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The Swiss chiropractic practice-based research network and musculoskeletal pain cohort: protocol of a nationwide resource to advance musculoskeletal health services research

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3 **1 The Swiss chiropractic practice-based research network and musculoskeletal pain cohort:**
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5 **2 protocol of a nationwide resource to advance musculoskeletal health services research**
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25 **Abstract**

26 **Introduction**

27 Musculoskeletal (MSK) pain conditions are a leading cause of disability. Evidence suggests that
28 many MSK pain conditions, such as low back pain and neck pain, share similarities with respect
29 to prognostic factors and clinical care recommendations. A nationwide Swiss chiropractic
30 practice-based research network (PBRN) and MSK pain patient cohort study has potential to
31 monitor the epidemiological trends of MSK pain conditions and contribute to health care quality
32 improvement. The four primary aims are to 1) develop a MSK focused PBRN within the Swiss
33 chiropractic setting and describe the characteristics of clinicians recruited; 2) describe
34 characteristics of patients with new healthcare seeking for MSK pain presenting to Swiss
35 chiropractors; 3) assess the clinical course of patients with new healthcare seeking for MSK pain;
36 4) examine the feasibility for a larger subsequent prospective cohort study using the newly
37 developed PBRN infrastructure.

39 **Methods and analysis**

40 This initiative is conceptualized with two distinct study phases. Phase 1 will focus on PBRN
41 development and description of the Swiss chiropractic PBRN and uses a cross-sectional design
42 to collect information from chiropractic clinicians nationwide. Phase 2 will recruit consecutive
43 patients aged 18 years or older with MSK pain from community-based chiropractic practices
44 participating in the PBRN into a prospective chiropractic cohort (Swiss ChiCo) study. All data
45 collection will occur through electronic surveys offered in the three Swiss national languages
46 (German, French, Italian) and English. Surveys will be provided to patient participants prior to
47 initial assessment, 1-hour after assessment and at 2-, 6-, and 12-weeks after assessment.

48

49 **Ethics and dissemination**

50 Ethics approval has been obtained from the independent research ethics committee of Canton
51 Zurich (BASEC-Nr: 2021-01479). Informed consent will be obtained electronically from all
52 participants. Findings will be reported to stakeholders after each study phase, presented at local
53 and international conferences, and disseminated through peer-reviewed publications.

54 55 **Trial registration**

56 Phase 1 – Swiss chiropractic PBRN (ClinicalTrials.gov identifier: NCT05046249); Phase 2 –
57 Swiss chiropractic cohort (Swiss ChiCo) study (ClinicalTrials.gov identifier: NCT05116020).

58 59 **Strengths and limitations of this study**

- 60 • Flexible practice-based research network model allows for a diverse range of nested study
61 design types as well as the future expansion of the network.
- 62 • Development of protocol methods guided by patient and public involvement activities with
63 the Swiss chiropractic patient association, the Swiss chiropractic association, Swiss
64 chiropractors, and researchers.
- 65 • A mixed musculoskeletal pain cohort study within a practice-based setting is innovative.
- 66 • The sole use electronic data capture methods may lead to selective participation of both
67 clinician and patient participants.
- 68 • Maintenance of the practice-based research network and subsequent expansion of the patient
69 cohort is dependent on ongoing stakeholder support.

70
71 **Keywords:** chiropractic, health care quality, musculoskeletal health, musculoskeletal pain,
72 manual medicine

73 INTRODUCTION

74 Musculoskeletal (MSK) pain conditions are the leading cause of disability worldwide, with low
75 back pain being the largest single cause in over 160 countries, including Switzerland.[1, 2] This
76 health burden translates to an economic cost of approximately 6.6 billion Euros or about 2% of
77 Switzerland's total GDP for low back pain alone.[3] Best practice recommendations and
78 systematic reviews on MSK pain largely focus primarily on regional pain locations, such as low
79 back pain or neck pain.[4-6] However, in the population and in primary care settings, it is
80 common that those experiencing a MSK pain complaint also present with co-existing pain in
81 another body region.[7, 8] There is increasing evidence suggesting that these pain conditions,
82 although localized to different regions, share similarities with respect to the course of symptoms,
83 prognostic factors, and clinical care recommendations.[9, 10] An entirely regional focus to MSK
84 health may create gaps in patient centered research and difficulties with knowledge
85 implementation in health care settings.

86 Further contributing to practice gaps, is the lack practice-based data collection in MSK
87 health care research.[11] To help bridge the divide between research and practice, countries such
88 as the UK, Denmark, Sweden, and Australia have engaged in practice-based research and
89 worked with MSK-focused practice-based research networks (PBRNs).[12-14] A PBRN is a
90 group of at least 15 primary-care settings united under a commitment to advance the science base
91 of clinical care.[15] These “real world” clinical research environments allow for sustained
92 collaborations between practitioners, patients, and academicians facilitating the co-creation of
93 relevant research questions and production of clinically applicable results.[11, 15, 16]

94 The chiropractic scope of practice in Switzerland includes the diagnosis and management
95 of MSK pain conditions through manual medicine, prescription medication, and diagnostic
96 imaging (radiography, ultrasound, CT, MRI). MSK complaints such as low back pain and neck

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3 97 pain, which result in the largest burdens of disability are commonly seen in chiropractic
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5 98 practice.[17] Chiropractic health care centres may serve as useful primary care settings to further
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7 99 investigate MSK pain conditions, to understand what role chiropractors play in the current
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10 100 management of these conditions, and to identify opportunities for Swiss MSK primary health
11
12 101 care quality improvement. As management of MSK conditions moves away from traditional
13
14 102 medical treatments and towards more physical and preventative approaches, there is a need to
15
16 103 describe non-pharmacological treatment options to make informed decisions on how best to use
17
18 104 this capacity in the current health care system.[4, 18]

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21 105 Our protocol describes the development of a nationwide Swiss chiropractic PBRN and
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23 106 subsequent nested prospective cohort (Swiss ChiCo) study for community-based patients
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25 107 presenting with MSK pain conditions. Development of the Swiss chiropractic PBRN and the
26
27 108 Swiss ChiCo study have been guided through participatory engagement of multiple stakeholder
28
29 109 groups including patients, clinicians, scientists, and policymakers. After consultation, it was
30
31 110 agreed to explore both clinical and feasibility related objectives to help drive recruitment and
32
33 111 facilitate buy-in from community-based chiropractors and patients. The main objectives are to:
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35 112 1) develop a MSK focused PBRN within the Swiss chiropractic setting and describe the
36
37 113 characteristics of clinicians enrolled in the PBRN; 2) describe characteristics of patients with
38
39 114 new healthcare seeking for MSK pain presenting to Swiss chiropractors; 3) assess the clinical
40
41 115 course of patients with new conservative healthcare seeking for MSK pain over 12 weeks; 4)
42
43 116 examine the feasibility for performing a larger subsequent prospective cohort study using the
44
45 117 established Swiss chiropractic PBRN. Once established, this PBRN may provide the framework
46
47 118 to help monitor the epidemiological trends of MSK pain in primary care settings, contribute to
48
49 119 MSK health care quality improvement, and support the development and growth of clinical
50
51 120 researchers.

121

122 METHODS AND ANALYSIS

123 Study design

124 The Swiss chiropractic PBRN uses a sub-study PBRN model, similar to that of the Australian
125 Chiropractic Research Network (ACORN).[12, 19, 20] In sub-study PBRN models, data is
126 initially collected from participating clinicians/clinical practices through self-report to first
127 establish and describe characteristics of the PBRN. Following development, nested sub-studies
128 may be performed using this PBRN framework.

129 Based on the sub-study model, this project has been conceptualized with two distinct
130 phases. Phase 1, the Swiss chiropractic PBRN, will focus on development and description of the
131 PBRN and uses a cross-sectional design to collect information from chiropractic clinicians
132 nationwide at study initiation (ClinicalTrials.gov identifier: NCT05046249). This will be
133 followed by Phase 2, the Swiss ChiCo study, which will recruit patients from community-based
134 chiropractic practices participating in the Swiss chiropractic PBRN infrastructure into a 12-week
135 observational prospective cohort study (ClinicalTrials.gov identifier: NCT05116020). **Figure 1**
136 provides an overview of the two nested phases of this project.

137

138 Patient and public involvement

139 Multistakeholder engagement activities were first performed collaboratively with all
140 stakeholders and focused on study relevance, team building, project infrastructure development
141 and the collaborative creation of relevant research questions. A shared understanding was
142 reached by all members which outlined the need for more clinical MSK research within the
143 Swiss setting and a pledge to provide in-kind support to achieve this project goal. Other

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3 144 recommendations from the advisory group included the practicality to start with a small cohort
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5 145 study to first test assumptions, data collection methods, and research infrastructure.
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8 146 Individualized one-on-one meetings were subsequently conducted to discuss specific
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10 147 study processes with each stakeholder group. Recommendations provided from the Swiss
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12 148 Chiropractic Association (ChiroSuisse) and the patient association (Pro Chiropractic
13
14 149 Switzerland) included the addition of several questions to the Swiss ChiCo study patient
15
16 150 participant questionnaires. Consequently, questions relating to patient work status, past use of
17
18 151 chiropractic care, and use of other healthcare in MSK pain management were added. Both
19
20 152 associations also recommended increasing patient participant recruitment weighting for the
21
22 153 Swiss ChiCo study in the French and Italian language regions of Switzerland by 5% from what
23
24 154 was initially proposed.
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28 155 One-on-one meetings with Swiss chiropractors were carried out for the purpose of
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30 156 understanding how best to integrate study processes into clinical practice settings. According to
31
32 157 all clinician advisors, the recruitment of approximately 5-10 consecutive patients per clinical
33
34 158 practice was feasible. Outside of clinical workflow processes, patient participant inclusion
35
36 159 criteria were revised from new healthcare seeking for a MSK pain condition (operationalized as
37
38 160 not having received any (patient-reported) health care for current MSK complaint) to new
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40 161 conservative healthcare seeking for a MSK complaint (not having received any (patient-reported)
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42 162 chiropractic, physiotherapy, osteopathy, or massage therapy for current MSK complaint in the
43
44 163 last 1 month, and not a follow-up visit). Many clinician advisors recommended this change based
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46 164 on the clinical profile of their patients and insurance coverage practices in Switzerland (where
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48 165 chiropractic care typically follows an initial visit with a primary care physician or general
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50 166 practitioner).
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3 167 Participatory engagement is an iterative process and requires continuous reflection of
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5 168 previous study processes and results to inform subsequent study phases (action-reflection
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7 169 process).[21] Following completion of each project phase, individual meetings with each
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10 170 stakeholder group will be scheduled to disseminate findings, discuss how best to generate future
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12 171 PBRN growth, and explore ways to expand the MSK clinical cohort study.
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17 173 **Phase 1 – Development of the Swiss chiropractic PBRN**

19 174 **Participants**

21 175 All registered active chiropractor members (fully licensed chiropractors and postgraduate
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23 176 assistant chiropractors) of the Swiss Chiropractic Association (ChiroSuisse) will be eligible and
24
25
26 177 invited to participate. Approximately 98% of all practicing Swiss chiropractors hold an active
27
28 178 membership with ChiroSuisse (personal communication, April 22, 2021).
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33 180 **Recruitment**

35 181 To aid with clinician recruitment, the PBRN development phase was scheduled for launch at the
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37 182 annual ChiroSuisse Continuing Education (CE) Convention 2021 (Lausanne, September 9-11,
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39 183 2021). Clinicians had the opportunity to ask questions directly of the study team, test electronic
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41
42 184 study methods, sign up as a clinician member of the PBRN, and provided input and feedback for
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44 185 the subsequent Swiss ChiCo study. Those interested, were invited to join the Swiss chiropractic
45
46 186 PBRN by scanning a quick response (QR) code and completing the linked clinician entry survey
47
48 187 using personal mobile devices. An invitation email containing a Research Electronic Data
49
50 188 Capture (REDCap) survey link will also be sent to eligible chiropractors not recruited at the CE
51
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53 189 Convention 2021. The invitation to join the Swiss chiropractic PBRN will be paired with an
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56 190 information sheet outlining study goals, good study conduct procedures for PBRN and
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191 subsequent sub study involvement, and risks and benefits for participation. We hope to achieve a
 192 participation proportion of 50% or greater.

193

194 **Data collection procedures and variables**

195 All data acquisition will occur electronically using the REDCap web application platform.[22]
 196 Clinicians participating in the Swiss chiropractic PBRN will be asked to fully complete 1
 197 electronic survey of approximately 10 minutes duration. Clinician surveys will only be provided
 198 in English as this is the official language used for communication by ChiroSuisse. **Table 1**
 199 outlines the specific data to be collected from clinicians for the development of the Swiss
 200 chiropractic PBRN. **Supplementary file 1** provides the data dictionary and specific response
 201 options to be used for the Swiss chiropractic PBRN phase.

202 **Table 1.** Outcome measures to be collected for description of the Swiss chiropractic PBRN

Construct	Measurement method / instrument	Inception
Demographics	Gender, age, year of graduation	X
Practice Characteristics	Number of years in practice, location of practice	X
	Primary language used in practice	X
	Number of healthcare practitioners involved in practice	X
	Type of healthcare offered	X
	Average number of patients seen per week	X
	Types of patients seen within practice	X
	Frequency of complaints seen within practice	X
Confidence	Practitioner self-confidence scale (PCS) [23]	X
Beliefs and Attitudes	Pain attitudes and beliefs scale – Musculoskeletal (PABS-MSK) [24]	X
	Level of motivation to be involved in the Swiss ChiCo	X
Digitalization of chiropractic practices	Electronic patient record system in practice	X
	Encrypted email use in practice	X
	Offering virtual care in practice	X
COVID-19 aspects	Change in quality of life, change in patient numbers, change in work hours, change in use of telehealth/e-health services.	X

203

204 **Main outcomes and analysis**

205 Both phase 1 and phase 2 of this study have been conceptualized with 2 primary clinical
206 outcomes and 2 primary feasibility outcomes.

207 The first primary clinical outcome is self-confidence in the clinical management of
208 patients with low back pain (as measured by the practitioner self-confidence scale (PCS)).[23]
209 The PCS contains four items with a total score of 20. A score of 4 represents higher self-
210 confidence in the management of patients with low back pain, while a score of 20 represents
211 lower self-confidence. The second primary clinical outcome is biomedical versus
212 biopsychosocial MSK pain treatment orientation (as measured by the pain attitudes and beliefs
213 scale, musculoskeletal version (PABS-MSK)).[24] The PABS-MSK contains two domains, with
214 a higher score on either the domains (each 10-items, with a score range of 10-60) representing
215 higher biomedical and biopsychosocial MSK pain treatment orientation. The order of 20 items of
216 the PABS-MSK was randomized using the “randomizeR” package in RStudio and administered
217 as a single questionnaire so as to mask respondents to the specific treatment orientation domains.
218 Both primary clinical outcomes will be reported as means and standard deviations (SDs), with
219 95% confidence intervals (CIs) calculated as appropriate. Primary feasibility outcomes of 1)
220 clinician participation proportion in the Swiss chiropractic PBRN will be assessed by reporting
221 the proportion of all eligible clinicians that enroll in the PBRN development phase using raw
222 numbers and percentages; and 2) motivation for clinician participation in the Swiss ChiCo study
223 will be assessed using a visual analog scale (VAS, 0-100), with higher scores reflecting higher
224 motivation for participation. Level of motivation to participate in the Swiss ChiCo study will be
225 reported as means, SDs, and with 95% CIs calculated as appropriate.

226

227 **Phase 2 – The Swiss chiropractic cohort (Swiss ChiCo) study**

228 **Participants**

229 Patient participants will be eligible to participate if they are 18 years of age or older; are seeking
230 new conservative healthcare for a MSK pain condition (new conservative healthcare seeking is
231 operationalised as not having received (patient-reported) chiropractic care, physiotherapy,
232 osteopathy or massage therapy for their current MSK complaint in the 1 month prior to their
233 current initial visit to the chiropractor and not a follow-up visit); consent to chiropractic
234 treatment; are able to respond to surveys in German, French, Italian, or English; have an active
235 email account; and are willing and able to complete electronic study questionnaires. Patient
236 participants will be excluded if they present to clinician practices with red flag symptoms (i.e.,
237 saddle anesthesia, loss of bowel and/or bladder control, history of major trauma, fracture, fever,
238 severe or rapidly progressive neurologic deficit, sudden unexplained weight loss), and/or with a
239 non-MSK based pain condition based on the chiropractor's clinical suspicion that symptoms
240 relate to a systemic disease.

241

242 **Recruitment**

243 Following the development of the Swiss chiropractic PBRN, a subset of clinicians will be
244 recruited to participate in the Swiss ChiCo study. Chiropractors will be recruited through general
245 interest and using a purposeful sampling approach based on Swiss chiropractic clinician
246 distribution across German, French, and Italian language regions of Switzerland (55% DE, 35%
247 FR, 10% IT). The Swiss ChiCo study aims to recruit at least 20 chiropractors. Participating
248 chiropractors will be asked to recruit new consecutive patient participants from their clinical
249 practices. The Swiss ChiCo study aims to recruit at least 100 patient participants to enable a

250 preliminary characterization of the population, enabled by representative selection of
251 chiropractic clinicians with respect to language region.

252 Potentially eligible patients visiting a participating clinician will be first provided a study
253 flyer, which will briefly outline the study objectives and participation requirements. Patients will
254 then be asked to rate their initial level of interest to participate using a brief electronic survey on
255 a dedicated study tablet device. Those not interested will be prompted to provide reasons for
256 non-participation. Patients expressing interest in participation will be forwarded to the full study
257 information form and electronic informed consent procedure. This in-clinic patient participant
258 procedure was developed in consultation with Swiss chiropractic clinicians (both women and
259 men) across all language regions. To aid with workflow, clinicians expressed interest in asking
260 new patients to arrive approximately 20 minutes prior to their appointment to complete
261 electronic study forms. Clinicians also recommended adding “disruption to clinic workflow” as
262 an option for eligible patient non-participation. This survey option would be selected by clinical
263 staff when patient participant recruitment would greatly impact clinical workflow (e.g., patient
264 was late for visit, emergency visit). **Figure 2** outlines the in-clinic patient recruitment procedure.

266 **Data collection procedures and variables**

267 Immediately following completion of the in-clinic recruitment procedure, study participants will
268 be forwarded to the first patient survey (pre-visit patient survey) on the study tablet. This pre-
269 visit initial patient survey will collect information on clinical measures that are likely to be
270 influenced by the first visit (i.e., pain impact, musculoskeletal health status, illness
271 perception).[25-27] The pre-visit patient survey will take approximately 5 minutes to complete
272 and is the only survey that is completed at clinical practices. Subsequent questionnaires will take

273 approximately 10-12 mins to complete and are emailed directly to patient participants 1 hour
 274 after (post-visit patient survey), and at 2-, 6-, and 12-weeks following completion of the pre-visit
 275 survey. Similar administration procedures were performed for the Danish chiropractic low back
 276 pain cohort study.[28] Patient participant surveys will be provided in English, German, French
 277 and Italian, with patients having the ability to choose their preferred language for completion.
 278 **Table 2** outlines specific outcome measures and timing of data collection for the Swiss ChiCo
 279 study. **Supplementary file 2** provides the data dictionary and specific response options to be
 280 used.

281 **Table 2.** Outcome measures and timing of data collection for the Swiss ChiCo study

Construct	Measurement method / instrument	Pre-visit	Post-visit	Wk 2	Wk 6	Wk 12
Demographics	Gender, age, nationality, level of education, smoking status		X			
	Work status, time lost from work due to pain complaint		X	X	X	X
Injury characteristics	Naïve to chiropractic care		X			
	Duration of complaint		X			
	Pain, enjoyment, general activity (PEG) scale [25]	X	X	X	X	X
	Other healthcare professional involved in care		X	X	X	X
Medication usage	Number of chiropractic visits since initial visit			X	X	X
	Medication use (prescription vs non-prescription)		X	X	X	X
Imaging use	Diagnostic imaging use for this specific MSK complaint			X	X	X
	Diagnostic imaging received in the past year for other complaint		X			
Psychosocial profile	Örebro Musculoskeletal Pain Screening Questionnaire – Short Form (ÖMPSQ short) [34]		X			
COVID-19 aspects	Quality of life now compared to before COVID-19		X			
	Activity compared to before COVID-19		X			
	Cancelled medical treatment due to COVID-19		X			
MSK health status	Musculoskeletal health questionnaire (MSK-HQ) [26]	X	X	X	X	X
Illness perception	Brief illness perception questionnaire (Brief IPQ, Question 9) [27]	X				
Change in condition	Patient Global Impression of Change (PGIC) scale [35]			X	X	X

282
 283 **Main outcomes and analysis**
 284 The prespecified primary clinical outcomes are: 1) change in musculoskeletal pain impact, as
 285 measured by the 3-item pain, enjoyment, and general activity scale (PEG scale, score range 0-10)

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3 286 [25] with higher scores representing worse outcomes; and 2) change in MSK health status, as
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5 287 measured by the musculoskeletal health questionnaire (MSK-HQ, score range 0-56) [26] with
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7 288 higher scores reflecting better health status. Clinical outcomes of the PEG scale and MSK-HQ
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9 289 prior to initial chiropractic assessment will be reported as means, SDs, and 95% CIs; and clinical
10
11 290 course of patient pain impact and MSK health status will be reported as a mean difference with
12
13 291 SDs and 95% CIs as appropriate. The primary feasibility outcomes are: 1) the proportion of
14
15 292 invited patients presenting to chiropractic practices who subsequently agree to participate in this
16
17 293 study; and 2) change in patient participant follow-up and retention over 12 weeks. Invited patient
18
19 294 participation will be reported as raw numbers and proportions. Patient participant retention will
20
21 295 be reported as the proportion of enrolled participants who complete follow-up surveys across 12-
22
23 296 weeks. Based on the definition of a PBRN from the Agency for Healthcare Research and Quality
24
25 297 (AHRQ),[15] it will be deemed feasible to initiate the Swiss chiropractic PBRN and expand the
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27 298 Swiss ChiCo study if at least 15 clinical practices agree to participate in the Swiss chiropractic
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29 299 PBRN and each recruit at least 5 patients for enrolment in the Swiss ChiCo study.
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301 **Ethics and dissemination**

302 The Swiss chiropractic PBRN and Swiss ChiCo study have been reviewed and jointly approved
303 by the independent research ethics committee of Canton Zurich (BASEC-Nr: 2021-01479).
304 Informed consent will be obtained from both clinician and patient participants electronically
305 upon entry into the Swiss chiropractic PBRN and the Swiss ChiCo study.

