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Prevention and therapy of orchestra musicians´ playing-related musculoskeletal disorders with transcranial direct current stimulation: a pilot study.

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Conflicts of Interest

The author declares that he has no conflicts of interest to disclose.

Affidavit

I hereby solemnly declare that this thesis was written independently and without the assistance of third parties, that other sources besides those cited were not used and that excerpts from the sources used – both content and verbatim quotations – are indicated as such.

eh

Vienna, 1st of March 2023 Signature

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Zusammenfassung auf Deutsch

Hintergrund. Tausende Orchestermusiker:innen und Musikstudent:innen weltweit leiden an spielinduzierten muskuloskelettalen Beschwerden (PRMDs), ohne hinreichende medizinische Betreuung zu erhalten. Außer vereinzelten Initiativen gibt es keine allgemein verfügbare medizinische Versorgung und kaum Forschung zur Behandlung musikerspezifischer Erkrankungen. Es besteht Notwendigkeit für neue Wege, um die PRMDs zugrunde liegenden pathophysiologischen neuromuskulären Mechanismen zu untersuchen, sowie für neue Mittel zur Prävention und Therapie dieser Gruppe von Erkrankungen.

Zielsetzung. Der Zweck dieser Arbeit war, ein Proof of Concept eines Therapieplans für Musiker:innen zu erbringen. Dieser Plan besteht aus transkranieller Gleichstromstimulation (tDCS), physiotherapeutischen Übungen und psychologischem Coaching, gemeinsam mit bildgebenden Verfahren und 3D Motion Capture.

Methoden. Pilotversuche zu den einzelnen Teilen des Behandlungsplans wurden mit insgesamt 7 Musiker:innen aus der Orchesterakademie der Wiener Philharmoniker durchgeführt. Zu diesen Versuchen gehörten initiale physiotherapeutische und psychologische Untersuchungen, von den Teilnehmer:innen eigenständig durchgeführte tDCS-Sessions zusammen mit physiotherapeutischen Übungen, und diagnostische Magnetresonanztomographie, Diffusions-Tensor-Bildgebung und Motion Capture.

Ergebnisse. Alle 10 durchgeführten Pilotversuche wurden erfolgreich, vollständig und ohne größere Probleme ausgeführt. Bei einigen Teilnehmer:innen traten kleinere Schwierigkeiten auf, welche entweder direkt durch die Untersucher:innen oder durch die Teilnehmer:innen selbst mittels einer Checkliste und einem Fragebogen dokumentiert wurden. Der Hauptzielpunkt des Therapieplans, der „pain assessment questionnaire“, wurde von 4 Teilnehmer:innen ausgefüllt und konnte deren muskuloskelettale Symptomatiken einwandfrei darstellen.

Diskussion. Die Pilotversuche mit tDCS, Physiotherapie, psychologischem Coaching und Monitoring mittels medizinischer Bildgebung und Motion Capture waren sicher und lieferten vielversprechende Resultate. Dadurch ist die beabsichtige Erforschung aller dieser Methoden in Musiker:innen demonstriert, was nun die Möglichkeit einer größer angelegten, randomisierten klinischen Studie zu einer Therapie für PRMDs von Orchestermusiker:innen eröffnet.

Abstract in English

Background. Thousands of orchestra musicians and music students worldwide suffer from playing-related musculoskeletal disorders (PRMDs) without receiving sufficient medical support. Aside from sporadic initiatives, there is no commonly accessible medical care and research specifically dedicated to the treatment of performing artist´s conditions. New ways of studying the pathophysiological neuromuscular mechanisms underlying PRMDs and new and innovative tools for prevention and treatment are needed.

Objectives. The purpose of this study is to provide a proof of concept of a treatment plan for musicians consisting of transcranial direct current stimulation (tDCS), physiotherapeutic exercises, and psychological coaching with concurrent medical imaging and motion capture.

Methods. Feasibility pilot trials of the individual parts of the therapy regimen were conducted with 7 musicians from the Orchestra Academy of the Vienna Philharmonic. These trials included initial physiotherapeutic and coaching evaluation sessions and self-administered tDCS sessions with concurrent physiotherapeutic exercises, as well as magnetic resonance imaging, diffusion tensor imaging, and 3D motion capture acquisitions.

