality scale
- First contact of care for health problems
- Number of visits to GP and specialists during the last 6 and 12 months
- Medical education twice a year
- Parallel visits
- Collaboration with specialists (joint consultation, enhanced communication)
- Modified SCI-SCS score: composite score and per health condition
- SCI-SCS sub-scores: pressure scores, urinary tract infection
- SCI-SCS sub-scores: other conditions
- In-patient hospitalization during the last 6 and 12 months
- Length of inpatient stays during last 6 and 12 months
- Satisfaction with health care provision
- SF-36 MH/Vitality scale
- First contact of care for health problems
- Number of visits to GP and specialists during the last 6 and 12 months
- Medical education once a year
- Parallel visits
- Collaboration with specialists (joint consultation, enhanced communication)
- Modified SCI-SCS score: composite score and per health condition
- SCI-SCS sub-scores: pressure scores, urinary tract infection
- SCI-SCS sub-scores: other conditions
- In-patient hospitalization during the last 6 and 12 months
- Length of inpatient stays during last 6 and 12 months
- Satisfaction with health care provision
- SF-36 MH/Vitality scale
- First contact of care for health problems
- Number of visits to GP and specialists during the last 6 and 12 months

**Patient outcome measures**

- Modified SCI-SCS score: composite score and per health condition
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- Satisfaction with health care provision
- SF-36 MH/Vitality scale
- First contact of care for health problems
- Number of visits to GP and specialists during the last 6 and 12 months

**Physician outcome measures**

- DOC questionnaire
- Physicians’ satisfaction with collaboration (Likert scale)
- Interviews with intervention group
- DOC questionnaire
- Physicians’ satisfaction with collaboration (Likert scale)
- Interviews with intervention group

SCI: Spinal cord injury; GP: general practitioner.

a SCI-SCS: Spinal Cord Injury Secondary Conditions Scale.
b SF-36 MH/Vitality scale: Short Form Mental Health Index.
c Outcome measures for both GPs and specialists.
d DOC: Doctors’ opinions on collaboration.
e Experiences with collaboration, role-distribution and improvement possibilities.

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Table 2
Group allocation, implementation, and time schedule of the study.

| Study participants | Group allocation | Pre-existing in cohort registrya | Assessment of endpoints |
|--------------------|------------------|---------------------------------|-------------------------|
| SCI specialists     | Participating    | Intervention                     | T0                      |
|                    | Non-participating| Control                          | T0                      |
| GPs                | Participating and perimeter-defining | Intervention | T0                      |
| Persons with SCI   | Inside perimeter and attending | Intervention | T1                      |
|                    | Inside perimeter and not attending |                           | T0                      |
|                    | Outside perimeter | Control                         | T1                      |

SCI: Spinal cord injury; GP: general practitioner.
a Swiss Spinal Cord Injury Cohort (SwISCI) Study, community survey 2017.

Eligibility criteria:
- GP practice is 60 minutes vehicle driving distance to the nearest SCI center
- Working in a group practice
- Availability of comprehensive services
- GP practice is physically accessible by wheelchair users
- Regular contact with GPs in daily practice

Fig. 1a. Selection and recruitment of study participants: physicians.

2.8. Data collection

Outcomes measures (primary, secondary and exploratory) among physicians in the intervention and control groups are collected via anonymized, self-administered online or paper-based questionnaires in German. Data is entered into the online survey tool “SoSci Survey,” and can be easily downloaded for analysis. Explorative interviews are recorded and transcribed verbatim. They are analyzed with thematic analysis using a hybrid approach of inductive and deductive coding according to Fereday [19] with the software MAXQDA.

Assessment of measures in persons with SCI relies on pseudo-anonymized data derived from online or paper-based questionnaires sent to both intervention and control groups in the three national languages of Switzerland (German, French and Italian). Postal mailings included an instructive invitation letter in addition to a paper version of the questionnaire with a coversheet containing an individual study ID, personal password for online completion, stamped return envelope and contact details of the study leader. Reminder management for the potential participants who did not respond included two reminders every 6–8 weeks (1 written reminder followed by a telephone reminder). No further contacts were made to persons who explicitly refused participation.