306 The findings from the Swiss chiropractic PBRN and the Swiss ChiCo study will be
307 disseminated first to the various stakeholder groups involved in study development through
308 individual meetings. Findings will also be presented through abstract and poster presentations at
309 academic conferences and in peer-reviewed journals.

310

311 Availability of data and materials

312 Data from this work will be made available for research purposes. Requests, including a synopsis
313 of the study plan, can be addressed to the corresponding author.

314

315 DISCUSSION

316 This study is designed to attract a large proportion of Swiss chiropractors into a nationwide
317 PBRN and subsequently recruit patients from participating clinics into a longitudinal cohort
318 study. This study approach combines a sub-study PBRN model, with longitudinal electronic
319 capture more readily seen in register-based approaches. The unique collaboration with clinicians,
320 advocacy groups and academicians, a growing trend in health care research, has led to the
321 promotion of research objectives which are clinically relevant and patient-centred, and a study
322 implementation strategy vetted by Swiss chiropractic primary care clinicians.

323 Traditional health care research approaches typically face challenges with regards to
324 study relevance, patient recruitment, and knowledge translation.[11, 29] The use of a
325 participatory research approach can help overcome such challenges by integrating the diverse
326 knowledge, values, and preferences of non-academics into the research process. An example of a
327 longitudinal register-based study successfully implementing this approach is the Swiss Multiple
328 Sclerosis Registry (SMSR).[30] This project was designed in collaboration with the Multiple
329 Sclerosis (MS) community in Switzerland to tackle the lack of epidemiological data and to
330 promote patient-perspectives in MS research. Participatory elements of the SMSR include a
331 flexible approach to study involvement based on participant comfort, involvement of patients in
332 the study design and execution, and data feedback to provide ongoing results to participants. Due
333 to such efforts, recruitment for the SMSR exceeded expectations; with the goal of 400

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3 334 participants achieved in under 20 days.[31] A second example of a participatory research
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5 335 approach driving recruitment are the recently established national osteopathy PBRNs of
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7 336 Australia (ORION) and New Zealand (ORC-NZ).[32] Here, the project team engaged with both
8
9 337 osteopathic communities for 12 months prior to clinician recruitment. Today, these two PBRNs
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11 338 represent the largest coverage of any voluntary health profession PBRN, with 43.5% of all
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13 339 registered osteopaths in Australasia. The Swiss chiropractic PBRN has followed a similar
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15 340 approach, with community outreach and promotion efforts lasting 12 months prior to clinician
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17 341 recruitment.

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21 342 What remains unclear is if early engagement of stakeholders can overcome the unique
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23 343 limitations of electronic observational studies. Typically, unequal access to technology resources
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25 344 and lack of digital literacy can lead to a young, well-educated, and high socio-economic status
26
27 345 study sample. For example, participants in the SMSR who opt for physical forms are older, show
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29 346 increased care-seeking behaviour, and suffer from more progressive illness compared to those
30
31 347 using electronic forms. This trend also extends to clinician participants, as our own 2019 survey
32
33 348 on eHealth technology use among Swiss chiropractors showed clinicians 65 years and over were
34
35 349 74% less likely to use electronic health records (EHRs) when compared to the those under 40
36
37 350 years.[33] To limit this threat to external validity, the Swiss chiropractic PBRN plans to recruit
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39 351 clinicians through both online and in-person channels. In addition, chiropractic clinician
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41 352 recruitment for the Swiss ChiCo will be proportionally overweighted in French and Italian
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43 353 language regions. These areas have shown lowered use eHealth technology use when compared
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45 354 to the German speaking regions of Switzerland. To recruit a diverse group of patient participants,
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47 355 clinicians will be asked to consecutively recruit eligible patients from private practice. Although
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49 356 consecutive recruitment does not eliminate the threat of self-selection bias, it ensures all eligible
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51 357 participants seeking chiropractic care are aware of the study and invited to participate in a
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3 358 nonselective manner. The Swiss chiropractic PBRN and Swiss ChiCo study presents a model for
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5 359 PBRN development and rapid engagement of a newly created clinical research network. Once
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7
8 360 complete, this PBRN will serve as a platform for answering important research questions in the
9
10 361 field of MSK primary health care.
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12 362

14 363 **Figure 1.** Nested design of the Swiss chiropractic PBRN and the Swiss ChiCo study

17 364

19 365 **Figure 2.** Summary of the Swiss ChiCo study in-clinic patient participant recruitment

22 366

24 367 **ACKNOWLEDGEMENTS**

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29
30 370 engagement and support.
31

33 371

35 372 **AUTHOR CONTRIBUTIONS**

38 373 CAH and RL conceived the idea for study. RL, CAH, AK, VvW, MAP, and LH contributed to
39
40 374 the design of the protocol. RL and CAH designed, undertook, and coordinated stakeholder
41
42 375 participatory activities. RL and CAH led the drafting of the protocol manuscript. All authors
43
44 376 gave important intellectual input and provided critical review of the protocol manuscript and
45
46 377 approved the final version of the manuscript. CAH obtained funding. RL and CAH are the
47
48 378 guarantors of this manuscript. The corresponding author attests that all listed authors meet
49
50 379 authorship criteria and that no others meeting the criteria have been omitted.
51

54 380

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8
9
10 385 considering the research questions, study design, protocol methods or analysis, or in writing of
11
12 386 the protocol manuscript, or the decision to submit the article for publication.
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16 388 **COMPETING INTERESTS**

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19 389 The authors declare that they have no competing interests.
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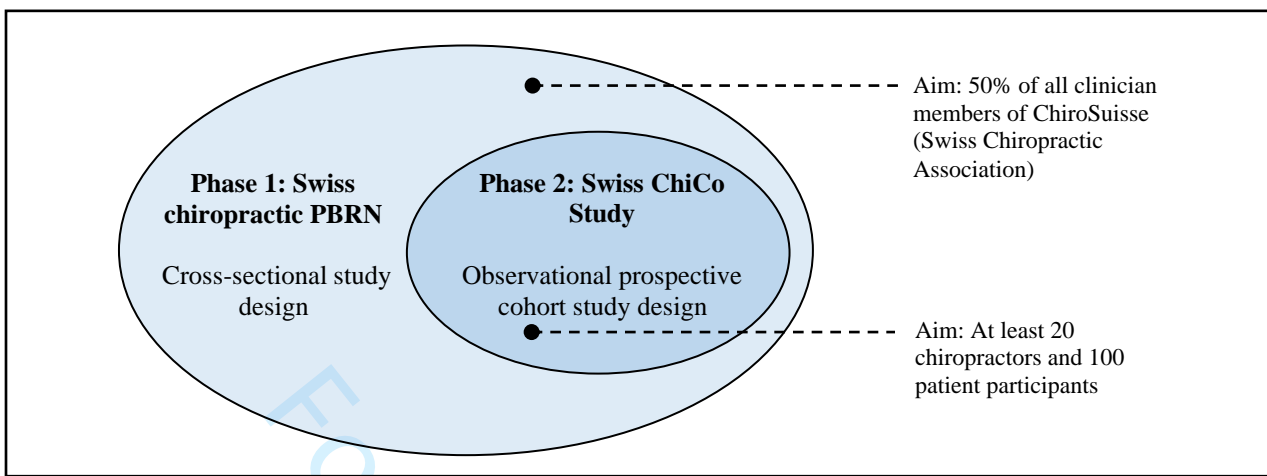
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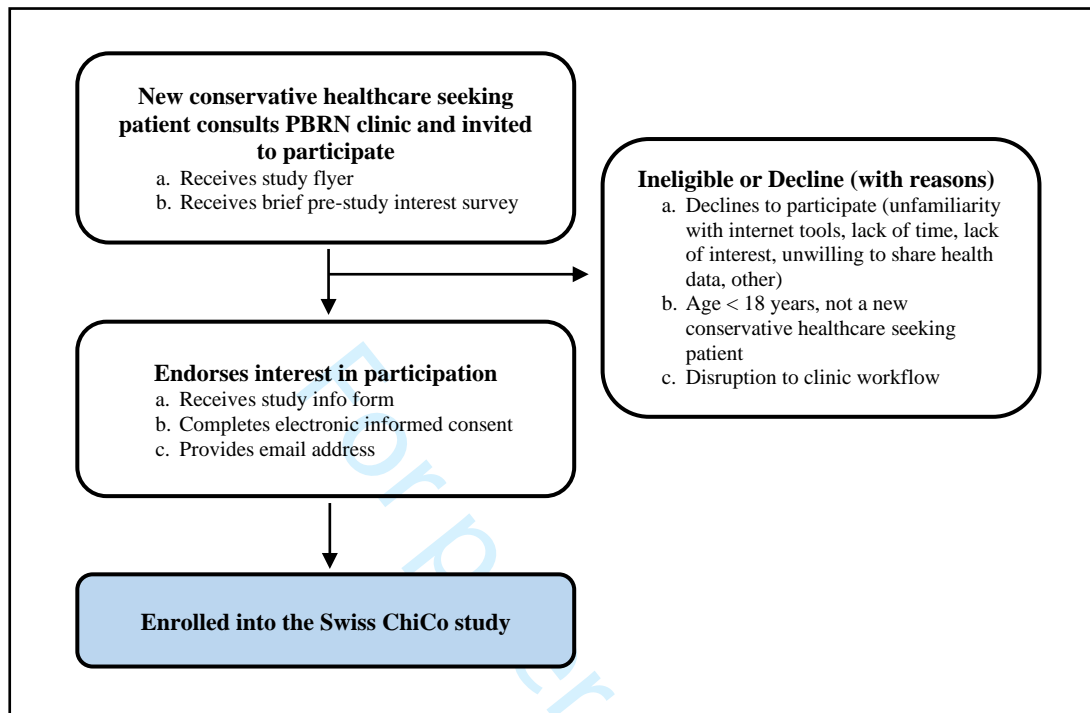
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Supplementary material 2. Patient-reported variables captured in the Swiss ChiCo patient cohort

Construct	Item Content	Variable Code	Choices, Calculations, OR Slider Labels	Branching Logic
Reasons for non-participation Collected at in-clinic recruitment	Record ID Are you interested in participating in this study? Reasons for not participating Other reason for not participating For clinic staff only	record_id chico_interest nonparticipation nonparticipation_other clinic_disrup	1, Yes 2, No 1, No email address 2, Unfamiliar with electronic or internet tools 3, Lack of time 4, Lack of interest in the study 5, Data privacy concerns 6, Other 1, Disruption to clinic workflow	[chico_interest] = '2' [nonparticipation(6)] = '1' [nonparticipation(6)] = '1'
Pain, enjoyment and general activity (PEG) scale Collected at baseline, 1 hour, 2-, 6-, and 12-wks	What number best describes your pain on average in the past week? What number best describes how, during the past week, pain has interfered with your enjoyment of life? What number best describes how, during the past week, pain has interfered with your general activity?	peg_q1_beforetex / peg_q1 / peg_q1_2wks / peg_q1_6wks / peg_q1_12wks peg_q2_beforetex / peg_q2 / peg_q2_2wks / peg_q2_6wks / peg_q2_12wks peg_q3_beforetex / peg_q3 / peg_q3_2wks / peg_q3_6wks / peg_q3_12wks	1, 0 = No pain 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Pain as bad as you can imagine 1, 0 = Does not interfere 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Completely interferes 1, 0 = Does not interfere 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Completely interferes	
Musculoskeletal health questionnaire (MSK-HQ) Collected at baseline, 1 hour, 2-, 6-, and 12-wks	1. Pain/stiffness during the day How severe was your usual joint or muscle pain and/or stiffness overall during the day in the last 2 weeks 2. Pain/stiffness during the night How severe was your usual joint or muscle pain and/or stiffness overall during the night in the last 2 weeks? 3. Walking How much have your symptoms interfered with your ability to walk in the last 2 weeks? 4. Washing/Dressing How much have your symptoms interfered with your ability to wash or dress yourself in the last 2 weeks? 5. Physical activity levels How much has it been a problem for you to do physical activities (e.g. going for a walk or jogging) to the level you want because of your joint or muscle symptoms in the last 2 weeks? 6. Work/daily routine How much have your joint or muscle symptoms interfered with your work or daily routine in the last 2 weeks (including work & jobs around the house)? 7. Social activities and hobbies How much have your joint or muscle symptoms interfered with your social activities and hobbies in the last 2 weeks? 8. Needing Help How often have you needed help from others (including family, friends or carers) because of your joint or muscle symptoms in the last 2 weeks? 9. Sleep How often have you had trouble with either falling asleep or staying asleep because of your joint or muscle symptoms in the last 2 weeks? 10. Fatigue or low energy How much fatigue or low energy have you felt in the last 2 weeks? 11. Emotional well-being How much have you felt anxious or low in your mood because of your joint or muscle symptoms in the last 2 weeks? 12. Understanding of your condition and any current treatment Thinking about your joint or muscle symptoms, how well do you feel you understand your condition and any current treatment (including your diagnosis and medication)? 13. Confidence in being able to manage your symptoms How confident have you felt in being able to manage your joint or muscle symptoms by yourself in the last 2 weeks (e.g. medication, changing lifestyle)? 14. Overall Impact How much have your joint or muscle symptoms bothered you overall in the last 2 weeks? Physical activity Levels In the past week, on how many days have you done a total of 30 minutes of moderate intensity physical activity?	mskhq_q1_beforetex / mskhq_q1 / mskhq_q1_2wks / mskhq_q1_6wks / mskhq_q1_12wks mskhq_q2_beforetex / mskhq_q2 / mskhq_q2_2wks / mskhq_q2_6wks / mskhq_q2_12wks mskhq_q3_beforetex / mskhq_q3 / mskhq_q3_2wks / mskhq_q3_6wks / mskhq_q3_12wks mskhq_q4_beforetex / mskhq_q4 / mskhq_q4_2wks / mskhq_q4_6wks / mskhq_q4_12wks mskhq_q5_beforetex / mskhq_q5 / mskhq_q5_2wks / mskhq_q5_6wks / mskhq_q5_12wks mskhq_q6_beforetex / mskhq_q6 / mskhq_q6_2wks / mskhq_q6_6wks / mskhq_q6_12wks mskhq_q7_beforetex / mskhq_q7 / mskhq_q7_2wks / mskhq_q7_6wks / mskhq_q7_12wks mskhq_q8_beforetex / mskhq_q8 / mskhq_q8_2wks / mskhq_q8_6wks / mskhq_q8_12wks mskhq_q9_beforetex / mskhq_q9 / mskhq_q9_2wks / mskhq_q9_6wks / mskhq_q9_12wks mskhq_q10_beforetex / mskhq_q10 / mskhq_q10_2wks / mskhq_q10_6wks / mskhq_q10_12wks mskhq_q11_beforetex / mskhq_q11 / mskhq_q11_2wks / mskhq_q11_6wks / mskhq_q11_12wks mskhq_q12_beforetex / mskhq_q12 / mskhq_q12_2wks / mskhq_q12_6wks / mskhq_q12_12wks mskhq_q13_beforetex / mskhq_q13 / mskhq_q13_2wks / mskhq_q13_6wks / mskhq_q13_12wks mskhq_q14_beforetex / mskhq_q14 / mskhq_q14_2wks / mskhq_q14_6wks / mskhq_q14_12wks mskhq_activity_beforetex / mskhq_activity / mskhq_activity_2wks / mskhq_activity_6wks / mskhq_activity_12wks	1, Not at all 2, Slightly 3, Moderately 4, Fairly severe 5, Very severe 1, Not at all 2, Slightly 3, Moderately 4, Fairly severe 5, Very severe 1, Not at all 2, Slightly 3, Moderately 4, Severely 5, Unable to walk 1, Not at all 2, Slightly 3, Moderately 4, Severely 5, Unable to wash or dress myself 1, Not at all 2, Slightly 3, Moderately 4, Very much 5, Unable to do physical activities 1, Not at all 2, Slightly 3, Moderately 4, Severely 5, Extremely 1, Not at all 2, Slightly 3, Moderately 4, Severely 5, Extremely 1, Not at all 2, Rarely 3, Sometimes 4, Frequently 5, All the time 1, Not at all 2, Rarely 3, Sometimes 4, Frequently 5, Every night 1, Not at all 2, Slight 3, Moderate 4, Severe 5, Extreme 1, Not at all 2, Slightly 3, Moderately 4, Severely 5, Extremely 1, Completely 2, Very well 3, Moderately 4, Slightly 5, Not at all 1, Extremely 2, Very 3, Moderately 4, Slightly 5, Not at all 1, Not at all 2, Slightly 3, Moderately 4, Very much 5, Extremely 1, 0 = None 2, 1 day 3, 2 days 4, 3 days 5, 4 days 6, 5 days 7, 6 days 8, 7 days	

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Construct	Item Content	Variable Code	Choices, Calculations, OR Slider Labels	Branching Logic
Brief illness perception (IPQ brief) Collected at baseline	Please list in rank-order the three most important factors that you believe caused your current pain complaint 1 2 3	briefillness ipq_q1 ipq_q2 ipq_q3		
Demographics Collected 1 hour after initial assessment	Sex Nationality Highest level of education At present, are you working How would you describe the total physical strain caused by your work? Have you missed any days of work due to your current pain complaint? How many days of sick leave have you had in the last 2 weeks ? Smoking Status How much do you smoke on average per day? Have you visited a chiropractor before?	sex_p nationality education Job workstrain sick_leave n_sickleave smoking n_cigarettes newpatient	1, Male 2, Female 1, Swiss 2, Non-Swiss 1, Compulsory 2, Secondary 3, Tertiary 1, Full time at your usual job 2, Full time at a lighter job 3, Part time 4, Not working - disability 5, Not working - IV/pensioner applicant 1, Homemaker/Househusband 7, Retired (not disability) 8, Unemployed 9, Student 1, Very light 2, Light 3, Somewhat strenuous 4, Strenuous 5, Very strenuous 1, Yes No 1, Current smoker 2, Previous smoker 3, Never smoker 1, I am new to chiropractic 2, I have visited a chiropractor before	[job] = '1' or [job] = '2' or [job] = '3' or [job] = '5' or [job] = '8' [sick_leave] = '1' [smoking] = '1'
Injury Characteristics Collected 1 hour after initial assessment	Have you visited a medical doctor for your current pain complaint? Were you referred to chiropractic care for your pain complaint from a healthcare professional? Which healthcare professional referred you to chiropractic care? Please specify which healthcare professional referred you to chiropractic care. How long has it been since your current pain complaint began? Main location of pain complaint Are you currently taking medication to reduce your pain?	md_currentpain referral_source herefer_specify hc_refer_other date_of_inj complaint medication	1, Yes No 1, Yes No 1, Other chiropractor 2, Family practitioner 3, Internist 4, Orthopaedic surgeon 5, Physical therapist 6, Massage therapist 7, Other 1, 1-2 days 2, 3-7 days 3, 1-2 weeks 4, 2-4 weeks 5, 1-3 months 6, 4-12 months 7, More than 12 months 1, Neck pain only 2, Neck pain with arm pain 3, Neck pain with headache 4, Mid back pain 5, Low back pain only 6, Low back pain with leg pain 1, Shoulder pain 8, Elbow pain 9, Wrist or hand pain 10, Hip pain 11, Knee pain 12, Ankle or foot pain 13, Jaw pain 14, Headache 1, Yes, prescription medication 2, Yes, non-prescription medication 3, No	[referral_source] = '1' [herefer_specify] = '7'
Imaging Use Collected 1 hour after initial assessment	In the last 1 month have you received any diagnostic imaging for your current pain complaint? X ray (radiography) in the last 1 month? Ultrasound scan in the last 1 month? MRI scan in the last 1 month? CT scan in the last 1 month? In the last 1 year have you received diagnostic imaging for any pain complaint? X-ray (radiography) in the last 1 year? Ultrasound scan in the last 1 year? MRI scan in the last 1 year? CT scan in the last 1 year?	image_postvisit xray_postvisit ultra_postvisit mri_postvisit ctscan_postvisit imaging1y_postvisit xray_1yr ultrasound_1yr mri_1yr ctscan_1yr	1, Yes No 1, Yes No 3, Unsure 1, Yes No 3, Unsure 1, Yes No 3, Unsure 1, Yes No 3, Unsure 1, Yes No 1, Yes No 3, Unsure 1, Yes No 3, Unsure 1, Yes No 3, Unsure 1, Yes No 3, Unsure	[image_postvisit] = '1' [image_postvisit] = '1' [image_postvisit] = '1' [image_postvisit] = '1' [imaging1y_postvisit] = '1' [imaging1y_postvisit] = '1' [imaging1y_postvisit] = '1' [imaging1y_postvisit] = '1'
COVID-19 aspects Collected 1 hour after initial assessment	How is your quality of life at the moment compared to the time before the COVID-19 pandemic? How are your physical activity habits at the moment compared to the time before the COVID-19 pandemic? Have you been unable to seek planned or necessary medical treatment because of the COVID-19 pandemic? What treatment could you not participate in because of the COVID-19 pandemic? Would you be interested in receiving virtual or telehealth chiropractic sessions?	patient_cov_1 pat_cov_2 pat_cov_3 pat_cov_4 virtual	1, Better 2, Similar 3, Worsened 1, Better 2, Similar 3, Worsened 1, Yes No 1, Yes No 3, Unsure	[pat_cov_3] = '1'