Results. All 10 trials done in total were successfully completed without any major issues. The participants faced some minor problems, which were recorded either by the investigators directly or by the participants themselves through a checklist and a questionnaire. The main outcome of the therapy regimen, the "pain assessment questionnaire", was filled out by 4 participants and managed to accurately capture their musculoskeletal symptoms.

Discussion. The pilot trials with tDCS, physiotherapy, psychological coaching, and medical imaging and motion monitoring were safe and yielded very promising results, thereby demonstrating the feasibility of studying all these medical techniques in musicians. This introduces the possibility of a large-scale, randomized clinical trial of a therapy regimen for orchestra musicians´ PRMDs involving these techniques.

1 Introduction

There are more than 3,000 classical symphony orchestras worldwide. (1) In 2017, there were approximately 1,600 U.S. orchestras distributed widely across all 50 states, with over 400 of these being youth orchestras. In that year, more than 25,800 performances were given by the adult orchestras alone, attracting an audience of over 29 million people. (2) Outside of the U.S., orchestra performance activity yields many thousand more concerts, operas, and other musical events with an estimated total audience of more than a billion people each year. Orchestras are much more than just providers of musical experiences, however. Their economic impact far exceeds their direct expenses ($2.1 billion total in 2017), as they generate many more jobs, interact with local businesses and encourage spending on a variety of goods and services (e.g. parking, restaurants, hotels, etc.). During the Covid-19 pandemic, when the possibility of giving concerts was severely reduced, many orchestras provided music digitally (approximately 64% of it was free of charge). Furthermore, the importance of their sociocultural role in promoting international cultural exchange, participation in civic life, musical education, and much more, is immeasurable. (2, 3, 4)

In the U.S. alone, there are approximately 160,000 musicians playing in an orchestra. Of these, about 25% or ~40,000 are professional musicians, compared to 15,800 professional athletes. (2, 5) Athletes are limited to about 20 hrs/week of team practice, whereas performing artists often play their instrument well over 40 hrs/week. (6) Musicians often start playing their instrument at a very young age with strict teachers, competitions and touring to endure, and a “no pain, no gain” mindset. (7) Having little to no training in dealing with the physical and emotional strains of high-level performance, musicians often struggle to recover from their demanding practice and concert schedule. (8) This can result in the development of a variety of different disorders and/or diseases, physical as well as mental. Prolonged postures and repetitive motions that result from playing a specific instrument can cause focal dystonia and a plethora of musculoskeletal complaints. (9) Also, musicians are often reluctant to perform exercises prior to performances or consult healthcare professionals, in order to not be seen as less competent or talented by others, (7) which all leads to these diseases being ignored and thus untreated. (10, 11) Furthermore, perfectionism leads to excessively high performance standards and harsh self-criticism, which can result in eating and substance use disorders, anxiety, and depression, often at a very young age. (12, 13, 14)

1.1 Performing Arts Medicine

The field of Performing Arts Medicine (PAM), a branch of occupational medicine, is concerned with the aetiology, treatment, and prevention of medical problems of performing artists that arise related to their performances. It combines medical expertise from many other fields, such as orthopedics, neurology, otorhinolaryngology, ophthalmology, and psychiatry. (11)

1.1.1 Early History

The association between music and medicine reaches back to as far as 2000 BCE when Assyrians depicted music being used to circumvent the path of evil spirits, which were thought to be the cause of diseases in many ancient cultures. (15) In Greek antiquity, Apollo was worshipped as the god of both music and the arts of healing. The philosopher Plato writes in his Socratic dialogue "Politeia" about the positive effect on health of not only physical activity, but also of listening to music. (16) In the middle ages, the Florentine physician Giovanni Michele Savonarola, personal physician of the Marques of Ferrara, Leonello d´Este, wrote about a possible relationship between inguinal hernias and playing the flute or the trumpet. (16, 17, 18) In the 17th century, the Dutch physician and anatomist Ysbrand van Diemerbroeck conducted research regarding too high air pressure with which brass players played their instruments. (16, 17)

One of the first authors to describe problems related to singing and playing in the context of work-related affections was the Italian physician Bernardino Ramazzini (1633-1714), the so-called "father of occupational medicine". (19, 20) In a time of church Inquisition and epidemics of smallpox, typhus, and the plague, he began systematically studying the role of work as a cause for diseases. (21) He visited different workplaces, observed workers´ patterns of motion, and enquired about their illnesses. In the year 1700, he arranged and published the knowledge he gained through his observations in his work "De morbis artificum diatriba" ("Diseases of workers"), a second edition of which was published shortly before his death in 1713. (22) It is the first comprehensive account of important diseases of over 50 professions, such as carpenters, blacksmiths, masons, tailors, bakers, clerks, and, in the second edition, also singers and musicians. Each chapter focuses on a different profession and gives descriptions of the clinical pictures of the diseases affecting the workers, their workplaces, remedies, and even some preventive measures. (23)