2.8.1. Patient data management and monitoring

Data management of the study aligns with guidelines of SwISCI (www.swisci.ch) database, a concept that defines the infrastructure and processes related to data management to enhance data quality and security within SwISCI and nested studies. As a nested study, a separate database is developed, and established Standard Operating Procedures (SOPs) are binding to all research team members, to ensure the consistency of data entry. In order to ensure the feasibility of the planned data collection procedures, critical elements of the data collection are piloted beforehand. One research assistant monitors the enrolment of participants and follow-up continuously for prompt identification of difficulties. Updated information on progress and interim analyses are made accessible to collaborators. Data storage, validation, monitoring, update, and backup are performed centrally at the SwISCI study center, and in accordance to SOPs. Personal data are only used for contacting people, e.g. to invite them for a survey or to send them the invitation letter to the GP’s practice, and thus cannot be applied for nor are they handed out for analytical purposes. An independent data manager, who is not part of the research team, manages personal data. Data is entered directly into the web-based entry forms by the study participants, or by research assistants for paper-based questionnaires. The setup, maintenance, and surveillance of the hardware infrastructure are under the responsibility of the IT Services of the Swiss Paraplegic Group. The communication between client and server is encrypted using https protocol.

2.8.2. Statistical methods

All endpoints are statistically analyzed for group comparison using analysis of covariance with follow-up measurement as outcome and as-
sessments at baseline as independent variable [20]. The main analysis is conducted for the 24 months follow-up (T2) for providers and patient outcomes, with the analysis on the 12 months follow-up (T1) as intermediate endpoint for patient outcomes. Adjustments for patient outcomes are conducted for lesion level and completeness, driving distance to GP practice and nearest SCI center, number of GPs in practice, language region and age. Multiple imputation is used to overcome item nonresponse.

The analyses of the primary endpoints are based on intention-to-treat. All other endpoints are evaluated based on intention-to-treat and per-protocol analysis. For the intention-to-treat analyses, the intervention group comprises persons inside the perimeter, and the control group includes those outside of that perimeter. For the per-protocol analysis, the outcomes are compared between participants attending a GP practice that collaborates in the program and those persons within the catchment area yet not attending the GP practice.

Using Rasch analysis, the DOC is converted to an interval scaled score. Then, a re-scaling of Rasch scores to a 0–100 range is performed. Based on a Dutch study, an average score of 56 with standard deviation (SD) of 12 is expected. An average difference in score of minus 12 (44) after 24 months in the group of participating physicians is hypothesized; meanwhile, the control group remains at an average score of 56. Given the sample size (N = 44), this difference will be statistically significant with power 90% (at 5% significance level).

For persons with SCI, 230 participants are expected to take part in the study, considering a response rate of 58%, compared to 61% in the SwiSCI community survey. The total score in modified SCI-SCS ranges from zero to 42. An average score at baseline of 12.0 (SD, ± 6.4) is hypothesized according to related literature in the same population in Switzerland [21]. The primary endpoint, change in score from baseline to 24 months follow-up, is expected to fall from 12.0 to 9.0 in the intervention group and to stay at 12.0 in the control group. This difference appears statistically significant with probability of 99% (significance level 5%) for the projected sample size in the two groups. All power calculations were based on a comparison of means by t-tests, not accounting for covariate adjustments.

2.8.3. Patient consent

Study information and informed consent forms for eligible study participants are prepared in German, French and Italian (Appendix 1). Along with the questionnaires, study information forms are sent by post to the study participants, to explain the nature and purpose of the study, the procedures involved, the expected duration and the potential risks and benefits this study may entail, and for making an informed decision for participation in the study. Participants are informed of their voluntarily participation and their right to unconditionally withdraw from the study. They were further reassured that withdrawal of consent has no subsequent effect on their medical assistance and treatment. Securing the formal consent of participants is required before initiating the study intervention.