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Construct	Item Content	Variable Code	Choices, Calculations, OR Slider Labels	Branching Logic
Orebro Musculoskeletal Pain Screening Questionnaire - Short Collected 1 hour after initial assessment	How long have you had your current pain complaint?	omps_q1	1, 0 = No pain 2, 1-3 weeks 3, 4-5 weeks 4, 6-7 weeks 5, 8-9 weeks 6, 10-11 weeks 7, 12-23 weeks 8, 24-35 weeks 9, 36-52 weeks 10, > 52 weeks	
	How would you rate the pain that you have had during the past week?	omps_q2	1, 0 = Pain as bad as it could be	
	How tense or anxious have you felt in the past week?	omps_q5	1, 0 = Absolutely calm and relaxed 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = As tense and anxious as I've ever felt	
	How much have you been bothered by feeling depressed in the past week?	omps_q6	1, 0 = Not at all 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Extremely	
	In your view, how large is the risk that your current pain may become persistent?	omps_q7	1, 0 = No risk 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Very large risk	
	In your estimation, what are the chances you will be working your normal duties in 3 months?	omps_q8	1, 0 = No chance 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Very large chance	
	An increase in pain is an indication that I should stop what I'm doing until the pain decreases.	omps_q9	1, 0 = Completely disagree 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Completely agree	
	I should not do my normal work with my present pain.	omps_q10	1, 0 = Completely disagree 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Completely agree	
	I can do light work for an hour	omps_q3	1, 0 = Can't do it because of the pain problem 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Can do it without pain being a problem	
	I can sleep at night.	omps_q4	1, 0 = Can't do it because of the pain problem 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Can do it without pain being a problem	
Follow-up Questionnaire: injury characteristics and imaging use Collected at 2-, 6-, and 12-wks	In the last 2 wks / 4 wks / 6 wks have you had any follow-up visits with the chiropractor for your pain complaint?	fu_chiro_2wks / fu_chiro_6wks / fu_chiro_12wks	1, Yes 2, No	[fu_chiro_2wks] / [fu_chiro_6wks] / [fu_chiro_12wks] = '1'
	How many times have you seen your chiropractor in the last 2 wks / 4 wks / 6 wks?	nfu_chiro_2wks / nfu_chiro_6wks / nfu_chiro_12wks	1, One 2, 2-4 times 3, More than 4 times	
	In the last 2 wks / 4 wks / 6 wks have you visited another healthcare professional other than your chiropractor for your pain complaint?	hc_2wks / hc_6wks / hc_12wks nfu_otherhealth_2wks / nfu_otherhealth_6wks / nfu_otherhealth_12wks	1, Yes 2, No	[hc_2wks] / [hc_6wks] / [hc_12wks] = '1'
	How many times have you visited another healthcare professional in the last 2 wks / 4 wks / 6 wks?	nfu_otherhealth_12wks	1, One 2, 2-4 times 3, More than 4 times	[hc_2wks] / [hc_6wks] / [hc_12wks] = '1'
	Medical doctor visit in the last 2 wks / 4 wks / 6 wks for your pain complaint?	gp_2wks / gp_6wks / gp_12wks	1, Yes 2, No	[hc_2wks] / [hc_6wks] / [hc_12wks] = '1'
	Physiotherapist visit in the last 2 wks / 4 wks / 6 wks for your pain complaint?	physo_2wks / physo_6wks / physo_12wks	1, Yes 2, No	[hc_2wks] / [hc_6wks] / [hc_12wks] = '1'
	Other healthcare professional seen in the last 2 wks / 4 wks / 6 wks for your pain complaint?	otherhealth_2wks / otherhealth_6wks / otherhealth_12wks	1, Yes 2, No	[hc_2wks] / [hc_6wks] / [hc_12wks] = '1'
	Which other healthcare professional did you see?	specif_otherhealth_2wks / specif_otherhealth_6wks / specif_otherhealth_12wks		[otherhealth_2wks] / [otherhealth_6wks] / [otherhealth_12wks] = '1'
	Are you currently taking medication to reduce your muscle and joint pain?	medication_2wks / medication_6wks / medication_12wks	1, Yes, prescription medication 2, Yes, non-prescription medication 3, No	
	Have you missed any days of work due to your pain complaint in the last 2 wks / 4 wks / 6 wks?	sickleave_2wks / sickleave_6wks / sickleave_12wks	1, Yes 2, No	[sickleave_2wks] / [sickleave_6wks] / [sickleave_12wks] = '1'
	How many days of sick leave have you had in the last 2 wks / 4 wks / 6 wks due to your pain complaint?	n_sickleave_2wks / n_sickleave_6wks / n_sickleave_12wks		[sickleave_2wks] / [sickleave_6wks] / [sickleave_12wks] = '1'
	In the last 2 wks / 4 wks / 6 wks have you received any diagnostic imaging for your pain complaint?	imaging_2wks / imaging_6wks / imaging_12wks	1, Yes 2, No	[imaging_2wks] / [imaging_6wks] / [imaging_12wks] = '1'
	X-Ray (radiography) in the last 2 wks / 4 wks / 6 wks	xray_2wks / xray_6wks / xray_12wks	1, Yes 2, No 3, Unsure	[imaging_2wks] / [imaging_6wks] / [imaging_12wks] = '1'
	Ultrasound scan in the last 2 wks / 4 wks / 6 wks	ultra_2wks / ultra_6wks / ultra_12wks	1, Yes 2, No 3, Unsure	[imaging_2wks] / [imaging_6wks] / [imaging_12wks] = '1'
	MRI scan in the last 2 wks / 4 wks / 6 wks	mri_2wks / mri_6wks / mri_12wks	1, Yes 2, No 3, Unsure	[imaging_2wks] / [imaging_6wks] / [imaging_12wks] = '1'
CT scan in the last 2 wks / 4 wks / 6 wks	ct_2wks / ct_6wks / ct_12wks	1, Yes 2, No 3, Unsure	[imaging_2wks] / [imaging_6wks] / [imaging_12wks] = '1'	
Patients' Global Impression of Change (PGIC) scale Collected at 2-, 6-, and 12-wks	To what extent has your pain complaint changed when compared with the situation just before you started chiropractic care?	pgic_q1_2wks / pgic_q1_6wks / pgic_q1_12wks	1, 1 = Completely recovered 2, 2. Much improved 3, 3. Slightly improved 4, 4. Not changed 5, 5. Slightly worsened 6, 6. Much worsened 7, 7. Worse than ever	

BMJ Open

The Swiss chiropractic practice-based research network and musculoskeletal pain cohort pilot study: protocol of a nationwide resource to advance musculoskeletal health services research

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3 **1 The Swiss chiropractic practice-based research network and musculoskeletal pain cohort**
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5 **2 pilot study: protocol of a nationwide resource to advance musculoskeletal health services**
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8 **3 research**
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3 25
45 26 **Abstract**7 27 **Introduction**

8 28 Musculoskeletal (MSK) pain conditions, a leading cause of global disability, are usually first
9
10 29 managed in primary care settings such as medical, physiotherapy, and chiropractic community-
11
12 30 based practices. While chiropractors often treat MSK conditions, there is limited real-world
13
14 31 evidence on the topic of health service outcomes among patients receiving this type of care. A
15
16 32 nationwide Swiss chiropractic practice-based research network (PBRN) and MSK pain patient
17
18 33 cohort study will have potential to monitor the epidemiological trends of MSK pain conditions
19
20 34 and contribute to health care quality improvement. The primary aims of this protocol are to 1)
21
22 35 describe the development of a MSK focused PBRN within the Swiss chiropractic setting; and 2)
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24 36 describe the methodology of the first nested study to be conducted within the PBRN – an
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26 37 observational prospective patient cohort pilot study.
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35 39 **Methods and analysis**

36 40 This initiative is conceptualized with two distinct phases. Phase 1 focuses on the development of
37
38 41 the Swiss chiropractic PBRN, and will use a cross-sectional design to collect information from
39
40 42 chiropractic clinicians nationwide. Phase 2 will recruit consecutive patients aged 18 years or
41
42 43 older with MSK pain from community-based chiropractic practices participating in the PBRN
43
44 44 into a prospective chiropractic cohort pilot study. All data collection will occur through
45
46 45 electronic surveys offered in the three Swiss national languages (German, French, Italian) and
47
48 46 English. Surveys will be provided to patients prior to initial assessment, 1-hour after assessment
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50 47 and at 2-, 6-, and 12-weeks after assessment.
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49 **Ethics and dissemination**

50 Ethics approval has been obtained from the independent research ethics committee of Canton
51 Zurich (BASEC-Nr: 2021-01479). Informed consent will be obtained electronically from all
52 participants. Findings will be reported to stakeholders after each study phase, presented at local
53 and international conferences, and disseminated through peer-reviewed publications.

54 55 **Trial registration**

56 Phase 1 – Swiss chiropractic PBRN (ClinicalTrials.gov identifier: NCT05046249);

57 Phase 2 – Swiss chiropractic cohort (Swiss ChiCo) pilot study (ClinicalTrials.gov identifier:
58 NCT05116020).

59 60 **Strengths and limitations of this study**

- 61 • Use of a flexible practice-based research network model will allow for a diverse range of
62 nested study design types as well as the future expansion of the network.
- 63 • Development of protocol methods is guided by patient and public involvement activities with
64 key stakeholders.
- 65 • Sole use electronic data capture methods may lead to selective participation of both clinician
66 and patient participants.

67
68 **Keywords:** chiropractic, health care quality, musculoskeletal health, musculoskeletal pain,
69 manual medicine

70

71

72

73 INTRODUCTION

74 Musculoskeletal (MSK) pain conditions are the leading cause of disability worldwide, with low
75 back pain being the largest single cause in over 160 countries, including Switzerland.[1,2] This
76 health burden translates to an economic cost of approximately 6.6 billion Euros or about 2% of
77 Switzerland's total gross domestic product for low back pain alone.[3] Best practice
78 recommendations and systematic reviews on MSK pain largely focus primarily on regional pain
79 locations, such as low back pain or neck pain.[4-6] However, in the population and in primary
80 care settings, it is common that those experiencing a MSK pain complaint also present with co-
81 existing pain in another body region.[7,8] There is increasing evidence suggesting that these pain
82 conditions, although localized to different regions, share similarities with respect to the course of
83 symptoms, prognostic factors, and clinical care recommendations.[9,10] An entirely regional
84 focus to MSK health may create gaps in patient centered research and difficulties with
85 knowledge implementation in health care settings.

86 Further contributing to practice gaps, is the lack of practice-based data collection in
87 MSK health care research.[11] To help bridge the divide between research and practice,
88 countries such as the UK, Denmark, Sweden, and Australia have engaged in practice-based
89 research and worked with MSK-focused practice-based research networks (PBRNs).[12-14] A
90 PBRN is a group of at least 15 primary-care settings united under a commitment to advance the
91 science base of clinical care.[15] These "real world" clinical research environments allow for
92 sustained collaborations between practitioners, patients, and academicians facilitating the co-
93 creation of relevant research questions and production of clinically applicable results.[11,15,16]

94 The chiropractic scope of practice in Switzerland includes the diagnosis and management
95 of MSK pain conditions through manual medicine, prescription medication, and diagnostic
96 imaging (radiography, ultrasound, CT, MRI). As of December 2021, there were approximately

1
2
3 97 326 chiropractors practicing across Switzerland with the large majority providing care in
4
5 98 community-based settings. MSK complaints such as low back pain and neck pain, which result
6
7 99 in the largest burdens of disability are commonly seen in chiropractic practice.[17] Chiropractic
8
9
10 100 health care centres may serve as useful settings to further investigate MSK pain conditions, to
11
12 101 understand what role chiropractors play in the current management of these conditions, and to
13
14 102 identify opportunities for Swiss MSK primary health care quality improvement. As management
15
16 103 of MSK conditions moves away from traditional medical treatments and towards more physical
17
18 104 and preventative approaches, there is a need to describe non-pharmacological treatment options
19
20 105 to make informed decisions on how best to use this capacity in the current health care
21
22 106 system.[4,18]

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26 107 Given the high burden of MSK pain conditions, which are frequently managed by
27
28 108 chiropractors, and limited practice-based evidence on the topic of chiropractic care for MSK
29
30 109 conditions, particularly in Switzerland, this protocol outlines the creation of a nationwide PBRN
31
32 110 and subsequent nested prospective cohort (Swiss ChiCo) pilot study for chiropractic patients
33
34 111 with MSK pain. Once established, this PBRN will provide the framework to help monitor the
35
36 112 epidemiological trends of MSK pain in primary care settings, contribute to MSK health care
37
38 113 quality improvement, and support future development and growth of practice-based MSK
39
40 114 clinical research.

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44 115 The main objectives of this report are to: 1) describe the development of a MSK
45
46 116 focused PBRN and describe the enrolment of Swiss chiropractors into the PBRN; and 2) describe
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48 117 the methods of the first nested study to be conducted within the PBRN – an observational
49
50 118 prospective patient cohort pilot study.

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55 56 120 **METHODS AND ANALYSIS**

121 **Study design**

122 The Swiss chiropractic PBRN will use a substudy PBRN model, similar to that of the Australian
123 Chiropractic Research Network (ACORN).[12,19,20] In substudy PBRN models, data is initially
124 collected from participating clinicians/clinical practices through self-report to first establish and
125 describe characteristics of the PBRN. Following development, nested substudies may be
126 performed using this PBRN framework.

127 The current project will consist of two phases. In phase 1, we aim to develop the Swiss
128 chiropractic PBRN and describe the demographics of participating chiropractors at project
129 initiation using a cross-sectional study design (ClinicalTrials.gov identifier: NCT05046249). In
130 phase 2, we aim to launch a 12-week observational prospective Swiss chiropractic cohort (Swiss
131 ChiCo) pilot study which will assess the feasibility for longitudinal data collection and describe
132 the clinical course of patients with MSK pain presenting to Swiss chiropractors.
133 (ClinicalTrials.gov identifier: NCT05116020). **Figure 1** provides an overview of the two nested
134 phases of this project.

135

136 **Patient and public involvement**

137 Key stakeholders identified for the development of this project include the Swiss Chiropractic
138 Association (ChiroSuisse), the Swiss Chiropractic Patient Association (Pro Chiropractic
139 Switzerland), Swiss chiropractors, and an international group of researchers with experience in
140 practice-based research. Participatory engagement activities were first performed collaboratively
141 with all stakeholders and focused on study relevance, team building, project infrastructure
142 development and the collaborative creation of relevant research questions. A consensus-based
143 understanding was reached by all members which outlined the need for more clinical MSK
144 research within the Swiss setting and a pledge to provide support to achieve this project goal.

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3 145 Other recommendations included the practicality to start with a small cohort study to first test
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5 146 data collection methods, as well to explore both clinical and feasibility related objectives to help
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7
8 147 drive recruitment from community-based chiropractors and patients.
9

10 148 Individualized one-on-one meetings were subsequently conducted to discuss specific
11
12 149 project methods with each stakeholder group. Recommendations provided by ChiroSuisse and
13
14 150 Pro Chiropractic Switzerland included the addition of several questions to the Swiss ChiCo pilot
15
16 151 study patient participant questionnaires. Consequently, questions relating to patient work status,
17
18 152 past use of chiropractic care, and use of other healthcare in MSK pain management were added.
19
20 153 Both associations also recommended increasing patient participant recruitment weighting for the
21
22 154 Swiss ChiCo pilot study in the French and Italian language regions of Switzerland by 5% from
23
24 155 what was initially proposed.
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28 156 One-on-one meetings with Swiss chiropractors were carried out for the purpose of
29
30 157 understanding how best to integrate study processes into clinical practice settings. According to
31
32 158 all clinician advisors, the recruitment of approximately 5-10 consecutive patients per clinical
33
34 159 practice was feasible. Outside of clinical workflow processes, patient participant inclusion
35
36 160 criteria were revised from new healthcare seeking for a MSK pain condition (operationalized as
37
38 161 not having received any (patient-reported) health care for current MSK complaint) to new
39
40 162 conservative healthcare seeking for a MSK complaint (not having received any (patient-reported)
41
42 163 chiropractic, physiotherapy, osteopathy, or massage therapy for current MSK complaint in the
43
44 164 last 1 month, and not a follow-up visit). Many clinician advisors recommended this change based
45
46 165 on the clinical profile of their patients and insurance coverage practices in Switzerland (where
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48 166 chiropractic care typically follows an initial visit with a primary care physician or general
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53 167 practitioner).
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3 168 Participatory engagement is an iterative process and requires continuous reflection of
4
5 169 previous project processes and results to inform subsequent phases (action-reflection
6
7 170 process).[21] Following completion of each project phase, individual meetings with each
8
9 171 stakeholder group will be scheduled to disseminate findings, discuss how best to generate future
10
11 172 PBRN growth, and explore ways to expand the MSK clinical cohort study.
12
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17 174 **Phase 1 – Development of the Swiss chiropractic PBRN**

19 175 **Participants**

21 176 All registered active chiropractor members (fully licensed chiropractors and postgraduate
22
23 177 assistant chiropractors) of ChiroSuisse will be eligible and invited to participate. Approximately
24
25 178 98% of all practicing Swiss chiropractors hold an active membership with ChiroSuisse (personal
26
27 179 communication, April 22, 2021).
28
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31 180

33 181 **Recruitment**

35 182 To aid with clinician recruitment, we plan to launch the PBRN development phase on September
36
37 183 9, 2021 at the annual ChiroSuisse Continuing Education (CE) Convention 2021 (Lausanne,
38
39 184 September 9-11, 2021). Clinicians will have the opportunity to ask questions directly of the
40
41 185 project team, test electronic study methods, sign up as a clinician member of the PBRN, and
42
43 186 provide input and feedback for the subsequent Swiss ChiCo pilot study. Those interested, will be
44
45 187 invited to join the Swiss chiropractic PBRN by scanning a quick response (QR) code and
46
47 188 completing the linked clinician entry survey using personal mobile devices. For those who do not
48
49 189 attend the conference, we plan to use electronic email invitations containing the Research
50
51 190 Electronic Data Capture (REDCap) PBRN entry survey link. This invitation will be paired with
52
53 191 an information sheet outlining project goals, good conduct procedures for the PBRN and
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192 subsequent substudy involvement, and risks and benefits for participation. Clinician recruitment
 193 for the Swiss chiropractic PBRN will be scheduled to end on December 19, 2021. Similar to
 194 other PBRNs within the scope of chiropractic and MSK health, we hope to achieve a clinician
 195 participation proportion of approximately 50%.[19,22]

197 **Data collection procedures and variables**

198 All data acquisition will occur electronically using the REDCap web application platform.[23]
 199 Clinicians participating in the Swiss chiropractic PBRN will be asked to fully complete 1
 200 electronic survey of approximately 10 minutes duration. Clinician surveys will only be provided
 201 in English as this is the official language used for communication by ChiroSuisse. **Table 1**
 202 outlines the specific data which will be collected from clinicians for the development of the
 203 Swiss chiropractic PBRN. **Supplementary file 1** provides the data dictionary and specific
 204 response options which will be used for the Swiss chiropractic PBRN.

205 **Table 1.** Outcome measures to be collected for description of the Swiss chiropractic PBRN

Construct	Measurement method / instrument	Inception
Demographics	Gender, age, year of graduation	X
Practice	Number of years in practice, location of practice	X
Characteristics	Primary language used in practice	X
	Number of healthcare practitioners involved in practice	X
	Type of healthcare offered	X
	Average number of patients seen per week	X
	Types of patients seen within practice	X
	Frequency of complaints seen within practice	X
	Confidence	Practitioner self-confidence scale (PCS) [24]
Beliefs and Attitudes	Pain attitudes and beliefs scale – Musculoskeletal (PABS-MSK) [25]	X
	Level of motivation to be involved in the Swiss ChiCo pilot	X
Digitalization of chiropractic practices	Electronic patient record system in practice	X
	Encrypted email use in practice	X
	Offering virtual care in practice	X
COVID-19 aspects	Change in quality of life, change in patient numbers, change in work hours, change in use of telehealth/e-health services.	X

206

207 **Main outcomes and analysis**

208 The primary clinical outcome will be practitioner self-confidence in the clinical
209 management of patients with low back pain (as measured by the practitioner self-confidence
210 scale (PCS)).[24] The PCS contains four items with a total score of 20. A score of 4 represents
211 higher self-confidence in the management of patients with low back pain, while a score of 20
212 represents lower self-confidence. The second primary clinical outcome will be practitioner
213 biomedical versus biopsychosocial MSK pain treatment orientation (as measured by the pain
214 attitudes and beliefs scale, musculoskeletal version (PABS-MSK)).[25] The PABS-MSK
215 contains two domains, with a higher score on either the domains (each 10-items, with a score
216 range of 10-60) representing higher biomedical and biopsychosocial MSK pain treatment
217 orientation. The order of 20 items of the PABS-MSK will be randomized using the
218 “randomizeR” package in RStudio and administered as a single questionnaire so as to mask
219 respondents to the specific treatment orientation domains. Both primary clinical outcomes will
220 be reported as means and standard deviations (SDs), with 95% confidence intervals (CIs)
221 calculated as appropriate.

222 The feasibility outcomes are: 1) clinician participation proportion in the Swiss
223 chiropractic PBRN will be assessed by reporting the proportion of all eligible clinicians that
224 enroll in the PBRN development phase using raw numbers and percentages; and 2) motivation
225 for clinician participation in the Swiss ChiCo pilot study will be assessed using a visual analog
226 scale (VAS, 0-100), with higher scores reflecting higher motivation for participation. Level of
227 motivation to participate in the Swiss ChiCo pilot study will be reported as means, SDs, and with
228 95% CIs calculated as appropriate. Participants who score 70 or more on the VAS will be
229 defined as “highly motivated”, and described using raw numbers, proportions and 95% CIs.