Ramazzini found that not only chemical agents like inhaled dust particles and physical agents such as noise or heat in the working environments could cause or contribute to diseases. He also identified unnatural or prolonged postures as well as repetitive, irregular, or violent motions as causes of musculoskeletal problems of workers. Moreover, he described the handling of heavy objects and the persistence in positions requiring physical effort as risk factors and recognized the importance of prevention and risk protection. (23, 24, 25) The diseases caused by these factors included hernias, valgus and varus deformities of the lower extremity, shoulder dislocation, sciatica, kyphosis, arthritis, and muscular tension, as well as pain, fatigue, and paralysis in different parts of the body. (26) Ramazzini meticulously recorded the duration and intensity of the risk factors underlying these diseases and concluded that any movement, if carried out carelessly, had the potential to cause functional disorders. (23, 24)

Although Ramazzini´s insights laid the foundation for modern occupational medicine and thereby performing arts medicine, his teachings were largely ignored and forgotten in the following centuries. (26) The only relevant finding of this time was by the English physician W.H. Stone, who refuted the long-standing myth that the forced expiration employed by brass instrument players could produce pulmonary emphysema. (27)

1.1.2 19th and early 20th Century

During the 19th century, physicians´ interests were stirred by a new disease, the so-called "musicians cramp", known today as focal dystonia. This work-related disease had also already been a problem for writers, scholars, and telegraphists as the "writer´s cramp" for many years. Most cases of focal dystonia in musicians manifested themselves as cramps or paralyses in pianists, but also violinists, (28) cornetists, (29) and others were affected. (24) Different treatments were practiced: on one hand, the American surgeon William S. Forbes developed a tenotomy of the accessory tendons of the extensor digitorum communis muscle, which increased ring finger motility with little to no complications. (30) On the other hand, the English physician George V. Poore tried other non-invasive treatments like arsenic and massages. (31)

The probably most well-known musician of this time who suffered from musculoskeletal conditions was the German pianist and composer Robert Schumann (1810-1856). For the entire duration of his career, he had a dysfunction of his right hand, which he tried to get rid of through many different treatments. Unfortunately, all of these treatments proved to be ineffective, however, which is why he had to give up his career as a pianist early. The etiology of his condition remains unknown. (24, 32)

In 1932, the first modern book about performing arts medicine, “Diseases of the musical profession”, was published by Kurt Singer, a German neurologist and musicologist. (33) This very extensive work discusses many physical and mental conditions of musicians, with the most detailed being the aforementioned focal dystonia and performance anxiety, describing clinical symptoms as well as possible etiologies and treatments. A great portion of the book is devoted to mental illnesses, which he also often saw as the cause of somatic complaints. Many of his views are outdated today, whereas others, like his emphasis on the importance of adequate recovery after every exertion, are fundamental tenets of modern (performing arts) medicine. (33, 34)

1.1.3 Birth of Performing Arts Medicine

In the 1960s and 1970s, there was a growth of interest in medical problems of musicians among physicians and other experts. Several papers, primarily case reports, were published in reputable medical journals such as the British Medical Journal (BMJ), (35, 36, 37, 38, 39) the Lancet, (40, 41) and the New England Journal of Medicine (NEJM). (42, 43, 44)

At the beginning of the 1980s, a new controversy brought performing arts medicine into the spotlight when beta-blockers started to be used as a treatment for performance anxiety, which had previously been treated with physiotherapy, relaxation exercises, or in self-medication with alcohol and/or tranquilizers. (45) Although beta-blockers had originally been developed for other applications, mainly cardiovascular diseases, they had a positive effect on the symptoms that resulted from stress and nervousness before and during the performance, and a significant improvement in performance quality was found in multiple clinical trials. (46, 47, 48, 49) Many musicians started taking beta-blockers without a prescription or any knowledge about side effects or contra-indications. Although this trend diminished after the publication of negative effects of beta blockers in 1987, they are still being used today by an unknown number of musicians, sometimes even with prescriptions from a doctor. (50, 51)