2.8.4. Confidentiality

Access to the study database is restricted to the database manager solely. Only the database manager can assign permissions of data retrieval. In particular, personal data of participants is stored separately from the study data. Both parts of data contain a unique identifier (ID) allowing linking the datasets when needed. For all data analyses, research assistants can only access the pseudonymized data set. If additional information is needed for the analysis, the study leader requests the data from SwiSCI study center. The data manager then trans-
forms sensitive data in a way that can no longer lead to individual identification.

2.8.5. Research ethics approval

Some patient information is used from SwiSCI community survey 2017. The SwiSCI study was approved by the local Ethics Committees appointed to the SCI centers and patient organizations (No. 11042, 206/11 and CCVEM 042/11 for the Ethics Committees of the Cantons Lucerne, Basel, and Valais, respectively). All participants signed a written consent form. For this nested study, the ethical approval was sought and awarded by the Ethics Committee of Northwest and Central Switzerland (EKNZ; # 2019-01527-2). The approval confirms that the study fulfills the general ethical and scientific standards for research with humans. The application for the ethics committee approval included measures for quality control and assurance, data protection, confidentiality and coding. The study was registered in clinicaltrials.gov (# NCT04071938, registered on August 26, 2019).

2.8.6. Dissemination plans

The study and its newly established primary care model are presented at conferences as posters or oral communications (e.g. International Spinal Cord Society annual conference; European Forum for Primary Care; Swiss Public Health Conference). Original papers are published in peer-reviewed journals, e.g. in Journal of Primary Care & Community Health, Family Practice, Disability and Health Journal, or BMC Health Services Research. Diffusion of findings is equally considered to stakeholders in primary care, health services and systems research, and specialists in spinal cord injury.

3. Discussion

The developed model of care builds on a pre-existing infrastructure in SCI care and expands it to primary care. The model may be exemplary for chronic conditions other than SCI where a related infrastructure is not in place and should be promoted. For a successful generalization of the care model’s collaboration, role-distributions, task allocations, and communication will be consolidated in order to apply to other complex care situations.

Hypothetically, the collaboration enhanced through medical education reduces morbidity and improves patients and providers’ experience with delivery of care in persons with SCI as compared to current best practice. It leads to interactive communication, knowledge exchange and shared care between GPs and specialists. The project pursues a social experiment using an intervention design in the wider context of health services research. It provides a proof of concept that system-wide, innovative health service research with inclusion of all relevant stakeholders is possible. Positive results of the study would change the standard of care away from a disease-centered and towards a patient-centered approach. In the end, an enhanced collaboration could eliminate potential competition between primary care and specialized physicians and improve patients’ continuum of care. If the study finds the intervention group to be superior to usual care, implications for patient pathways in long-term SCI care are made. Ultimately, the defined pathways are captured in a policy brief, and brought to a stakeholder dialogue for an agreement on its implementation. The stakeholder dialogue will be embedded into the methodological and logistical framework provided by the Swiss Learning Health System hosted by the University of Lucerne [22].

Author statement

Stefan Essig & Armin Gemperli: Conceptualization, Methodology, Investigation, Project Administration, Supervision, Writing - Review and Editing.

Rebecca Tomaszek & Dima Touhami: Investigation, Formal Analysis, Data Curation, Writing, Visualization, Writing – Original Draft, Writing – Review and Editing.

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Data statement

Owing to the commitment and privacy of our study participants, information generated from the study are not publicly available. However, under reasonable request and a methodologically sound proposal, data may be available if there is no conflict with institutional interests.

Ethics approval and consent to participate

For this nested study, the ethical approval was sought and awarded by the Ethics Committee of Northwest and Central Switzerland (EKNZ; # 2019-01527-2). All study participants have signed a written consent to participate.

Declaration of interests

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: DT and AG were salaried by an organization financially compensated by the Swiss Paraplegic Foundation. The other authors declare that they have no known competing interests.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2021.100873.

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