230

231 **Phase 2 – The Swiss chiropractic cohort (Swiss ChiCo) pilot study**

232 **Participants**

233 Patients will be eligible to participate if they are 18 years of age or older; are seeking new
234 conservative healthcare for a MSK pain condition (new conservative healthcare seeking is
235 operationalised as not having received (patient-reported) chiropractic care, physiotherapy,
236 osteopathy or massage therapy for their current MSK complaint in the 1 month prior to their
237 current initial visit to the chiropractor and not a follow-up visit); consent to chiropractic
238 treatment; are able to respond to surveys in German, French, Italian, or English; have an active
239 email account; and are willing and able to complete electronic study questionnaires. Patient
240 participants will be excluded if they present to clinician practices with red flag symptoms (i.e.,
241 saddle anesthesia, loss of bowel and/or bladder control, history of major trauma, fracture, fever,
242 severe or rapidly progressive neurologic deficit, sudden unexplained weight loss), and/or with a
243 non-MSK based pain condition based on the chiropractor's clinical suspicion that symptoms
244 relate to a systemic disease.

245

246 **Recruitment**

247 Following the development of the Swiss chiropractic PBRN, we plan to recruit a subset of
248 clinicians to participate in the Swiss ChiCo pilot study. Chiropractors will be recruited through
249 general interest, VAS motivation score (≥ 70) on the PBRN entry questionnaire, and using a
250 purposeful sampling approach based on Swiss chiropractic clinician distribution across German,
251 French, and Italian language regions of Switzerland (55% DE, 35% FR, 10% IT). The Swiss
252 ChiCo pilot study aims to recruit at least 20 chiropractors. Participating chiropractors will be
253 asked to recruit new consecutive patient participants from their clinical practices. We will hold

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3 254 pilot study introductory meetings with participant clinicians and clinical staff to reinforce study
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5 255 objectives, methods and procedures prior to the tentative date for initiation of the patient cohort
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8 256 pilot study recruitment of April 01, 2022. During previous patient and public involvement work,
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10 257 Swiss chiropractors described the recruitment of 5 to 10 consecutive patients with new
11
12 258 conservative onset MSK pain as feasible. Based on this work, we will aim to recruit at least 100
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14 259 patient participants to enable a preliminary characterisation of the population, enabled by
15
16 260 representative selection of chiropractic clinicians with respect to language region. A stopping
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19 261 point for recruitment will be set at 200 patients.
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22 262 Potentially eligible patients visiting a participating clinician will be first provided a study
23
24 263 flyer, which will briefly outline the study objectives and participation requirements. Patients will
25
26 264 then be asked to rate their initial level of interest to participate using a brief electronic survey.
27
28 265 Those not interested will be prompted to provide reasons for non-participation. Patients
29
30 266 expressing interest in participation will be forwarded to the full study information form and
31
32 267 electronic informed consent procedure. This in-clinic patient participant procedure was
33
34 268 developed in consultation with Swiss chiropractic clinicians (both women and men) across all
35
36 269 language regions. To aid with workflow, clinicians expressed interest in asking new patients to
37
38 270 arrive approximately 20 minutes prior to their appointment to complete electronic study forms.
39
40 271 Clinicians also recommended adding “disruption to clinic workflow” as an option for eligible
41
42 272 patient non-participation. This survey option would be selected by clinical staff when patient
43
44 273 participant recruitment may greatly impact clinical workflow (e.g., patient was late for visit,
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46 274 emergency visit). **Figure 2** outlines the in-clinic patient recruitment procedure.
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53 54 276 **Data collection procedures and variables**

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3 277 Immediately following completion of the in-clinic recruitment procedure, study participants will
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5 278 be forwarded to the first patient survey (pre-visit patient survey) on an electronic device (mobile
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7
8 279 phone or tablet). This pre-visit initial patient survey will collect information on clinical measures
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10 280 that are likely to be influenced by the first visit (i.e., pain impact, musculoskeletal health status,
11
12 281 illness perception).[26-28] The pre-visit patient survey will take approximately 5 minutes to
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14 282 complete and is the only survey that is completed at clinical practices. Subsequent questionnaires
15
16 283 will take approximately 10-12 mins to complete and are emailed directly to patient participants 1
17
18 284 hour after (post-visit patient survey), and at 2-, 6-, and 12-weeks following completion of the
19
20 285 pre-visit survey. REDCap will be used for longitudinal data collection, with survey data
21
22 286 transmitted automatically to the research team at Balgrist University Hospital and the University
23
24 287 of Zurich. Similar administration procedures were performed for the Danish chiropractic low
25
26 288 back pain cohort study.[29] Patient participant surveys will be provided in English, German,
27
28
29 289 French and Italian, with patients having the ability to choose their preferred language for
30
31 290 completion. Validated, translated versions of the patient reported outcome measures (PROMs)
32
33 291 will be used when possible.[30-37] If not available, translation of the PROMs by a native
34
35 292 speaker will be performed. **Table 2** outlines specific outcome measures and timing of data
36
37 293 collection for the Swiss ChiCo pilot study. **Supplementary file 2** provides the data dictionary
38
39 294 and specific response options to be used.
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300 **Table 2.** Outcome measures and timing of data collection for the Swiss ChiCo patient pilot study

Construct	Measurement method / instrument	Pre-visit	Post-visit	Wk 2	Wk 6	Wk 12
Clinic	Clinic name, clinician	X				
Demographics	Gender, age, nationality, level of education, smoking status		X			
	Work status, time lost from work due to pain complaint		X	X	X	X
Injury characteristics	Naïve to chiropractic care		X			
	Duration of complaint		X			
	Location of pain complaint		X			
Pain medication use	Pain, enjoyment, general activity (PEG) scale [26]	X	X	X	X	X
	Other healthcare professional involved in care		X	X	X	X
	Number of chiropractic visits since initial visit			X	X	X
	Medication use for pain reduction (prescription or non-prescription)		X	X	X	X
	Diagnostic imaging use for this specific MSK complaint			X	X	X
Imaging use	Diagnostic imaging received in the past year for other complaint		X			
	Örebro Musculoskeletal Pain Screening Questionnaire – Short Form (ÖMPSQ short) [38]		X			
	COVID-19 aspects		X			
Psychosocial profile	Quality of life now compared to before COVID-19		X			
	Activity compared to before COVID-19		X			
	Cancelled medical treatment due to COVID-19		X			
MSK health status	Musculoskeletal health questionnaire (MSK-HQ) [27]	X	X	X	X	X
Illness perception	Brief illness perception questionnaire (Brief IPQ, Question 9) [28]	X				
Change in condition	Patient Global Impression of Change (PGIC) scale [39]			X	X	X

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302 **Main outcomes and analysis**

303 The prespecified primary clinical outcomes will be: 1) change in musculoskeletal pain impact, as
304 measured by the 3-item pain, enjoyment, and general activity scale (PEG scale, score range 0-10)
305 [26] with higher scores representing worse outcomes; and 2) change in MSK health status, as
306 measured by the musculoskeletal health questionnaire (MSK-HQ, score range 0-56) [27] with
307 higher scores reflecting better health status. Clinical outcomes of the PEG scale and MSK-HQ
308 prior to initial chiropractic assessment will be reported as means, SDs, and 95% CIs; and clinical
309 course of patient pain impact and MSK health status will be reported as a mean difference with
310 SDs and 95% CIs as appropriate. The primary feasibility outcomes will be: 1) the proportion of
311 invited patients presenting to chiropractic practices who subsequently agree to participate in this

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3 312 study; and 2) change in patient participant follow-up and retention over 12 weeks. Invited patient
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5 313 participation will be reported as raw numbers and proportions. Patient participant retention will
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7 314 be reported as the proportion of enrolled participants who complete follow-up surveys across 12-
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9 315 weeks. Based on the definition of a PBRN from the Agency for Healthcare Research and Quality
10
11 316 (AHRQ),^[15] it will be deemed feasible to initiate the Swiss chiropractic PBRN and expand the
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13 317 Swiss ChiCo pilot study if at least 15 clinical practices agree to participate in the Swiss
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15 318 chiropractic PBRN and each recruit at least 5 patients for enrolment in the Swiss ChiCo pilot
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17 319 study.
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24 321 **Ethics and dissemination**

25
26 322 The Swiss chiropractic PBRN and Swiss ChiCo pilot study have been reviewed and jointly
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28 323 approved by the independent research ethics committee of Canton Zurich (BASEC-Nr: 2021-
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30 324 01479). Informed consent will be obtained from both clinician and patient participants
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32 325 electronically upon entry into the Swiss chiropractic PBRN and the Swiss ChiCo pilot study.
33
34 326 Clinician responses for PBRN development will be stored securely within REDCap, but not
35
36 327 anonymous due to necessity of identifying clinicians to participate in future nested research
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38 328 projects. Data collected for PBRN development and for the Swiss ChiCo pilot study will be
39
40 329 stored as two separate projects within REDCap. Individual-level data will not be shared with
41
42 330 study stakeholders.
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47 331 The findings from the Swiss chiropractic PBRN and the Swiss ChiCo pilot study will be
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49 332 disseminated first to the various stakeholder groups involved in study development through
50
51 333 individual meetings. Findings will also be presented through abstract and poster presentations at
52
53 334 academic conferences and fully reported in peer-reviewed publications.
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336 **Availability of data and materials**

337 Data from this work will be made available for research purposes. Requests, including a synopsis
338 of the study proposal, can be addressed to the corresponding author.

339

340 **DISCUSSION**

341 This project is designed to attract a large proportion of Swiss chiropractors into a nationwide
342 PBRN and subsequently recruit patients from participating clinics into a longitudinal cohort pilot
343 study. This approach combines a substudy PBRN model, with longitudinal electronic capture
344 more readily seen in register-based approaches. The unique collaboration with clinicians,
345 advocacy groups and academicians, a growing trend in health care research, has led to the
346 promotion of research objectives which are clinically relevant and patient-centred, and a study
347 implementation strategy vetted by Swiss chiropractic primary care clinicians.

348 Traditional health care research approaches typically face challenges with regards to
349 study relevance, patient recruitment, and knowledge translation.[11,40] The use of a
350 participatory research approach can help overcome such challenges by integrating the diverse
351 knowledge, values, and preferences of non-academics into the research process. An example of a
352 longitudinal register-based study successfully implementing this approach is the Swiss Multiple
353 Sclerosis Registry (SMSR).[41] This project was designed in collaboration with the Multiple
354 Sclerosis (MS) community in Switzerland to tackle the lack of epidemiological data and to
355 promote patient-perspectives in MS research. Participatory elements of the SMSR include a
356 flexible approach to study involvement based on participant comfort, involvement of patients in
357 the study design and execution, and data feedback to provide ongoing results to participants. Due
358 to such efforts, recruitment for the SMSR exceeded expectations; with the goal of 400
359 participants achieved in under 20 days.[42] A second example of a participatory research

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3 360 approach driving recruitment are the recently established national osteopathy PBRNs of
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5 361 Australia (ORION) and New Zealand (ORC-NZ).[22] Here, the project team engaged with both
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7 362 osteopathic communities for 12 months prior to clinician recruitment. Today, these two PBRNs
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10 363 represent the largest coverage of any voluntary health profession PBRN, with 43.5% of all
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12 364 registered osteopaths in Australasia. The Swiss chiropractic PBRN has followed a similar
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14 365 approach, with community outreach and promotion efforts lasting 12 months prior to clinician
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16 366 recruitment.

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19 367 What remains unclear is if early engagement of stakeholders can overcome the unique
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21 368 limitations of electronic observational studies. Typically, unequal access to technology resources
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23 369 and lack of digital literacy can lead to a young, well-educated, and high socio-economic status
24
25 370 study sample. For example, participants in the SMSR who opt for physical forms are older, show
26
27 371 increased care-seeking behaviour, and suffer from more progressive illness compared to those
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29 372 using electronic forms. This trend also extends to clinician participants, as our own 2019 survey
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31 373 on eHealth technology use among Swiss chiropractors showed clinicians 65 years and over were
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33 374 74% less likely to use electronic health records (EHRs) when compared to the those under 40
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35 375 years.[43] To limit this threat to external validity, the Swiss chiropractic PBRN will recruit
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37 376 clinicians through both online and in-person channels. In addition, chiropractic clinician
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39 377 recruitment for the Swiss ChiCo pilot study will be proportionally overweighted in French and
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41 378 Italian language regions. These areas have shown lowered use eHealth technology use when
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43 379 compared to the German speaking regions of Switzerland. To recruit a diverse group of patient
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45 380 participants, clinicians will be asked to consecutively recruit eligible patients from private
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47 381 practice. Although consecutive recruitment does not eliminate the threat of self-selection bias, it
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49 382 ensures all eligible participants seeking chiropractic care will be aware of the study and invited
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51 383 to participate in a nonselective manner. The Swiss chiropractic PBRN and Swiss ChiCo pilot
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3 384 study presents a model for PBRN development and rapid engagement of a newly created clinical
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5 385 research network. Once complete, this PBRN will serve as a platform for answering important
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8 386 research questions in the field of MSK primary health care.
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11
12 388 **Figure 1.** Nested design of the Swiss chiropractic PBRN and the Swiss ChiCo pilot study
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14 389
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17 390 **Figure 2.** Summary of the Swiss ChiCo pilot study in-clinic patient participant recruitment
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19 391

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27
28 395 engagement and support.
29

30 396

31 397 **AUTHOR CONTRIBUTIONS**

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35 398 CAH and RL conceived the project idea. RL, CAH, AK, VvW, MAP, and LH contributed to the
36
37 399 design of the protocol. RL and CAH designed, undertook, and coordinated stakeholder
38
39 400 participatory activities. RL and CAH led the drafting of the protocol manuscript. All authors
40
41 401 gave important intellectual input and provided critical review of the protocol manuscript and
42
43 402 approved the final version of the manuscript. CAH obtained funding. RL and CAH are the
44
45 403 guarantors of this manuscript. The corresponding author attests that all listed authors meet
46
47 404 authorship criteria and that no others meeting the criteria have been omitted.
48

49 405

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4
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6
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8
9 410 considering the research questions, study design, protocol methods or analysis, or in writing of
10
11 411 the protocol manuscript, or the decision to submit the article for publication.
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16 17 413 **COMPETING INTERESTS**

18
19 414 The authors declare that they have no competing interests. AK's position at University of
20
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25 26 417 **REFERENCES:**

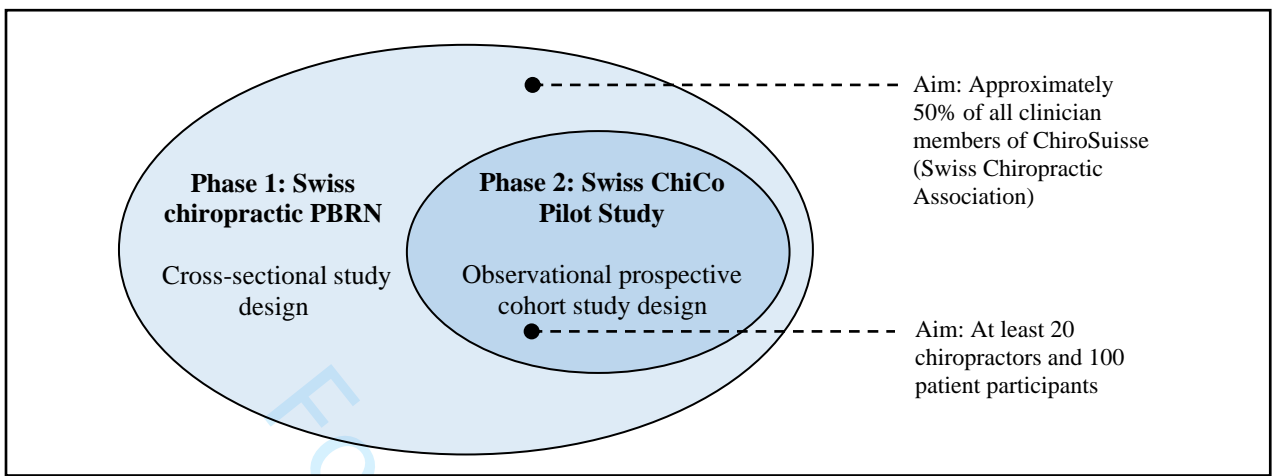
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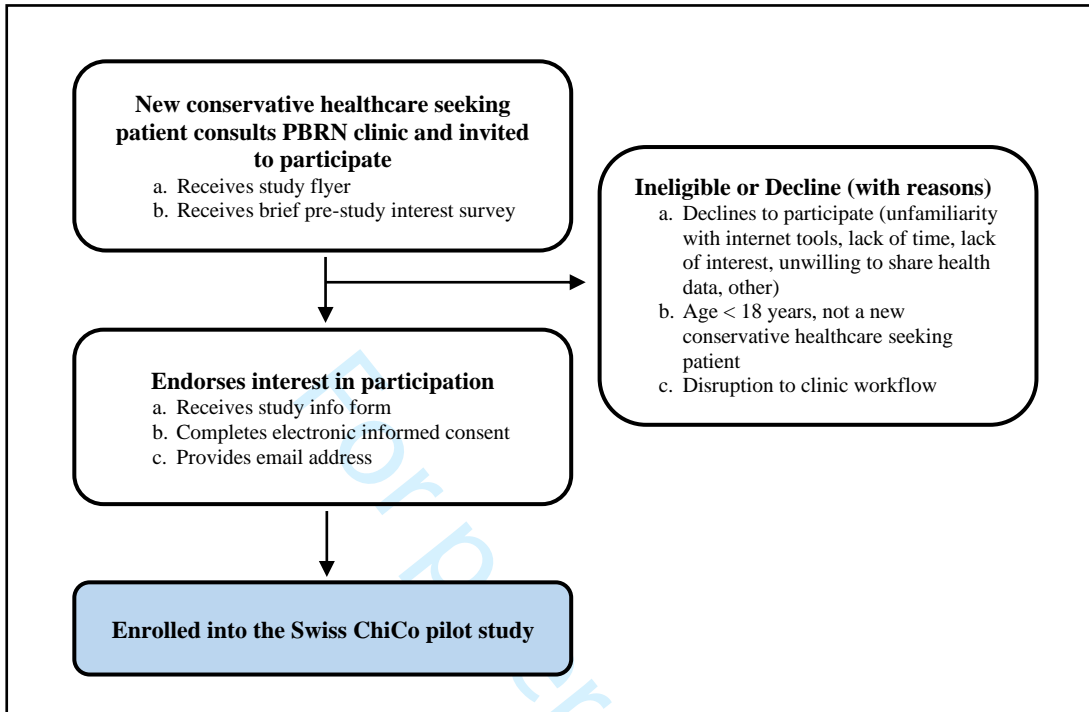
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For peer review only



Supplementary material 2. Patient-reported variables captured in the Swiss ChiCo pilot patient cohort

Construct	Item Content	Variable Code	Choices, Calculations, OR Slider Labels	Branching Logic
Reasons for non-participation Collected at in-clinic recruitment	Record ID Are you interested in participating in this study? Reasons for not participating Other reason for not participating For clinic staff only	record_id chico_interest nonparticipation nonparticipation_other clinic_disrup	1, Yes 2, No 1, No email address 2, Unfamiliar with electronic or internet tools 3, Lack of time 4, Lack of interest in the study 5, Data privacy concerns 6, Other 1, Disruption to clinic workflow	[chico_interest] = '2' [nonparticipation(6)] = '1' [nonparticipation(6)] = '1'
Pain, enjoyment and general activity (PEG) scale Collected at baseline, 1 hour, 2-, 6-, and 12-wks	What number best describes your pain on average in the past week? What number best describes how, during the past week, pain has interfered with your enjoyment of life? What number best describes how, during the past week, pain has interfered with your general activity?	peg_q1_beforetex / peg_q1 / peg_q1_2wks / peg_q1_6wks / peg_q1_12wks peg_q2_beforetex / peg_q2 / peg_q2_2wks / peg_q2_6wks / peg_q2_12wks peg_q3_beforetex / peg_q3 / peg_q3_2wks / peg_q3_6wks / peg_q3_12wks	1, 0 = No pain 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Pain as bad as you can imagine 1, 0 = Does not interfere 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Completely interferes 1, 0 = Does not interfere 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Completely interferes	
Musculoskeletal health questionnaire (MSK-HQ) Collected at baseline, 1 hour, 2-, 6-, and 12-wks	1. Pain/stiffness during the day How severe was your usual joint or muscle pain and/or stiffness overall during the day in the last 2 weeks 2. Pain/stiffness during the night How severe was your usual joint or muscle pain and/or stiffness overall during the night in the last 2 weeks? 3. Walking How much have your symptoms interfered with your ability to walk in the last 2 weeks? 4. Washing/Dressing How much have your symptoms interfered with your ability to wash or dress yourself in the last 2 weeks? 5. Physical activity levels How much has it been a problem for you to do physical activities (e.g. going for a walk or jogging) to the level you want because of your joint or muscle symptoms in the last 2 weeks? 6. Work/daily routine How much have your joint or muscle symptoms interfered with your work or daily routine in the last 2 weeks (including work & jobs around the house)? 7. Social activities and hobbies How much have your joint or muscle symptoms interfered with your social activities and hobbies in the last 2 weeks? 8. Needing Help How often have you needed help from others (including family, friends or carers) because of your joint or muscle symptoms in the last 2 weeks? 9. Sleep How often have you had trouble with either falling asleep or staying asleep because of your joint or muscle symptoms in the last 2 weeks? 10. Fatigue or low energy How much fatigue or low energy have you felt in the last 2 weeks? 11. Emotional well-being How much have you felt anxious or low in your mood because of your joint or muscle symptoms in the last 2 weeks? 12. Understanding of your condition and any current treatment Thinking about your joint or muscle symptoms, how well do you feel you understand your condition and any current treatment (including your diagnosis and medication)? 13. Confidence in being able to manage your symptoms How confident have you felt in being able to manage your joint or muscle symptoms by yourself in the last 2 weeks (e.g. medication, changing lifestyle)? 14. Overall Impact How much have your joint or muscle symptoms bothered you overall in the last 2 weeks? Physical activity Levels In the past week, on how many days have you done a total of 30 minutes of moderate to vigorous activity?	mskhq_q1_beforetex / mskhq_q1 / mskhq_q1_2wks / mskhq_q1_6wks / mskhq_q1_12wks mskhq_q2_beforetex / mskhq_q2 / mskhq_q2_2wks / mskhq_q2_6wks / mskhq_q2_12wks mskhq_q3_beforetex / mskhq_q3 / mskhq_q3_2wks / mskhq_q3_6wks / mskhq_q3_12wks mskhq_q4_beforetex / mskhq_q4 / mskhq_q4_2wks / mskhq_q4_6wks / mskhq_q4_12wks mskhq_q5_beforetex / mskhq_q5 / mskhq_q5_2wks / mskhq_q5_6wks / mskhq_q5_12wks mskhq_q6_beforetex / mskhq_q6 / mskhq_q6_2wks / mskhq_q6_6wks / mskhq_q6_12wks mskhq_q7_beforetex / mskhq_q7 / mskhq_q7_2wks / mskhq_q7_6wks / mskhq_q7_12wks mskhq_q8_beforetex / mskhq_q8 / mskhq_q8_2wks / mskhq_q8_6wks / mskhq_q8_12wks mskhq_q9_beforetex / mskhq_q9 / mskhq_q9_2wks / mskhq_q9_6wks / mskhq_q9_12wks mskhq_q10_beforetex / mskhq_q10 / mskhq_q10_2wks / mskhq_q10_6wks / mskhq_q10_12wks mskhq_q11_beforetex / mskhq_q11 / mskhq_q11_2wks / mskhq_q11_6wks / mskhq_q11_12wks mskhq_q12_beforetex / mskhq_q12 / mskhq_q12_2wks / mskhq_q12_6wks / mskhq_q12_12wks mskhq_q13_beforetex / mskhq_q13 / mskhq_q13_2wks / mskhq_q13_6wks / mskhq_q13_12wks mskhq_q14_beforetex / mskhq_q14 / mskhq_q14_2wks / mskhq_q14_6wks / mskhq_q14_12wks mskhq_activity_beforetex / mskhq_activity / mskhq_activity_2wks / mskhq_activity_6wks / mskhq_activity_12wks	1, Not at all 2, Slightly 3, Moderately 4, Fairly severe 5, Very severe 1, Not at all 2, Slightly 3, Moderately 4, Fairly severe 5, Very severe 1, Not at all 2, Slightly 3, Moderately 4, Severely 5, Unable to walk 1, Not at all 2, Slightly 3, Moderately 4, Severely 5, Unable to wash or dress myself 1, Not at all 2, Slightly 3, Moderately 4, Very much 5, Unable to do physical activities 1, Not at all 2, Slightly 3, Moderately 4, Severely 5, Extremely 1, Not at all 2, Slightly 3, Moderately 4, Severely 5, Extremely 1, Not at all 2, Rarely 3, Sometimes 4, Frequently 5, All the time 1, Not at all 2, Rarely 3, Sometimes 4, Frequently 5, Every night 1, Not at all 2, Slight 3, Moderate 4, Severe 5, Extreme 1, Not at all 2, Slightly 3, Moderately 4, Severely 5, Extremely 1, Completely 2, Very well 3, Moderately 4, Slightly 5, Not at all 1, Extremely 2, Very 3, Moderately 4, Slightly 5, Not at all 1, Not at all 2, Slightly 3, Moderately 4, Very much 5, Extremely 1, 0 = None 2, 1-2 days 3, 3 days 4, 4 days 5, 5 days 6, 6 days 7, 7 days 8, 7 days	

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Construct	Item Content	Variable Code	Choices, Calculations, OR Slider Labels	Branching Logic
Brief illness perception (IPQ brief) Collected at baseline	Please list in rank-order the three most important factors that you believe caused your current pain complaint 1 2 3	briefillness ipq_q1 ipq_q2 ipq_q3		
Demographics Collected 1 hour after initial assessment	Sex Nationality Highest level of education At present, are you working How would you describe the total physical strain caused by your work? Have you missed any days of work due to your current pain complaint? How many days of sick leave have you had in the last 2 weeks ? Smoking Status How much do you smoke on average per day? Have you visited a chiropractor before?	sex_p nationality education job workstrain sick_leave n_sickleave smoking n_cigarettes newpatient	1, Male 2, Female 1, Swiss 2, Non-Swiss 1, Compulsory 2, Secondary 3, Tertiary 1, Full time at your usual job 2, Full time at a lighter job 3, Part time 4, Not working - disability 5, Not working - IV/pensioner applicant 1, Homemaker/Housewife 2, Retired (not disability) 3, Unemployed 4, Student 1, Very light 2, Light 3, Somewhat strenuous 4, Strenuous 5, Very strenuous 1, Yes 2, No 1, Current smoker 2, Previous smoker 3, Never smoker 1, I am new to chiropractic 2, I have visited a chiropractor before	[job] = '1' or [job] = '2' or [job] = '3' or [job] = '6' or [job] = '9' [sick_leave] = '1' [smoking] = '1'
Injury Characteristics Collected 1 hour after initial assessment	Have you visited a medical doctor for your current pain complaint? Were you referred to chiropractic care for your pain complaint from a healthcare professional? Which healthcare professional referred you to chiropractic care? Please specify which healthcare professional referred you to chiropractic care. How long has it been since your current pain complaint began? Main location of pain complaint Please specify the main location of your pain complaint Are you currently taking medication to reduce your pain?	md_currentpain referral_source hrefer_specify hc_refer_other date_of_inj pain_complaint pain_complaint_other medication	1, Yes 2, No 1, Yes 2, No 1, Other chiropractor 2, Family practitioner 3, Internist 4, Orthopaedic surgeon 5, Physical therapist 6, Massage therapist 7, Other 1, 1-2 days 2, 3-7 days 3, 1-2 weeks 4, 2-4 weeks 5, 1-3 months 6, 4-12 months 7, More than 12 months 1, Low back pain 2, Low back pain with leg pain 3, Neck pain 4, Neck pain with arm pain 5, Middle back pain 6, Headache 7, Shoulder pain 8, Hip pain 9, Knee pain 10, Pain in multiple areas 11, Other 1, Yes, prescription medication 2, Yes, non-prescription medication 3, No	[referral_source] = '1' [hrefer_specify] = '7' [pain_complaint] = '11'
Imaging Use Collected 1 hour after initial assessment	In the last 1 month have you received any diagnostic imaging for your current pain complaint? X ray (radiography) in the last 1 month? Ultrasound scan in the last 1 month? MRI scan in the last 1 month? CT scan in the last 1 month? In the last 1 year have you received diagnostic imaging for any pain complaint? X-ray (radiography) in the last 1 year? Ultrasound scan in the last 1 year? MRI scan in the last 1 year? CT scan in the last 1 year?	image_postvisit xray_postvisit ultra_postvisit mri_postvisit ctscan_postvisit imaging1y_postvisit xray_1yr ultrasound_1yr mri_1yr ctscan_1yr	1, Yes 2, No 1, Yes 2, No 3, Unsure 1, Yes 2, No 3, Unsure 1, Yes 2, No 3, Unsure 1, Yes 2, No 3, Unsure 1, Yes 2, No 1, Yes 2, No 3, Unsure 1, Yes 2, No 3, Unsure 1, Yes 2, No 3, Unsure 1, Yes 2, No 3, Unsure	[image_postvisit] = '1' [image_postvisit] = '1' [image_postvisit] = '1' [image_postvisit] = '1' [imaging1y_postvisit] = '1' [imaging1y_postvisit] = '1' [imaging1y_postvisit] = '1' [imaging1y_postvisit] = '1'
COVID-19 aspects Collected 1 hour after initial assessment	How is your quality of life at the moment compared to the time before the COVID-19 pandemic? How are your physical activity habits at the moment compared to the time before the COVID-19 pandemic? Have you been unable to seek planned or necessary medical treatment because of the COVID-19 pandemic? What treatment could you not participate in because of the COVID-19 pandemic? Would you be interested in receiving virtual or telehealth chiropractic sessions?	patient_cov_1 pat_cov_2 pat_cov_3 pat_cov_4 virtual	1, Better 2, Similar 3, Worsened 1, Better 2, Similar 3, Worsened 1, Yes 2, No 1, Yes 2, No 3, Unsure	[pat_cov_3] = '1'

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Construct	Item Content	Variable Code	Choices, Calculations, OR Slider Labels	Branching Logic	
Orebro Musculoskeletal Pain Screening Questionnaire - Short Collected 1 hour after initial assessment	How long have you had your current pain complaint?	omps_q1	1, 0 = No pain 2, 1-3 weeks 3, 4-5 weeks 4, 6-7 weeks 5, 8-9 weeks 6, 10-11 weeks 7, 12-23 weeks 8, 24-35 weeks 9, 36-52 weeks 10, > 52 weeks		
	How would you rate the pain that you have had during the past week?	omps_q2	1, 0 = Pain as bad as it could be		
	How tense or anxious have you felt in the past week?	omps_q5	1, 0 = Absolutely calm and relaxed 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = As tense and anxious as I've ever felt		
	How much have you been bothered by feeling depressed in the past week?	omps_q6	1, 0 = Not at all 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Extremely		
	In your view, how large is the risk that your current pain may become persistent?	omps_q7	1, 0 = No risk 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Very large risk		
	In your estimation, what are the chances you will be working your normal duties in 3 months?	omps_q8	1, 0 = No chance 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Very large chance		
	An increase in pain is an indication that I should stop what I'm doing until the pain decreases.	omps_q9	1, 0 = Completely disagree 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Completely agree		
	I should not do my normal work with my present pain.	omps_q10	1, 0 = Completely disagree 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Completely agree		
		I can do light work for an hour	omps_q3	1, 0 = Can't do it because of the pain problem 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Can do it without pain being a problem	
		I can sleep at night.	omps_q4	1, 0 = Can't do it because of the pain problem 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Can do it without pain being a problem	
Follow-up Questionnaire: injury characteristics and imaging use Collected at 2-, 6-, and 12-wks	In the last 2 wks / 4 wks / 6 wks have you had any follow-up visits with the chiropractor for your pain complaint?	fu_chiro_2wks / fu_chiro_6wks / fu_chiro_12wks	1, Yes 2, No	[fu_chiro_2wks] / [fu_chiro_6wks] / [fu_chiro_12wks] = '1'	
	How many times have you seen your chiropractor in the last 2 wks / 4 wks / 6 wks?	nfu_chiro_2wks / nfu_chiro_6wks / nfu_chiro_12wks	1, One 2, 2-4 times 3, More than 4 times		
	In the last 2 wks / 4 wks / 6 wks have you visited another healthcare professional other than your chiropractor for your pain complaint?	hc_2wks / hc_6wks / hc_12wks nfu_otherhealth_2wks / nfu_otherhealth_6wks / nfu_otherhealth_12wks	1, Yes 2, No	[hc_2wks] / [hc_6wks] / [hc_12wks] = '1'	
	How many times have you visited another healthcare professional in the last 2 wks / 4 wks / 6 wks?	nfu_otherhealth_12wks	1, One 2, 2-4 times 3, More than 4 times	[hc_2wks] / [hc_6wks] / [hc_12wks] = '1'	
	Medical doctor visit in the last 2 wks / 4 wks / 6 wks for your pain complaint?	gp_2wks / gp_6wks / gp_12wks	1, Yes 2, No	[hc_2wks] / [hc_6wks] / [hc_12wks] = '1'	
	Physiotherapist visit in the last 2 wks / 4 wks / 6 wks for your pain complaint?	physo_2wks / physo_6wks / physo_12wks	1, Yes 2, No	[hc_2wks] / [hc_6wks] / [hc_12wks] = '1'	
	Other healthcare professional seen in the last 2 wks / 4 wks / 6 wks for your pain complaint?	otherhealth_2wks / otherhealth_6wks / otherhealth_12wks	1, Yes 2, No	[hc_2wks] / [hc_6wks] / [hc_12wks] = '1'	
	Which other healthcare professional did you see?	specif_otherhealth_2wks / specif_otherhealth_6wks / specif_otherhealth_12wks		[otherhealth_2wks] / [otherhealth_6wks] / [otherhealth_12wks] = '1'	
	Are you currently taking medication to reduce your pain?	medication_2wks / medication_6wks / medication_12wks	1, Yes, prescription medication 2, Yes, non-prescription medication 3, No		
	Have you missed any days of work due to your pain complaint in the last 2 wks / 4 wks / 6 wks?	sickleave_2wks / sickleave_6wks / sickleave_12wks	1, Yes 2, No	[sickleave_2wks] / [sickleave_6wks] / [sickleave_12wks] = '1'	
	How many days of sick leave have you had in the last 2 wks / 4 wks / 6 wks due to your pain complaint?	n_sickleave_2wks / n_sickleave_6wks / n_sickleave_12wks		[sickleave_2wks] / [sickleave_6wks] / [sickleave_12wks] = '1'	
	In the last 2 wks / 4 wks / 6 wks have you received any diagnostic imaging for your pain complaint?	imaging_2wks / imaging_6wks / imaging_12wks	1, Yes 2, No	[imaging_2wks] / [imaging_6wks] / [imaging_12wks] = '1'	
	X-Ray (radiography) in the last 2 wks / 4 wks / 6 wks	xray_2wks / xray_6wks / xray_12wks	1, Yes 2, No 3, Unsure	[imaging_2wks] / [imaging_6wks] / [imaging_12wks] = '1'	
	Ultrasound scan in the last 2 wks / 4 wks / 6 wks	ultra_2wks / ultra_6wks / ultra_12wks	1, Yes 2, No 3, Unsure	[imaging_2wks] / [imaging_6wks] / [imaging_12wks] = '1'	
	MRI scan in the last 2 wks / 4 wks / 6 wks	mri_2wks / mri_6wks / mri_12wks	1, Yes 2, No 3, Unsure	[imaging_2wks] / [imaging_6wks] / [imaging_12wks] = '1'	
CT scan in the last 2 wks / 4 wks / 6 wks	ct_2wks / ct_6wks / ct_12wks	1, Yes 2, No 3, Unsure	[imaging_2wks] / [imaging_6wks] / [imaging_12wks] = '1'		
Patients' Global Impression of Change (PGIC) scale Collected at 2-, 6-, and 12-wks	To what extent has your pain complaint changed when compared with the situation just before you started chiropractic care?	pgic_q1_2wks / pgic_q1_6wks / pgic_q1_12wks	1, 1 = Completely recovered 2, 2. Much improved 3, 3. Slightly improved 4, 4. Not changed 5, 5. Slightly worsened 6, 6. Much worsened 7, 7. Worse than ever		

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 1 and 2	<p>"The Swiss chiropractic practice-based research network and musculoskeletal pain cohort pilot study: protocol of a nationwide resource to advance musculoskeletal health services research." (pg 1)</p> <p>"Phase 1 focuses on the development of the Swiss chiropractic PBRN, and will use a cross sectional design to collect information from chiropractic clinicians nationwide." (pg 2)</p> <p>"Phase 2 will recruit consecutive patients aged 18 years or older with MSK pain from community-based chiropractic practices participating in the PBRN into a prospective chiropractic cohort pilot study." (pg 2)</p>
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2	"All data collection will occur through electronic surveys. Surveys will be provided to patients prior to initial assessment, 1-hour after assessment and at 2-, 6-, and 12-weeks after assessment."
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 5	"Given the high burden of MSK pain conditions, which are frequently managed by chiropractors, and limited practice-based evidence on the topic of chiropractic care for MSK conditions, particularly in Switzerland, this protocol outlines the creation of a nationwide PBRN and subsequent nested prospective cohort (Swiss ChiCo) pilot study for chiropractic patients with MSK pain."
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 5	"The main objectives of this report are to: 1) describe the development of a MSK focused PBRN and describe the enrolment of Swiss chiropractors into the PBRN; and 2) describe the methods of the first nested study to be conducted

					within the PBRN – an observational prospective patient cohort pilot study.”
Methods					
Study design	4	Present key elements of study design early in the paper		Page 6	<p>“In phase 1, we will aim to develop the Swiss Chiropractic PBRN and describe the demographics of participating chiropractors at project initiation using a cross-sectional study design.”</p> <p>“In phase 2, we aim to launch a 12-week observational prospective Swiss chiropractic cohort (Swiss ChiCo) pilot study which will assess the feasibility for longitudinal data collection and describe the clinical course of patients with MSK pain presenting to Swiss chiropractors.”</p>
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection		Page 8, 9, 12 and 13	<p>“To aid with clinician recruitment, we plan to launch the PBRN development phase on September 9, 2021.” (pg 8)</p> <p>“Clinician recruitment for the Swiss chiropractic PBRN will be scheduled to end on December 19, 2021.” (pg 9)</p> <p>“Clinicians participating in the Swiss chiropractic PBRN will be asked to fully complete 1 electronic survey of approximately 10 minutes duration.” (pg 9)</p> <p>“We will hold pilot study introductory meetings with participant clinicians and clinical staff to reinforce study objectives, methods and procedures prior to the tentative date for initiation of the patient cohort pilot study recruitment of April 01, 2022.” (pg 12)</p> <p>“Subsequent questionnaires will take approximately 10-12 mins to complete and are emailed directly to patient participants 1 hour after (post-visit patient survey), and at 2-, 6-, and 12-weeks following completion of the pre-visit survey.” (pg 13)</p>
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up		Page 8 and 11	<p>“All registered active chiropractor members (fully licensed chiropractors and postgraduate assistant chiropractors) of the Swiss Chiropractic Association</p>

	<p><i>Case-control study</i>—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls</p> <p><i>Cross-sectional study</i>—Give the eligibility criteria, and the sources and methods of selection of participants</p>	<p>(ChiroSuisse) will be eligible and invited to participate.” (pg 8)</p> <p>“Patients will be eligible to participate if they are 18 years of age or older; are seeking new conservative healthcare for a MSK pain condition (new conservative healthcare seeking is operationalised as not having received (patient-reported) chiropractic care, physiotherapy, osteopathy or massage therapy for their current MSK complaint in the 1 month prior to their current initial visit to the chiropractor and not a follow-up visit); consent to chiropractic treatment; are able to respond to surveys in German, French, Italian, or English; have an active email account; and are willing and able to complete electronic study questionnaires.” (pg 11)</p>
	<p>(b) <i>Cohort study</i>—For matched studies, give matching criteria and number of exposed and unexposed</p> <p><i>Case-control study</i>—For matched studies, give matching criteria and the number of controls per case</p>	<p>N/A</p>
<p>Variables</p>	<p>7 Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable</p>	<p>page 10 and 14</p> <p>“The primary clinical outcome will be practitioner self-confidence in the clinical management of patients with low back pain (measured by practitioner self-confidence scale). The second primary clinical outcome will be practitioner biomedical versus biopsychosocial MSK pain treatment orientation (as measured by the pain attitudes and beliefs scale, musculoskeletal version).” (pg 10)</p> <p>“The feasibility outcomes are 1) clinician participation proportion in the Swiss chiropractic PBRN will be assessed by reporting the proportion of all eligible clinicians that enroll in the PBRN development phase using raw numbers and percentages; and 2) motivation for clinician participation in the Swiss ChiCo pilot study will be assessed using a visual analog scale (VAS, 0-100), with higher scores reflecting higher motivation for participation.” (pg 10)</p>

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			<p>“The prespecified primary clinical outcomes will be: 1) change in musculoskeletal pain impact, as measured by the 3-item pain, enjoyment, and general activity scale; and 2) change in MSK health status, as measured by the musculoskeletal health questionnaire.” (pg 14)</p> <p>“The primary feasibility outcomes will be: 1) the proportion of invited patients presenting to chiropractic practices who subsequently agree to participate in this study; and 2) change in patient participant follow-up and retention over 12 weeks.” (pg 14)</p>
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	<p>page 10 and 14</p> <p>“The PCS contains four items with a total score of 20. A score of 4 represents higher self-confidence in the management of patients with low back pain, while a score of 20 represents lower self-confidence.” (pg 10)</p> <p>“The PABS-MSK contains two domains, with a higher score on either the domains (each 10-items, with a score range of 10-60) representing higher biomedical and biopsychosocial MSK pain treatment orientation.” (pg 10)</p> <p>“Motivation for clinician participation in the Swiss ChiCo pilot study will be assessed using a visual analog scale (VAS, 0-100), with higher scores reflecting higher motivation for participation.” (pg 10)</p> <p>“3-item pain, enjoyment, and general activity scale (PEG scale, score range 0-10) with higher scores representing worse outcomes; and 2) change in MSK health status, as measured by the musculoskeletal health questionnaire (MSK-HQ, score range 0-56) with higher scores reflecting better health status.” (pg 14)</p>
Bias	9	Describe any efforts to address potential sources of bias	<p>page 13 and 17</p> <p>“Patient participant surveys will be provided in English, German, French and Italian, with patients having the ability to choose their preferred language for completion. Validated, translated versions of the patient</p>

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reported outcome measures (PROM) will be used when possible.” (pg 13)

“To limit this threat to external validity, the Swiss chiropractic PBRN will recruit clinicians through both online and in-person channels. In addition, chiropractic clinician recruitment for the Swiss ChiCo pilot study will be proportionally overweighted in French and Italian language regions. These areas have shown lowered use eHealth technology use when compared to the German speaking regions of Switzerland.” (pg 17)

“To recruit a diverse group of patient participants, clinicians will be asked to consecutively recruit eligible patients from private practice. Although consecutive recruitment does not eliminate the threat of self-selection bias, it ensures all eligible participants seeking chiropractic care will be aware of the study.” (pg 17)

Study size 10 Explain how the study size was arrived at

Page 7, 9 and 12

“One-on-one meetings with Swiss chiropractors were carried out for the purpose of understanding how best to integrate study processes into clinical practice settings. According to all clinician advisors, the recruitment of approximately 5-10 consecutive patients per clinical practice was feasible.” (pg 7)

“Similar to other PBRNs within the scope of chiropractic and MSK health, we hope to achieve a clinician participation proportion of approximately 50%.” (pg 9)

“Based on this work, we will aim to recruit at least 100 patient participants to enable a preliminary characterisation of the population, enabled by representative selection of chiropractic clinicians with respect to language region.” (pg 12)

Continued on next page

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2	Quantitative	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which	Page 10	“Participants who score 70 or more on the
3	variables		groupings were chosen and why		VAS will be defined as “highly motivated”,
4					and described using raw numbers,
5					proportions and 95% CIs.” (pg 10)
6	Statistical	12	(a) Describe all statistical methods, including those used to control for confounding	Page 10 and 14	“Both primary clinical outcomes will be
7	methods				reported as means and standard deviations
8					(SDs), with 95% confidence intervals (CIs)
9					calculated as appropriate.” (pg 10)
10					“Clinician participation proportion in the
11					Swiss chiropractic PBRN will be assessed by
12					reporting the proportion of all eligible
13					clinicians that enroll in the PBRN
14					development phase using raw numbers and
15					percentages.” (pg 10)
16					“Clinical outcomes of the PEG scale and
17					MSK-HQ prior to initial chiropractic
18					assessment will be reported as means, SDs,
19					and 95% CIs; and clinical course of patient
20					pain impact and MSK health status will be
21					reported as a mean difference with SDs and
22					95% CIs as appropriate.” (pg 14)
23					“Invited patient participation will be reported
24					as raw numbers and proportions. Patient
25					participant retention will be reported as the
26					proportion of enrolled participants who
27					complete follow-up surveys across 12-
28					weeks.” (pg 14)
29			(b) Describe any methods used to examine subgroups and interactions	N/A	
30			(c) Explain how missing data were addressed	N/A	
31			(d) Cohort study—If applicable, explain how loss to follow-up was addressed	N/A	
32			Case-control study—If applicable, explain how matching of cases and controls was addressed		
33			Cross-sectional study—If applicable, describe analytical methods taking account of sampling		
34			strategy		
35			(e) Describe any sensitivity analyses	N/A	
36	Results				
37	Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined	N/A	
38			for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed		
39			(b) Give reasons for non-participation at each stage	N/A	
40			(c) Consider use of a flow diagram	N/A	

Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	N/A
		(b) Indicate number of participants with missing data for each variable of interest	N/A
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	N/A
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	N/A
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	N/A
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	N/A
		(b) Report category boundaries when continuous variables were categorized	N/A
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A

Continued on next page

1				
2	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
3				
4	Discussion			
5	Key results	18	Summarise key results with reference to study objectives	Page 16 “This project is designed to attract a large proportion of Swiss chiropractors into a nationwide PBRN and subsequently recruit patients from participating clinics into a longitudinal cohort pilot study.”
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16	Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 17 “Typically, unequal access to technology resources and lack of digital literacy can lead to a young, well-educated, and high socio-economic status study sample.”
17				
18				
19	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	N/A
20				
21	Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 17 “To limit this threat to external validity, the Swiss chiropractic PBRN will recruit clinicians through both online and in-person channels. In addition, chiropractic clinician recruitment for the Swiss ChiCo pilot study will be proportionally overweighted in French and Italian language regions. These areas have shown lowered use eHealth technology use when compared to the German speaking regions of Switzerland. To recruit a diverse group of patient participants, clinicians will be asked to consecutively recruit eligible patients from private practice. Although consecutive recruitment does not eliminate the threat of self-selection bias, it ensures all eligible participants seeking chiropractic care will be aware of the study.”
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35	Other information			
36	Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 18 “This work was internally supported by the Department of Chiropractic Medicine, Faculty of Medicine, at University of Zurich and Balgrist University Hospital through funding from the Foundation for the Education of Chiropractors in Switzerland.”
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3 *Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.
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6 **Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE
7 checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at
8 <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.
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BMJ Open

The Swiss chiropractic practice-based research network and musculoskeletal pain cohort pilot study: protocol of a nationwide resource to advance musculoskeletal health services research

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Manuscripts

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3 **1 The Swiss chiropractic practice-based research network and musculoskeletal pain cohort**
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5 **2 pilot study: protocol of a nationwide resource to advance musculoskeletal health services**
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8 **3 research**
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25 **Abstract**

26 **Introduction**

27 Musculoskeletal (MSK) pain conditions, a leading cause of global disability, are usually first
28 managed in primary care settings such as medical, physiotherapy, and chiropractic community-
29 based practices. While chiropractors often treat MSK conditions, there is limited real-world
30 evidence on the topic of health service outcomes among patients receiving this type of care. A
31 nationwide Swiss chiropractic practice-based research network (PBRN) and MSK pain patient
32 cohort study will have potential to monitor the epidemiological trends of MSK pain conditions
33 and contribute to health care quality improvement. The primary aims of this protocol are to 1)
34 describe the development of a MSK focused PBRN within the Swiss chiropractic setting; and 2)
35 describe the methodology of the first nested study to be conducted within the PBRN – an
36 observational prospective patient cohort pilot study.

38 **Methods and analysis**

39 This initiative is conceptualized with two distinct phases. Phase 1 focuses on the development of
40 the Swiss chiropractic PBRN, and will use a cross-sectional design to collect information from
41 chiropractic clinicians nationwide. Phase 2 will recruit consecutive patients aged 18 years or
42 older with MSK pain from community-based chiropractic practices participating in the PBRN
43 into a prospective chiropractic cohort pilot study. All data collection will occur through
44 electronic surveys offered in the three Swiss national languages (German, French, Italian) and
45 English. Surveys will be provided to patients prior to initial assessment, 1-hour after assessment
46 and at 2-, 6-, and 12-weeks after assessment.

48 **Ethics and dissemination**

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3 49 Ethics approval has been obtained from the independent research ethics committee of Canton
4
5 50 Zurich (BASEC-Nr: 2021-01479). Informed consent will be obtained electronically from all
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8 51 participants. Findings will be reported to stakeholders after each study phase, presented at local
9
10 52 and international conferences, and disseminated through peer-reviewed publications.
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14 54 **Trial registration**

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17 55 Phase 1 – Swiss chiropractic PBRN (ClinicalTrials.gov identifier: NCT05046249);
18
19 56 Phase 2 – Swiss chiropractic cohort (Swiss ChiCo) pilot study (ClinicalTrials.gov identifier:
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21 57 NCT05116020).
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25 59 **Strengths and limitations of this study**

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28 60 • Use of a flexible practice-based research network model will allow for a diverse range of
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31 61 nested study design types as well as the future expansion of the network.
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33 62 • Development of protocol methods is guided by patient and public involvement activities with
34
35 63 key stakeholders.
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37 64 • Sole use electronic data capture methods may lead to selective participation of both clinician
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39 65 and patient participants.
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41 66 • Maintenance of the practice-based research network and subsequent expansion of the patient
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43 67 cohort will depend on ongoing stakeholder support and involvement.
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49 69 **Keywords:** chiropractic, health care quality, musculoskeletal health, musculoskeletal pain,
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73 INTRODUCTION

74 Musculoskeletal (MSK) pain conditions are the leading cause of disability worldwide, with low
75 back pain being the largest single cause in over 160 countries, including Switzerland.[1, 2] This
76 health burden translates to an economic cost of approximately 6.6 billion Euros or about 2% of
77 Switzerland's total gross domestic product for low back pain alone.[3] Best practice
78 recommendations and systematic reviews on MSK pain largely focus primarily on regional pain
79 locations, such as low back pain or neck pain.[4-6] However, in the population and in primary
80 care settings, it is common that those experiencing a MSK pain complaint also present with co-
81 existing pain in another body region.[7, 8] There is increasing evidence suggesting that these
82 pain conditions, although localized to different regions, share similarities with respect to the
83 course of symptoms, prognostic factors, and clinical care recommendations.[9, 10] An entirely
84 regional focus to MSK health may create gaps in patient centered research and difficulties with
85 knowledge implementation in health care settings.

86 Further contributing to practice gaps, is the lack of practice-based data collection in
87 MSK health care research.[11] To help bridge the divide between research and practice,
88 countries such as the UK, Denmark, Sweden, and Australia have engaged in practice-based
89 research and worked with MSK-focused practice-based research networks (PBRNs).[12-14] A
90 PBRN is a group of at least 15 primary-care settings united under a commitment to advance the
91 science base of clinical care.[15] These "real world" clinical research environments allow for
92 sustained collaborations between practitioners, patients, and academicians facilitating the co-
93 creation of relevant research questions and production of clinically applicable results.[11, 15, 16]

94 The chiropractic scope of practice in Switzerland includes the diagnosis and management
95 of MSK pain conditions through manual medicine, prescription medication, and diagnostic
96 imaging (radiography, ultrasound, CT, MRI). As of December 2021, there were approximately

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3 97 326 chiropractors practicing across Switzerland with the large majority providing care in
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5 98 community-based settings. MSK complaints such as low back pain and neck pain, which result
6
7 99 in the largest burdens of disability are commonly seen in chiropractic practice.[17] Chiropractic
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9
10 100 health care centres may serve as useful settings to further investigate MSK pain conditions, to
11
12 101 understand what role chiropractors play in the current management of these conditions, and to
13
14 102 identify opportunities for Swiss MSK primary health care quality improvement. As management
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16 103 of MSK conditions moves away from traditional medical treatments and towards more physical
17
18 104 and preventative approaches, there is a need to describe non-pharmacological treatment options
19
20 105 to make informed decisions on how best to use this capacity in the current health care system.[4,
21
22 106 18]

26 107 Given the high burden of MSK pain conditions, which are frequently managed by
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28 108 chiropractors, and limited practice-based evidence on the topic of chiropractic care for MSK
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30 109 conditions, particularly in Switzerland, this protocol report outlines the creation of a nationwide
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32 110 PBRN and subsequent nested prospective cohort (Swiss ChiCo) pilot study for chiropractic
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34 111 patients with MSK pain. Once established, this PBRN will provide the framework to help
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36 112 monitor the epidemiological trends of MSK pain in primary care settings, contribute to MSK
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38 113 health care quality improvement, and support future development and growth of practice-based
39
40 114 MSK clinical research.

44 115 The main objectives of this protocol report are to: 1) describe the development of a
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46 116 MSK focused PBRN and describe the enrolment of Swiss chiropractors into the PBRN; and 2)
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48 117 describe the methods of the first nested study to be conducted within the PBRN – an
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50 118 observational prospective patient cohort pilot study.

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56 120 **METHODS AND ANALYSIS**

121 Study design

122 The Swiss chiropractic PBRN will use a substudy PBRN model, similar to that of the Australian
123 Chiropractic Research Network (ACORN).[12, 19, 20] In substudy PBRN models, data is
124 initially collected from participating clinicians/clinical practices through self-report to first
125 establish and describe characteristics of the PBRN. Following development, nested substudies
126 may be performed using this PBRN framework.

127 The current project will consist of two phases. Each project phase will have a specific
128 aim and report on two primary feasibility and clinical outcomes related to this aim. In phase 1,
129 we aim to develop the Swiss chiropractic PBRN and describe the demographics of participating
130 chiropractors at project initiation using a cross-sectional study design (ClinicalTrials.gov
131 identifier: NCT05046249). In phase 2, we aim to launch a 12-week observational prospective
132 Swiss chiropractic cohort (Swiss ChiCo) pilot study which will assess the feasibility for
133 longitudinal data collection and describe the clinical course of patients with MSK pain
134 presenting to Swiss chiropractors. (ClinicalTrials.gov identifier: NCT05116020). **Figure 1**
135 provides an overview of the two nested phases of this project.

137 Patient and public involvement

138 To guide development of this project, we hosted several events to gather information from key
139 stakeholders. Key stakeholders identified include the Swiss Chiropractic Association
140 (ChiroSuisse), the Swiss Chiropractic Patient Association (Pro Chiropractic Switzerland), Swiss
141 chiropractors, and an international group of researchers with experience in practice-based
142 research. Participatory engagement activities were first performed collaboratively with all
143 stakeholders and focused on study relevance, team building, project infrastructure development
144 and the collaborative creation of relevant research questions. A consensus-based understanding

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3 145 was reached by all members which outlined the need for more clinical MSK research within the
4
5 146 Swiss setting and a pledge to provide support to achieve this project goal. Other
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8 147 recommendations included the practicality to start with a small cohort study to first test data
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10 148 collection methods, as well to explore both clinical and feasibility related objectives to help drive
11
12 149 recruitment from community-based chiropractors and patients.
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15 150 Individualized one-on-one meetings were subsequently conducted to discuss specific
16
17 151 project methods with each stakeholder group. Recommendations provided by ChiroSuisse and
18
19 152 Pro Chiropractic Switzerland included the addition of several questions to the Swiss ChiCo pilot
20
21 153 study patient participant questionnaires. Consequently, questions relating to patient work status,
22
23 154 past use of chiropractic care, and use of other healthcare in MSK pain management were added.
24
25 155 Both associations also recommended increasing patient participant recruitment weighting for the
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27 156 Swiss ChiCo pilot study in the French and Italian language regions of Switzerland by 5% from
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29 157 what was initially proposed.
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33 158 One-on-one meetings with Swiss chiropractors were carried out for the purpose of
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35 159 understanding how best to integrate study processes into clinical practice settings. According to
36
37 160 all clinician advisors, the recruitment of approximately 5-10 consecutive patients per clinical
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39 161 practice was feasible. Outside of clinical workflow processes, patient participant inclusion
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41 162 criteria were revised from new healthcare seeking for a MSK pain condition (operationalized as
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43 163 not having received any (patient-reported) health care for current MSK complaint) to new
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45 164 conservative healthcare seeking for a MSK complaint (not having received any (patient-reported)
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47 165 chiropractic, physiotherapy, osteopathy, or massage therapy for current MSK complaint in the
48
49 166 last 1 month, and not a follow-up visit). Many clinician advisors recommended this change based
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52 167 on the clinical profile of their patients and insurance coverage practices in Switzerland (where
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3 168 chiropractic care typically follows an initial visit with a primary care physician or general
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5 169 practitioner).

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8 170 Participatory engagement is an iterative process and requires continuous reflection of
9
10 171 previous project processes and results to inform subsequent phases (action-reflection
11
12 172 process).[21] Following completion of each project phase, individual meetings with each
13
14 173 stakeholder group will be scheduled to disseminate findings, discuss how best to generate future
15
16 174 PBRN growth, and explore ways to expand the MSK clinical cohort study.
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21 176 **Phase 1 – Development of the Swiss chiropractic PBRN**

22 177 **Participants**

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24 178 All registered active chiropractor members (fully licensed chiropractors and postgraduate
25
26 179 assistant chiropractors) of ChiroSuisse will be eligible and invited to participate. Approximately
27
28 180 98% of all practicing Swiss chiropractors hold an active membership with ChiroSuisse (personal
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30 181 communication, April 22, 2021).
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34 182

35 183 **Recruitment**

36
37 184 To aid with clinician recruitment, we plan to launch the PBRN development phase on September
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39 185 9, 2021 at the annual ChiroSuisse Continuing Education (CE) Convention 2021 (Lausanne,
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41 186 September 9-11, 2021). Clinicians will have the opportunity to ask questions directly of the
42
43 187 project team, test electronic study methods, sign up as a clinician member of the PBRN, and
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45 188 provide input and feedback for the subsequent Swiss ChiCo pilot study. Those interested, will be
46
47 189 invited to join the Swiss chiropractic PBRN by scanning a quick response (QR) code and
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49 190 completing the linked clinician entry survey using personal mobile devices. For those who do not
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51 191 attend the conference, we plan to use electronic email invitations containing the Research
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3 192 Electronic Data Capture (REDCap) PBRN entry survey link. This invitation will be paired with
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5 193 an information sheet outlining project goals, good conduct procedures for the PBRN and
6
7 194 subsequent substudy involvement, and risks and benefits for participation. Clinician recruitment
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9 195 for the Swiss chiropractic PBRN will be scheduled to end on December 19, 2021. Similar to
10
11 196 other PBRNs within the scope of chiropractic and MSK health, we hope to achieve a clinician
12
13 197 participation proportion of approximately 50%. [19, 22]
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17 198
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19 199 **Data collection procedures and variables**

20 200 All data acquisition will occur electronically using the REDCap web application platform. [23]
21
22 201 Clinicians participating in the Swiss chiropractic PBRN will be asked to fully complete 1
23
24 202 electronic survey of approximately 10 minutes duration. Clinician surveys will only be provided
25
26 203 in English as this is the official language used for communication by ChiroSuisse. **Table 1**
27
28 204 outlines the specific data which will be collected from clinicians for the development of the
29
30 205 Swiss chiropractic PBRN. **Supplementary file 1** provides the data dictionary and specific
31
32 206 response options which will be used for the Swiss chiropractic PBRN.
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215 **Table 1.** Outcome measures to be collected for description of the Swiss chiropractic PBRN

Construct	Measurement method / instrument	Inception
Demographics	Gender, age, year of graduation	X
Practice	Number of years in practice, location of practice	X
Characteristics	Primary language used in practice	X
	Number of healthcare practitioners involved in practice	X
	Type of healthcare offered	X
	Average number of patients seen per week	X
	Types of patients seen within practice	X
	Frequency of complaints seen within practice	X
Confidence	Practitioner self-confidence scale (PCS) [24]	X
Beliefs and Attitudes	Pain attitudes and beliefs scale – Musculoskeletal (PABS-MSK) [25]	X
	Level of motivation to be involved in the Swiss ChiCo pilot	X
Digitalization of chiropractic practices	Electronic patient record system in practice	X
	Encrypted email use in practice	X
	Offering virtual care in practice	X
COVID-19 aspects	Change in quality of life, change in patient numbers, change in work hours, change in use of telehealth/e-health services.	X

216

217 Main outcomes and analysis

218 The first primary clinical outcome will be practitioner self-confidence in the clinical
 219 management of patients with low back pain (as measured by the practitioner self-confidence
 220 scale (PCS)).[24] The PCS contains four items with a total score of 20. A score of 4 represents
 221 higher self-confidence in the management of patients with low back pain, while a score of 20
 222 represents lower self-confidence. The second primary clinical outcome will be practitioner
 223 biomedical versus biopsychosocial MSK pain treatment orientation (as measured by the pain
 224 attitudes and beliefs scale, musculoskeletal version (PABS-MSK)).[25] The PABS-MSK
 225 contains two domains, with a higher score on either the domains (each 10-items, with a score
 226 range of 10-60) representing higher biomedical and biopsychosocial MSK pain treatment
 227 orientation. The order of 20 items of the PABS-MSK will be randomized using the
 228 “randomizeR” package in RStudio and administered as a single questionnaire so as to mask
 229 respondents to the specific treatment orientation domains. Both primary clinical outcomes will
 230 be reported as means and standard deviations (SDs), with 95% confidence intervals (CIs)

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3 231 calculated as appropriate. Primary feasibility outcomes of 1) clinician participation proportion in
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5 232 the Swiss chiropractic PBRN will be assessed by reporting the proportion of all eligible
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8 233 clinicians that enroll in the PBRN development phase using raw numbers and percentages; and
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10 234 2) motivation for clinician participation in the Swiss ChiCo pilot study will be assessed using a
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12 235 visual analog scale (VAS, 0-100), with higher scores reflecting higher motivation for
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14 236 participation. Level of motivation to participate in the Swiss ChiCo pilot study will be reported
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16 237 as means, SDs, and with 95% CIs calculated as appropriate. Participants who score 70 or more
17
18 238 on the VAS will be defined as “highly motivated”, and described using raw numbers, proportions
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20 239 and 95% CIs.
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24 240

26 241 **Phase 2 – The Swiss chiropractic cohort (Swiss ChiCo) pilot study**

28 242 **Participants**

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31 243 Patients will be eligible to participate if they are 18 years of age or older; are seeking new
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33 244 conservative healthcare for a MSK pain condition (new conservative healthcare seeking is
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35 245 operationalised as not having received (patient-reported) chiropractic care, physiotherapy,
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37 246 osteopathy or massage therapy for their current MSK complaint in the 1 month prior to their
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39 247 current initial visit to the chiropractor and not a follow-up visit); consent to chiropractic
40
41 248 treatment; are able to respond to surveys in German, French, Italian, or English; have an active
42
43 249 email account; and are willing and able to complete electronic study questionnaires. Patient
44
45 250 participants will be excluded if they present to clinician practices with red flag symptoms (i.e.,
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47 251 saddle anesthesia, loss of bowel and/or bladder control, history of major trauma, fracture, fever,
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49 252 severe or rapidly progressive neurologic deficit, sudden unexplained weight loss), and/or with a
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253 non-MSK based pain condition based on the chiropractor's clinical suspicion that symptoms
254 relate to a systemic disease.

255

256 **Recruitment**

257 Following the development of the Swiss chiropractic PBRN, we plan to recruit a subset of
258 clinicians to participate in the Swiss ChiCo pilot study. Chiropractors will be recruited through
259 general interest, VAS motivation score (≥ 70) on the PBRN entry questionnaire, and using a
260 purposeful sampling approach based on Swiss chiropractic clinician distribution across German,
261 French, and Italian language regions of Switzerland (55% DE, 35% FR, 10% IT). The Swiss
262 ChiCo pilot study aims to recruit at least 20 chiropractors. Participating chiropractors will be
263 asked to recruit new consecutive patient participants from their clinical practices. We will hold
264 pilot study introductory meetings with participant clinicians and clinical staff to reinforce study
265 objectives, methods and procedures prior to the tentative date for initiation of the patient cohort
266 pilot study recruitment of April 01, 2022. During previous patient and public involvement work,
267 Swiss chiropractors described the recruitment of 5 to 10 consecutive patients with new
268 conservative onset MSK pain as feasible. Based on this work, we will aim to recruit at least 100
269 patient participants to enable a preliminary characterisation of the population, enabled by
270 representative selection of chiropractic clinicians with respect to language region. A stopping
271 point for recruitment will be considered at 200 patients.

272 Potentially eligible patients visiting a participating clinician will be first provided a study
273 flyer, which will briefly outline the study objectives and participation requirements. Patients will
274 then be asked to rate their initial level of interest to participate using a brief electronic survey.

275 Those not interested will be prompted to provide reasons for non-participation. Patients

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3 276 expressing interest in participation will be forwarded to the full study information form and
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5 277 electronic informed consent procedure. This in-clinic patient participant procedure was
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7 278 developed in consultation with Swiss chiropractic clinicians (both women and men) across all
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9 279 language regions. To aid with workflow, clinicians expressed interest in asking new patients to
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11 280 arrive approximately 20 minutes prior to their appointment to complete electronic study forms.
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13 281 Clinicians also recommended adding “disruption to clinic workflow” as an option for eligible
14
15 282 patient non-participation. This survey option would be selected by clinical staff when patient
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17 283 participant recruitment may greatly impact clinical workflow (e.g., patient was late for visit,
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19 284 emergency visit). **Figure 2** outlines the in-clinic patient recruitment procedure.
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27 **Data collection procedures and variables**

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29 287 Immediately following completion of the in-clinic recruitment procedure, study participants will
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31 288 be forwarded to the first patient survey (pre-visit patient survey) on an electronic device (mobile
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33 289 phone or tablet). This pre-visit initial patient survey will collect information on clinical measures
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35 290 that are likely to be influenced by the first visit (i.e., pain impact, musculoskeletal health status,
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37 291 illness perception).[26-28] The pre-visit patient survey will take approximately 5 minutes to
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39 292 complete and is the only survey that is completed at clinical practices. Subsequent questionnaires
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41 293 will take approximately 10-12 mins to complete and are emailed directly to patient participants 1
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43 294 hour after (post-visit patient survey), and at 2-, 6-, and 12-weeks following completion of the
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45 295 pre-visit survey. REDCap will be used for longitudinal data collection, with survey data
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47 296 transmitted automatically to the research team at Balgrist University Hospital and the University
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49 297 of Zurich. Similar administration procedures were performed for the Danish chiropractic low
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51 298 back pain cohort study.[29] Patient participant surveys will be provided in English, German,
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53 299 French and Italian, with patients having the ability to choose their preferred language for
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300 completion. Validated, translated versions of the patient reported outcome measures (PROMs)
 301 will be used when possible.[30-37] If not available, translation of the PROMs by a native
 302 speaker will be performed. **Table 2** outlines specific outcome measures and timing of data
 303 collection for the Swiss ChiCo pilot study. **Supplementary file 2** provides the data dictionary
 304 and specific response options to be used.

306 **Table 2.** Outcome measures and timing of data collection for the Swiss ChiCo patient pilot study

Construct	Measurement method / instrument	Pre-visit	Post-visit	Wk 2	Wk 6	Wk 12
Clinic	Clinic name, clinician	X				
Demographics	Gender, age, nationality, level of education, smoking status		X			
	Work status, time lost from work due to pain complaint		X	X	X	X
Injury characteristics	Naïve to chiropractic care		X			
	Duration of complaint		X			
	Location of pain complaint		X			
	Pain, enjoyment, general activity (PEG) scale[26]	X	X	X	X	X
	Other healthcare professional involved in care		X	X	X	X
	Number of chiropractic visits since initial visit			X	X	X
Pain medication use	Medication use for pain reduction (prescription or non-prescription)		X	X	X	X
Imaging use	Diagnostic imaging use for this specific MSK complaint			X	X	X
	Diagnostic imaging received in the past year for other complaint		X			
Psychosocial profile	Örebro Musculoskeletal Pain Screening Questionnaire – Short Form (ÖMPSQ short)[38]		X			
COVID-19 aspects	Quality of life now compared to before COVID-19		X			
	Activity compared to before COVID-19		X			
	Cancelled medical treatment due to COVID-19		X			
MSK health status	Musculoskeletal health questionnaire (MSK-HQ)[27]	X	X	X	X	X
Illness perception	Brief illness perception questionnaire (Brief IPQ, Question 9)[28]	X				
Change in condition	Patient Global Impression of Change (PGIC) scale[39]			X	X	X

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308 **Main outcomes and analysis**

309 The prespecified primary clinical outcomes will be: 1) change in musculoskeletal pain impact, as
 310 measured by the 3-item pain, enjoyment, and general activity scale (PEG scale, score range 0-
 311 10)[26] with higher scores representing worse outcomes; and 2) change in MSK health status, as

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3 312 measured by the musculoskeletal health questionnaire (MSK-HQ, score range 0-56)[27] with
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5 313 higher scores reflecting better health status. Clinical outcomes of the PEG scale and MSK-HQ
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7 314 prior to initial chiropractic assessment will be reported as means, SDs, and 95% CIs; and clinical
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9 315 course of patient pain impact and MSK health status will be reported as a mean difference with
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11 316 SDs and 95% CIs as appropriate. The primary feasibility outcomes will be: 1) the proportion of
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13 317 invited patients presenting to chiropractic practices who subsequently agree to participate in this
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15 318 study; and 2) change in patient participant follow-up and retention over 12 weeks. Invited patient
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17 319 participation will be reported as raw numbers and proportions. Patient participant retention will
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19 320 be reported as the proportion of enrolled participants who complete follow-up surveys across 12-
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21 321 weeks. Based on the definition of a PBRN from the Agency for Healthcare Research and Quality
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23 322 (AHRQ),[15] it will be deemed feasible to initiate the Swiss chiropractic PBRN and expand the
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25 323 Swiss ChiCo pilot study if at least 15 clinical practices agree to participate in the Swiss
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27 324 chiropractic PBRN and each recruit at least 5 patients for enrolment in the Swiss ChiCo pilot
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29 325 study.
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327 **Ethics and dissemination**

38 328 The Swiss chiropractic PBRN and Swiss ChiCo pilot study have been reviewed and jointly
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40 329 approved by the independent research ethics committee of Canton Zurich (BASEC-Nr: 2021-
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42 330 01479). Informed consent will be obtained from both clinician and patient participants
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44 331 electronically upon entry into the Swiss chiropractic PBRN and the Swiss ChiCo pilot study.
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46 332 Clinician responses for PBRN development will be stored securely within REDCap, but not
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48 333 anonymous due to necessity of identifying clinicians to participate in future nested research
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50 334 projects. Data collected for PBRN development and for the Swiss ChiCo pilot study will be
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3 335 stored as two separate projects within REDCap. Individual-level data will not be shared with
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5 336 study stakeholders.

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8 337 The findings from the Swiss chiropractic PBRN and the Swiss ChiCo pilot study will be
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10 338 disseminated first to the various stakeholder groups involved in study development through
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12 339 individual meetings. Findings will also be presented through abstract and poster presentations at
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14 340 academic conferences and fully reported in peer-reviewed publications.

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18 19 342 **Availability of data and materials**

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21 343 Data from this work will be made available for research purposes. Requests, including a synopsis
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23 344 of the study proposal, can be addressed to the corresponding author.

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27 28 346 **DISCUSSION**

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30 347 This project is designed to attract a large proportion of Swiss chiropractors into a nationwide
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32 348 PBRN and subsequently recruit patients from participating clinics into a longitudinal cohort pilot
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34 349 study. This approach combines a substudy PBRN model, with longitudinal electronic capture
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36 350 more readily seen in register-based approaches. The unique collaboration with clinicians,
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38 351 advocacy groups and academicians, a growing trend in health care research, has led to the
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40 352 promotion of research objectives which are clinically relevant and patient-centred, and a study
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42 353 implementation strategy vetted by Swiss chiropractic primary care clinicians.

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45 354 Traditional health care research approaches typically face challenges with regards to
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47 355 study relevance, patient recruitment, and knowledge translation.[11, 40] The use of a
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49 356 participatory research approach can help overcome such challenges by integrating the diverse
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51 357 knowledge, values, and preferences of non-academics into the research process. An example of a
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53 358 longitudinal register-based study successfully implementing this approach is the Swiss Multiple
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3 359 Sclerosis Registry (SMSR).[41] This project was designed in collaboration with the Multiple
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5 360 Sclerosis (MS) community in Switzerland to tackle the lack of epidemiological data and to
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7 361 promote patient-perspectives in MS research. Participatory elements of the SMSR include a
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10 362 flexible approach to study involvement based on participant comfort, involvement of patients in
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12 363 the study design and execution, and data feedback to provide ongoing results to participants. Due
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14 364 to such efforts, recruitment for the SMSR exceeded expectations; with the goal of 400
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16 365 participants achieved in under 20 days.[42] A second example of a participatory research
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18 366 approach driving recruitment are the recently established national osteopathy PBRNs of
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20 367 Australia (ORION) and New Zealand (ORC-NZ).[22] Here, the project team engaged with both
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22 368 osteopathic communities for 12 months prior to clinician recruitment. Today, these two PBRNs
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24 369 represent the largest coverage of any voluntary health profession PBRN, with 43.5% of all
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26 370 registered osteopaths in Australasia. The Swiss chiropractic PBRN has followed a similar
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28 371 approach, with community outreach and promotion efforts lasting 12 months prior to clinician
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30 372 recruitment.

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33 373 What remains unclear is if early engagement of stakeholders can overcome the unique
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35 374 limitations of electronic observational studies. Typically, unequal access to technology resources
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37 375 and lack of digital literacy can lead to a young, well-educated, and high socio-economic status
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39 376 study sample. For example, participants in the SMSR who opt for physical forms are older, show
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41 377 increased care-seeking behaviour, and suffer from more progressive illness compared to those
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43 378 using electronic forms. This trend also extends to clinician participants, as our own 2019 survey
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45 379 on eHealth technology use among Swiss chiropractors showed clinicians 65 years and over were
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47 380 74% less likely to use electronic health records (EHRs) when compared to the those under 40
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49 381 years.[43] To limit this threat to external validity, the Swiss chiropractic PBRN will recruit
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51 382 clinicians through both online and in-person channels. In addition, chiropractic clinician
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3 383 recruitment for the Swiss ChiCo pilot study will be proportionally overweighted in French and
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5 384 Italian language regions. These areas have shown lowered use eHealth technology use when
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8 385 compared to the German speaking regions of Switzerland. To recruit a diverse group of patient
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10 386 participants, clinicians will be asked to consecutively recruit eligible patients from private
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12 387 practice. Although consecutive recruitment does not eliminate the threat of self-selection bias, it
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14 388 ensures all eligible participants seeking chiropractic care will be aware of the study and invited
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16 389 to participate in a nonselective manner. The Swiss chiropractic PBRN and Swiss ChiCo pilot
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18 390 study presents a model for PBRN development and rapid engagement of a newly created clinical
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20 391 research network. Once complete, this PBRN will serve as a platform for answering important
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22 392 research questions in the field of MSK primary health care.
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28 394 **Figure 1.** Nested design of the Swiss chiropractic PBRN and the Swiss ChiCo pilot study
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33 396 **Figure 2.** Summary of the Swiss ChiCo pilot study in-clinic patient participant recruitment
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40
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42
43 401 engagement and support.
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48 403 **AUTHOR CONTRIBUTIONS**

49
50 404 CAH and RL conceived the project idea. RL, CAH, AK, VvW, MAP, and LH contributed to the
51
52 405 design of the protocol. RL and CAH designed, undertook, and coordinated stakeholder
53
54 406 participatory activities. RL and CAH led the drafting of the protocol manuscript. All authors
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2
3 407 gave important intellectual input and provided critical review of the protocol manuscript and
4
5 408 approved the final version of the manuscript. CAH obtained funding. RL and CAH are the
6
7 409 guarantors of this manuscript. The corresponding author attests that all listed authors meet
8
9 410 authorship criteria and that no others meeting the criteria have been omitted.

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417

418 **COMPETING INTERESTS**

419 The authors declare that they have no competing interests.

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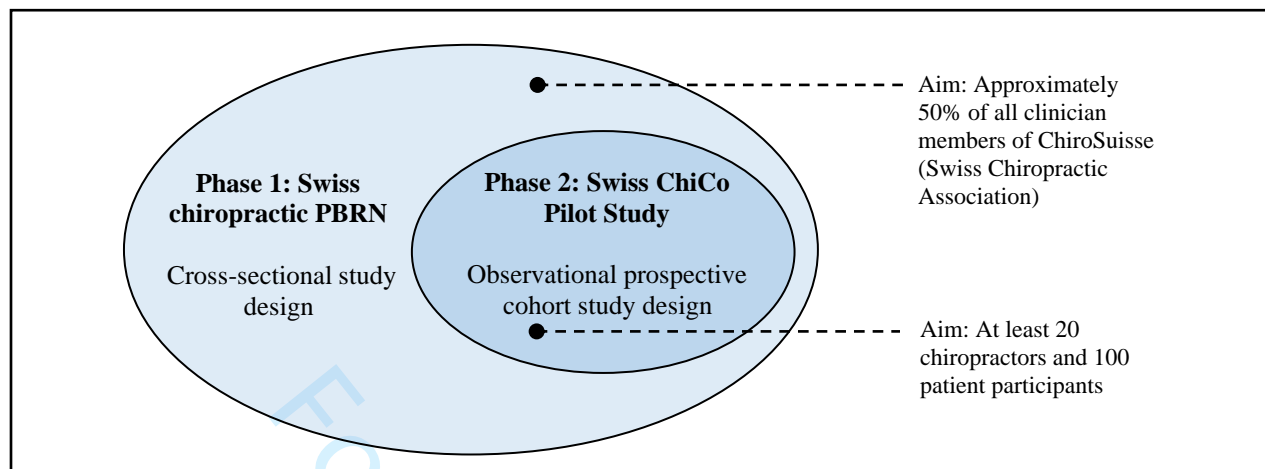
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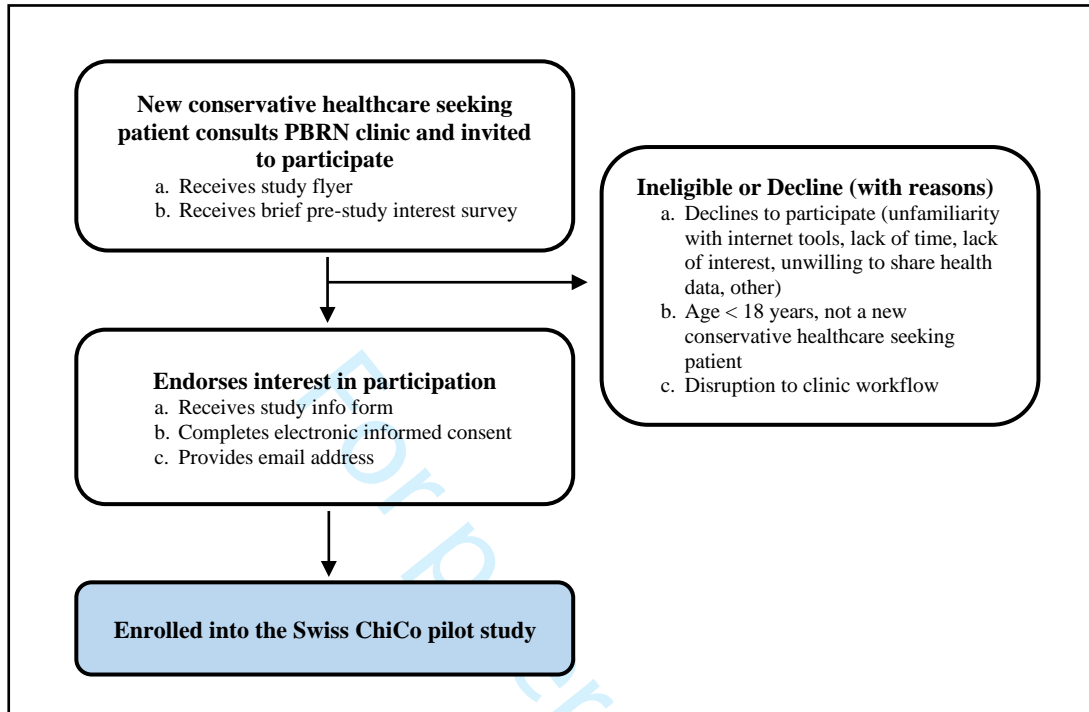
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Supplementary material 2. Patient-reported variables captured in the Swiss ChiCo pilot patient cohort

Construct	Item Content	Variable Code	Choices, Calculations, OR Slider Labels	Branching Logic
Reasons for non-participation Collected at in-clinic recruitment	Record ID Are you interested in participating in this study? Reasons for not participating Other reason for not participating For clinic staff only	record_id chico_interest nonparticipation nonparticipation_other clinic_disrup	1, Yes 2, No 1, No email address 2, Unfamiliar with electronic or internet tools 3, Lack of time 4, Lack of interest in the study 5, Data privacy concerns 6, Other 1, Disruption to clinic workflow	[chico_interest] = '2' [nonparticipation(6)] = '1' [nonparticipation(6)] = '1'
Pain, enjoyment and general activity (PEG) scale Collected at baseline, 1 hour, 2-, 6-, and 12-wks	What number best describes your pain on average in the past week? What number best describes how, during the past week, pain has interfered with your enjoyment of life? What number best describes how, during the past week, pain has interfered with your general activity?	peg_q1_beforetex / peg_q1 / peg_q1_2wks / peg_q1_6wks / peg_q1_12wks peg_q2_beforetex / peg_q2 / peg_q2_2wks / peg_q2_6wks / peg_q2_12wks peg_q3_beforetex / peg_q3 / peg_q3_2wks / peg_q3_6wks / peg_q3_12wks	1, 0 = No pain 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Pain as bad as you can imagine 1, 0 = Does not interfere 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Completely interferes 1, 0 = Does not interfere 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Completely interferes	
Musculoskeletal health questionnaire (MSK-HQ) Collected at baseline, 1 hour, 2-, 6-, and 12-wks	1. Pain/stiffness during the day How severe was your usual joint or muscle pain and/or stiffness overall during the day in the last 2 weeks 2. Pain/stiffness during the night How severe was your usual joint or muscle pain and/or stiffness overall during the night in the last 2 weeks? 3. Walking How much have your symptoms interfered with your ability to walk in the last 2 weeks? 4. Washing/Dressing How much have your symptoms interfered with your ability to wash or dress yourself in the last 2 weeks? 5. Physical activity levels How much has it been a problem for you to do physical activities (e.g. going for a walk or jogging) to the level you want because of your joint or muscle symptoms in the last 2 weeks? 6. Work/daily routine How much have your joint or muscle symptoms interfered with your work or daily routine in the last 2 weeks (including work & jobs around the house)? 7. Social activities and hobbies How much have your joint or muscle symptoms interfered with your social activities and hobbies in the last 2 weeks? 8. Needing Help How often have you needed help from others (including family, friends or carers) because of your joint or muscle symptoms in the last 2 weeks? 9. Sleep How often have you had trouble with either falling asleep or staying asleep because of your joint or muscle symptoms in the last 2 weeks? 10. Fatigue or low energy How much fatigue or low energy have you felt in the last 2 weeks? 11. Emotional well-being How much have you felt anxious or low in your mood because of your joint or muscle symptoms in the last 2 weeks? 12. Understanding of your condition and any current treatment Thinking about your joint or muscle symptoms, how well do you feel you understand your condition and any current treatment (including your diagnosis and medication)? 13. Confidence in being able to manage your symptoms How confident have you felt in being able to manage your joint or muscle symptoms by yourself in the last 2 weeks (e.g. medication, changing lifestyle)? 14. Overall Impact How much have your joint or muscle symptoms bothered you overall in the last 2 weeks? Physical activity Levels In the past week, on how many days have you done a total of 30 minutes of moderate to vigorous activity?	mskhq_q1_beforetex / mskhq_q1 / mskhq_q1_2wks / mskhq_q1_6wks / mskhq_q1_12wks mskhq_q2_beforetex / mskhq_q2 / mskhq_q2_2wks / mskhq_q2_6wks / mskhq_q2_12wks mskhq_q3_beforetex / mskhq_q3 / mskhq_q3_2wks / mskhq_q3_6wks / mskhq_q3_12wks mskhq_q4_beforetex / mskhq_q4 / mskhq_q4_2wks / mskhq_q4_6wks / mskhq_q4_12wks mskhq_q5_beforetex / mskhq_q5 / mskhq_q5_2wks / mskhq_q5_6wks / mskhq_q5_12wks mskhq_q6_beforetex / mskhq_q6 / mskhq_q6_2wks / mskhq_q6_6wks / mskhq_q6_12wks mskhq_q7_beforetex / mskhq_q7 / mskhq_q7_2wks / mskhq_q7_6wks / mskhq_q7_12wks mskhq_q8_beforetex / mskhq_q8 / mskhq_q8_2wks / mskhq_q8_6wks / mskhq_q8_12wks mskhq_q9_beforetex / mskhq_q9 / mskhq_q9_2wks / mskhq_q9_6wks / mskhq_q9_12wks mskhq_q10_beforetex / mskhq_q10 / mskhq_q10_2wks / mskhq_q10_6wks / mskhq_q10_12wks mskhq_q11_beforetex / mskhq_q11 / mskhq_q11_2wks / mskhq_q11_6wks / mskhq_q11_12wks mskhq_q12_beforetex / mskhq_q12 / mskhq_q12_2wks / mskhq_q12_6wks / mskhq_q12_12wks mskhq_q13_beforetex / mskhq_q13 / mskhq_q13_2wks / mskhq_q13_6wks / mskhq_q13_12wks mskhq_q14_beforetex / mskhq_q14 / mskhq_q14_2wks / mskhq_q14_6wks / mskhq_q14_12wks mskhq_activity_beforetex / mskhq_activity / mskhq_activity_2wks / mskhq_activity_6wks / mskhq_activity_12wks	1, Not at all 2, Slightly 3, Moderately 4, Fairly severe 5, Very severe 1, Not at all 2, Slightly 3, Moderately 4, Fairly severe 5, Very severe 1, Not at all 2, Slightly 3, Moderately 4, Severely 5, Unable to walk 1, Not at all 2, Slightly 3, Moderately 4, Severely 5, Unable to wash or dress myself 1, Not at all 2, Slightly 3, Moderately 4, Very much 5, Unable to do physical activities 1, Not at all 2, Slightly 3, Moderately 4, Severely 5, Extremely 1, Not at all 2, Slightly 3, Moderately 4, Severely 5, Extremely 1, Not at all 2, Rarely 3, Sometimes 4, Frequently 5, All the time 1, Not at all 2, Rarely 3, Sometimes 4, Frequently 5, Every night 1, Not at all 2, Slight 3, Moderate 4, Severe 5, Extreme 1, Not at all 2, Slightly 3, Moderately 4, Severely 5, Extremely 1, Completely 2, Very well 3, Moderately 4, Slightly 5, Not at all 1, Extremely 2, Very 3, Moderately 4, Slightly 5, Not at all 1, Not at all 2, Slightly 3, Moderately 4, Very much 5, Extremely 1, 0 days 2, 1 day 3, 2 days 4, 3 days 5, 4 days 6, 5 days 7, 6 days 8, 7 days	

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Construct	Item Content	Variable Code	Choices, Calculations, OR Slider Labels	Branching Logic
Brief illness perception (IPQ brief) Collected at baseline	Please list in rank-order the three most important factors that you believe caused your current pain complaint 1 2 3	briefillness ipq_q1 ipq_q2 ipq_q3		
Demographics Collected 1 hour after initial assessment	Sex Nationality Highest level of education At present, are you working How would you describe the total physical strain caused by your work? Have you missed any days of work due to your current pain complaint? How many days of sick leave have you had in the last 2 weeks ? Smoking Status How much do you smoke on average per day? Have you visited a chiropractor before?	sex_p nationality education job workstrain sick_leave n_sickleave smoking n_cigarettes newpatient	1, Male 2, Female 1, Swiss 2, Non-Swiss 1, Compulsory 2, Secondary 3, Tertiary 1, Full time at your usual job 2, Full time at a lighter job 3, Part time 4, Not working - disability 5, Not working - IV/pensioner applicant 1, Homemaker/Househusband 7, Retired (not disability) 8, Unemployed 9, Student 1, Very light 2, Light 3, Somewhat strenuous 4, Strenuous 5, Very strenuous 1, Yes No 1, Current smoker 2, Previous smoker 3, Never smoker 1, I am new to chiropractic 2, I have visited a chiropractor before	[job] = '1' or [job] = '2' or [job] = '3' or [job] = '6' or [job] = '9' [sick_leave] = '1' [smoking] = '1'
Injury Characteristics Collected 1 hour after initial assessment	Have you visited a medical doctor for your current pain complaint? Were you referred to chiropractic care for your pain complaint from a healthcare professional? Which healthcare professional referred you to chiropractic care? Please specify which healthcare professional referred you to chiropractic care. How long has it been since your current pain complaint began? Main location of pain complaint Please specify the main location of your pain complaint Are you currently taking medication to reduce your pain?	md_currentpain referral_source herefer_specify hc_refer_other date_of_inj pain_complaint pain_complaint_other medication	1, Yes No 1, Yes No 1, Other chiropractor 2, Family practitioner 3, Internist 4, Orthopaedic surgeon 5, Physical therapist 6, Massage therapist 7, Other 1, 1-2 days 2, 3-7 days 3, 1-2 weeks 4, 2-4 weeks 5, 1-3 months 6, 4-12 months 7, More than 12 months 1, Low back pain 2, Low back pain with leg pain 3, Neck pain 4, Neck pain with arm pain 5, Middle back pain 6, Headache 7, Shoulder pain 8, Hip pain 9, Knee pain 10, Pain in multiple areas 11, Other 1, Yes, prescription medication 2, Yes, non-prescription medication 3, No	[referral_source] = '1' [herefer_specify] = '7' [pain_complaint] = '11'
Imaging Use Collected 1 hour after initial assessment	In the last 1 month have you received any diagnostic imaging for your current pain complaint? X ray (radiography) in the last 1 month? Ultrasound scan in the last 1 month? MRI scan in the last 1 month? CT scan in the last 1 month? In the last 1 year have you received diagnostic imaging for any pain complaint? X-ray (radiography) in the last 1 year? Ultrasound scan in the last 1 year? MRI scan in the last 1 year? CT scan in the last 1 year?	image_postvisit xray_postvisit ultra_postvisit mri_postvisit ctscan_postvisit imaging1y_postvisit xray_1yr ultrasound_1yr mri_1yr ctscan_1yr	1, Yes No 1, Yes No 3, Unsure 1, Yes No 3, Unsure 1, Yes No 3, Unsure 1, Yes No 3, Unsure 1, Yes No 1, Yes No 3, Unsure 1, Yes No 3, Unsure 1, Yes No 3, Unsure 1, Yes No 3, Unsure	[image_postvisit] = '1' [image_postvisit] = '1' [image_postvisit] = '1' [image_postvisit] = '1' [imaging1y_postvisit] = '1' [imaging1y_postvisit] = '1' [imaging1y_postvisit] = '1' [imaging1y_postvisit] = '1'
COVID-19 aspects Collected 1 hour after initial assessment	How is your quality of life at the moment compared to the time before the COVID-19 pandemic? How are your physical activity habits at the moment compared to the time before the COVID-19 pandemic? Have you been unable to seek planned or necessary medical treatment because of the COVID-19 pandemic? What treatment could you not participate in because of the COVID-19 pandemic? Would you be interested in receiving virtual or telehealth chiropractic sessions?	patient_cov_1 pat_cov_2 pat_cov_3 pat_cov_4 virtual	1, Better 2, Similar 3, Worsened 1, Better 2, Similar 3, Worsened 1, Yes No 1, Yes No 3, Unsure	[pat_cov_3] = '1'

Construct	Item Content	Variable Code	Choices, Calculations, OR Slider Labels	Branching Logic
Orebro Musculoskeletal Pain Screening Questionnaire - Short Collected 1 hour after initial assessment	How long have you had your current pain complaint? How would you rate the pain that you have had during the past week? How tense or anxious have you felt in the past week? How much have you been bothered by feeling depressed in the past week? In your view, how large is the risk that your current pain may become persistent? In your estimation, what are the chances you will be working your normal duties in 3 months? An increase in pain is an indication that I should stop what I'm doing until the pain decreases. I should not do my normal work with my present pain. I can do light work for an hour I can sleep at night.	omps_q1 omps_q2 omps_q5 omps_q6 omps_q7 omps_q8 omps_q9 omps_q10 omps_q3 omps_q4	1, 0 = No pain 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Pain as bad as it could be 1, 0 = Absolutely calm and relaxed 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = As tense and anxious as I've ever felt 1, 0 = Not at all 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Extremely 1, 0 = No risk 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Very large risk 1, 0 = No chance 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Very large chance 1, 0 = Completely disagree 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Completely agree 1, 0 = Completely disagree 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Completely agree 1, 0 = Can't do it because of the pain problem 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Can do it without pain being a problem 1, 0 = Can't do it because of the pain problem 2, 1 3, 2 4, 3 5, 4 6, 5 7, 6 8, 7 9, 8 10, 9 11, 10 = Can do it without pain being a problem	
Follow-up Questionnaire: injury characteristics and imaging use Collected at 2-, 6-, and 12-wks	In the last 2 wks / 4 wks / 6 wks have you had any follow-up visits with the chiropractor for your pain complaint? How many times have you seen your chiropractor in the last 2 wks / 4 wks / 6 wks? In the last 2 wks / 4 wks / 6 wks have you visited another healthcare professional other than your chiropractor for your pain complaint? How many times have you visited another healthcare professional in the last 2 wks / 4 wks / 6 wks? Medical doctor visit in the last 2 wks / 4 wks / 6 wks for your pain complaint? Physiotherapist visit in the last 2 wks / 4 wks / 6 wks for your pain complaint? Other healthcare professional seen in the last 2 wks / 4 wks / 6 wks for your pain complaint? Which other healthcare professional did you see? Are you currently taking medication to reduce your pain? Have you missed any days of work due to your pain complaint in the last 2 wks / 4 wks / 6 wks? How many days of sick leave have you had in the last 2 wks / 4 wks / 6 wks due to your pain complaint? In the last 2 wks / 4 wks / 6 wks have you received any diagnostic imaging for your pain complaint? X-Ray (radiography) in the last 2 wks / 4 wks / 6 wks Ultrasound scan in the last 2 wks / 4 wks / 6 wks MRI scan in the last 2 wks / 4 wks / 6 wks CT scan in the last 2 wks / 4 wks / 6 wks	fu_chiro_2wks / fu_chiro_6wks / fu_chiro_12wks nfu_chiro_2wks / nfu_chiro_6wks / nfu_chiro_12wks hc_2wks / hc_6wks / hc_12wks nfu_otherhealth_2wks / nfu_otherhealth_6wks / nfu_otherhealth_12wks gp_2wks / gp_6wks / gp_12wks physo_2wks / physo_6wks / physo_12wks otherhealth_2wks / otherhealth_6wks / otherhealth_12wks specif_otherhealth_2wks / specif_otherhealth_6wks / specif_otherhealth_12wks medication_2wks / medication_6wks / medication_12wks sickleave_2wks / sickleave_6wks / sickleave_12wks n_sickleave_2wks / n_sickleave_6wks / n_sickleave_12wks imaging_2wks / imaging_6wks / imaging_12wks xray_2wks / xray_6wks / xray_12wks ultra_2wks / ultra_6wks / ultra_12wks mri_2wks / mri_6wks / mri_12wks ct_2wks / ct_6wks / ct_12wks	1, Yes 2, No 1, One 2, 2-4 times 3, More than 4 times 1, Yes 2, No 1, One 2, 2-4 times 3, More than 4 times 1, Yes 2, No 1, Yes 2, No 1, Yes 2, No 1, Yes, prescription medication 2, Yes, non-prescription medication 3, No 1, Yes 2, No 1, Yes 2, No 1, Yes 2, No 3, Unsure 1, Yes 2, No 3, Unsure 1, Yes 2, No 3, Unsure 1, Yes 2, No 3, Unsure	[fu_chiro_2wks] / [fu_chiro_6wks] / [fu_chiro_12wks] = '1' [hc_2wks] / [hc_6wks] / [hc_12wks] = '1' [hc_2wks] / [hc_6wks] / [hc_12wks] = '1' [hc_2wks] / [hc_6wks] / [hc_12wks] = '1' [hc_2wks] / [hc_6wks] / [hc_12wks] = '1' [otherhealth_2wks] / [otherhealth_6wks] / [otherhealth_12wks] = '1' [sickleave_2wks] / [sickleave_6wks] / [sickleave_12wks] = '1' [imaging_2wks] / [imaging_6wks] / [imaging_12wks] = '1' [imaging_2wks] / [imaging_6wks] / [imaging_12wks] = '1' [imaging_2wks] / [imaging_6wks] / [imaging_12wks] = '1' [imaging_2wks] / [imaging_6wks] / [imaging_12wks] = '1'
Patients' Global Impression of Change (PGIC) scale Collected at 2-, 6-, and 12-wks	To what extent has your pain complaint changed when compared with the situation just before you started chiropractic care?	pgic_q1_2wks / pgic_q1_6wks / pgic_q1_12wks	1, 1 = Completely recovered 2, 2. Much improved 3, 3. Slightly improved 4, 4. Not changed 5, 5. Slightly worsened 6, 6. Much worsened 7, 7. Worse than ever	

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 1 and 2	<p>"The Swiss chiropractic practice-based research network and musculoskeletal pain cohort pilot study: protocol of a nationwide resource to advance musculoskeletal health services research." (pg 1)</p> <p>"Phase 1 focuses on the development of the Swiss chiropractic PBRN, and will use a cross sectional design to collect information from chiropractic clinicians nationwide." (pg 2)</p> <p>"Phase 2 will recruit consecutive patients aged 18 years or older with MSK pain from community-based chiropractic practices participating in the PBRN into a prospective chiropractic cohort pilot study." (pg 2)</p>
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2	"All data collection will occur through electronic surveys. Surveys will be provided to patients prior to initial assessment, 1-hour after assessment and at 2-, 6-, and 12-weeks after assessment."
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 5	"Given the high burden of MSK pain conditions, which are frequently managed by chiropractors, and limited practice-based evidence on the topic of chiropractic care for MSK conditions, particularly in Switzerland, this protocol outlines the creation of a nationwide PBRN and subsequent nested prospective cohort (Swiss ChiCo) pilot study for chiropractic patients with MSK pain."
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 5	"The main objectives of this report are to: 1) describe the development of a MSK focused PBRN and describe the enrolment of Swiss chiropractors into the PBRN; and 2) describe the methods of the first nested study to be conducted

					within the PBRN – an observational prospective patient cohort pilot study.”
Methods					
Study design	4	Present key elements of study design early in the paper		Page 6	<p>“In phase 1, we will aim to develop the Swiss Chiropractic PBRN and describe the demographics of participating chiropractors at project initiation using a cross-sectional study design.”</p> <p>“In phase 2, we aim to launch a 12-week observational prospective Swiss chiropractic cohort (Swiss ChiCo) pilot study which will assess the feasibility for longitudinal data collection and describe the clinical course of patients with MSK pain presenting to Swiss chiropractors.”</p>
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection		Page 8, 9, 12 and 13	<p>“To aid with clinician recruitment, we plan to launch the PBRN development phase on September 9, 2021.” (pg 8)</p> <p>“Clinician recruitment for the Swiss chiropractic PBRN will be scheduled to end on December 19, 2021.” (pg 9)</p> <p>“Clinicians participating in the Swiss chiropractic PBRN will be asked to fully complete 1 electronic survey of approximately 10 minutes duration.” (pg 9)</p> <p>“We will hold pilot study introductory meetings with participant clinicians and clinical staff to reinforce study objectives, methods and procedures prior to the tentative date for initiation of the patient cohort pilot study recruitment of April 01, 2022.” (pg 12)</p> <p>“Subsequent questionnaires will take approximately 10-12 mins to complete and are emailed directly to patient participants 1 hour after (post-visit patient survey), and at 2-, 6-, and 12-weeks following completion of the pre-visit survey.” (pg 13)</p>
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up		Page 8 and 11	<p>“All registered active chiropractor members (fully licensed chiropractors and postgraduate assistant chiropractors) of the Swiss Chiropractic Association</p>

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	<p><i>Case-control study</i>—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls</p> <p><i>Cross-sectional study</i>—Give the eligibility criteria, and the sources and methods of selection of participants</p>	<p>(ChiroSuisse) will be eligible and invited to participate.” (pg 8)</p> <p>“Patients will be eligible to participate if they are 18 years of age or older; are seeking new conservative healthcare for a MSK pain condition (new conservative healthcare seeking is operationalised as not having received (patient-reported) chiropractic care, physiotherapy, osteopathy or massage therapy for their current MSK complaint in the 1 month prior to their current initial visit to the chiropractor and not a follow-up visit); consent to chiropractic treatment; are able to respond to surveys in German, French, Italian, or English; have an active email account; and are willing and able to complete electronic study questionnaires.” (pg 11)</p>
	<p>(b) <i>Cohort study</i>—For matched studies, give matching criteria and number of exposed and unexposed</p> <p><i>Case-control study</i>—For matched studies, give matching criteria and the number of controls per case</p>	<p>N/A</p>
Variables	<p>7 Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable</p>	<p>page 10 and 14</p> <p>“The primary clinical outcome will be practitioner self-confidence in the clinical management of patients with low back pain (measured by practitioner self-confidence scale). The second primary clinical outcome will be practitioner biomedical versus biopsychosocial MSK pain treatment orientation (as measured by the pain attitudes and beliefs scale, musculoskeletal version).” (pg 10)</p> <p>“The feasibility outcomes are 1) clinician participation proportion in the Swiss chiropractic PBRN will be assessed by reporting the proportion of all eligible clinicians that enroll in the PBRN development phase using raw numbers and percentages; and 2) motivation for clinician participation in the Swiss ChiCo pilot study will be assessed using a visual analog scale (VAS, 0-100), with higher scores reflecting higher motivation for participation.” (pg 10)</p>

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			<p>“The prespecified primary clinical outcomes will be: 1) change in musculoskeletal pain impact, as measured by the 3-item pain, enjoyment, and general activity scale; and 2) change in MSK health status, as measured by the musculoskeletal health questionnaire.” (pg 14)</p> <p>“The primary feasibility outcomes will be: 1) the proportion of invited patients presenting to chiropractic practices who subsequently agree to participate in this study; and 2) change in patient participant follow-up and retention over 12 weeks.” (pg 14)</p>
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	<p>page 10 and 14</p> <p>“The PCS contains four items with a total score of 20. A score of 4 represents higher self-confidence in the management of patients with low back pain, while a score of 20 represents lower self-confidence.” (pg 10)</p> <p>“The PABS-MSK contains two domains, with a higher score on either the domains (each 10-items, with a score range of 10-60) representing higher biomedical and biopsychosocial MSK pain treatment orientation.” (pg 10)</p> <p>“Motivation for clinician participation in the Swiss ChiCo pilot study will be assessed using a visual analog scale (VAS, 0-100), with higher scores reflecting higher motivation for participation.” (pg 10)</p> <p>“3-item pain, enjoyment, and general activity scale (PEG scale, score range 0-10) with higher scores representing worse outcomes; and 2) change in MSK health status, as measured by the musculoskeletal health questionnaire (MSK-HQ, score range 0-56) with higher scores reflecting better health status.” (pg 14)</p>
Bias	9	Describe any efforts to address potential sources of bias	<p>page 13 and 17</p> <p>“Patient participant surveys will be provided in English, German, French and Italian, with patients having the ability to choose their preferred language for completion. Validated, translated versions of the patient</p>

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reported outcome measures (PROM) will be used when possible.” (pg 13)

“To limit this threat to external validity, the Swiss chiropractic PBRN will recruit clinicians through both online and in-person channels. In addition, chiropractic clinician recruitment for the Swiss ChiCo pilot study will be proportionally overweighted in French and Italian language regions. These areas have shown lowered use eHealth technology use when compared to the German speaking regions of Switzerland.” (pg 17)

“To recruit a diverse group of patient participants, clinicians will be asked to consecutively recruit eligible patients from private practice. Although consecutive recruitment does not eliminate the threat of self-selection bias, it ensures all eligible participants seeking chiropractic care will be aware of the study.” (pg 17)

Study size 10 Explain how the study size was arrived at

Page 7, 9 and 12

“One-on-one meetings with Swiss chiropractors were carried out for the purpose of understanding how best to integrate study processes into clinical practice settings. According to all clinician advisors, the recruitment of approximately 5-10 consecutive patients per clinical practice was feasible.” (pg 7)

“Similar to other PBRNs within the scope of chiropractic and MSK health, we hope to achieve a clinician participation proportion of approximately 50%.” (pg 9)

“Based on this work, we will aim to recruit at least 100 patient participants to enable a preliminary characterisation of the population, enabled by representative selection of chiropractic clinicians with respect to language region.” (pg 12)

Continued on next page

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2	Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 10	“Participants who score 70 or more on the VAS will be defined as “highly motivated”, and described using raw numbers, proportions and 95% CIs.” (pg 10)
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5	Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 10 and 14	“Both primary clinical outcomes will be reported as means and standard deviations (SDs), with 95% confidence intervals (CIs) calculated as appropriate.” (pg 10)
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10					“Clinician participation proportion in the Swiss chiropractic PBRN will be assessed by reporting the proportion of all eligible clinicians that enroll in the PBRN development phase using raw numbers and percentages.” (pg 10)
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26			(b) Describe any methods used to examine subgroups and interactions	N/A	
27			(c) Explain how missing data were addressed	N/A	
28			(d) Cohort study—If applicable, explain how loss to follow-up was addressed	N/A	
29			Case-control study—If applicable, explain how matching of cases and controls was addressed		
30			Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy		
31					
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33			(e) Describe any sensitivity analyses	N/A	
34					
35	Results				
36	Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A	
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38			(b) Give reasons for non-participation at each stage	N/A	
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40			(c) Consider use of a flow diagram	N/A	
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2	Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on	N/A
3			exposures and potential confounders	
4			(b) Indicate number of participants with missing data for each variable of interest	N/A
5			(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N/A
6	Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	N/A
7			<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	N/A
8			<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	N/A
9	Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision	N/A
10			(eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were	
11			included	
12			(b) Report category boundaries when continuous variables were categorized	N/A
13			(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time	N/A
14			period	

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Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 16 <p>“This project is designed to attract a large proportion of Swiss chiropractors into a nationwide PBRN and subsequently recruit patients from participating clinics into a longitudinal cohort pilot study.”</p> <p>“The unique collaboration with clinicians, advocacy groups and academicians, a growing trend in health care research, has led to the promotion of research objectives which are clinically relevant and patient-centred, and a study implementation strategy vetted by Swiss chiropractic primary care clinicians.”</p>
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 17 <p>“Typically, unequal access to technology resources and lack of digital literacy can lead to a young, well-educated, and high socio-economic status study sample.”</p>
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	N/A
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 17 <p>“To limit this threat to external validity, the Swiss chiropractic PBRN will recruit clinicians through both online and in-person channels. In addition, chiropractic clinician recruitment for the Swiss ChiCo pilot study will be proportionally overweighted in French and Italian language regions. These areas have shown lowered use eHealth technology use when compared to the German speaking regions of Switzerland. To recruit a diverse group of patient participants, clinicians will be asked to consecutively recruit eligible patients from private practice. Although consecutive recruitment does not eliminate the threat of self-selection bias, it ensures all eligible participants seeking chiropractic care will be aware of the study.”</p>
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 18 <p>“This work was internally supported by the Department of Chiropractic Medicine, Faculty of Medicine, at University of Zurich and Balgrist University Hospital through funding from the Foundation for the Education of Chiropractors in Switzerland.”</p>

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*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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