The first academic conference on the topic "Medical Problems of Musicians" was held in Aspen, Colorado, in 1983. It was organized by Alice Brandfonbrener, a physician from Michigan, who specialized in performing arts medicine and was also the physician of the Aspen festival for many years. (52) Over 100 physicians and many musicians attended and presented their papers, gave demonstrations, and discussed case reports. (53) The conference was a milestone in the development of performing arts medicine and became a yearly event thereafter. (52, 54) In the same year, the Australian surgeon Hunter J.H. Fry founded the first performing arts medicine-related organization, the "Performing Arts Medicine Society", with a few of his colleagues. (55) Fry also contributed substantially to the definition, classification, and treatment of the overuse syndrome, which is caused by excessive exertion without adequate regeneration. (56, 57, 58, 59)

1.1.4 Journals and Organizations

In the following years, congresses, lecture series, and articles about performing arts medicine became ever more frequent. (54, 60, 61) This warranted the foundation of a new Journal in 1986, "Medical Problems of Performing Artists" (MPPA), with Alice Brandfonbrener as the first editor-in-chief, a position which she served in for 20 years. (52, 62) Musicians and physicians alike contributed to the Journal, which was and continues to be a platform for interprofessional dialogue and a medium for many important publications in the field of performing arts medicine. (63, 64, 65, 66, 67) Besides MPPA, which is the central journal of the field, a few other journals were also founded in the next few years, such as the "Journal of Voice" (1987) and the "International Journal of Arts Medicine" (1991). (68, 69, 70)

The 1980s were also the time in which PAM organizations emerged all over the world, with the first being the aforementioned "Performing Arts Medicine Society" in Australia. (55) In 1984, the "British Performing Arts Medicine Trust", known today as the "British Association for Performing Arts Medicine" (BAPAM), was founded. (71) The following year, Richard Lippin called for an international society of professionals in order to facilitate better communication, (72) which lead to the foundation of the "International Arts-Medicine Association" in the same year. (73)

Outside of the Anglo-American area, societies and medical centers for PAM were established in many other countries, such as the Netherlands (NVDMG), (74) Italy (CEIMArs), (75) Spain (IAB+H), (76) Austria (ÖGfMM), (77) and Germany (DGfMM).

(78, 79, 80, 81) The “German Society of Music Physiology and Musicians´ Medicine” (DGfMM) even has its own magazine, “Music Physiology and Musicians´ Medicine”, which publishes regularly. (82)

At the conference in Aspen in 1989, the “Performing Arts Medicine Association” (PAMA), was established with Alice Brandfonbrener as its founding president. The wide variety of its members´ professions, including physicians of different specialties, dentists, medical students, teachers, dancers, and, of course, musicians, allowed PAMA to optimally accommodate performing artists´ medical needs on multiple levels. Since the year 2000, it is also responsible for organizing the conferences in Aspen every year. (83, 84) In 1989, Brandfonbrener wrote in an editorial in MPPA that performing arts medicine had established itself as an independent medical specialty. (85)

1.2 Playing-related Musculoskeletal Disorders

The complex neuromuscular demands and hour-long training sessions required to learn to play at the level of a professional orchestra musician are comparable to the physical demands of a professional athlete´s training. (86, 87, 88, 89, 90) In fact, performing artists can be seen as a subset of athletes. (91) It is no surprise that the strains on the musculoskeletal system caused by unnatural, prolonged postures and repetitive motions can cause a variety of musculoskeletal problems in athletes, musicians, or workers of any other profession, as was described by Ramazzini more than 300 years ago. (25)

Before there was a standard definition of playing-related musculoskeletal disorders (PRMDs), these dysfunctions and diseases of the musculoskeletal system in musicians were referred to using a number of terms that actually described different clinical entities, such as “cumulative trauma disorder”, (92, 93) “repetitive strain injury”, (93, 94, 95) and the aforementioned “overuse syndrome”. (56, 57, 96) As these terms differ from each other and implicate aetiologies which do not apply to all cases of musicians´ musculoskeletal problems, the result was a somewhat confusing terminology. (97, 98)

This problem was indirectly addressed by Hagsberg, who provided musicians´ pain in the neck and arm as an example of a “work-related musculoskeletal disorder”, a phrase which remained unspecific regarding the cause of the symptoms and was thus better suited. (99, 100) Because the “playing” of an instrument is the musician´s work, the analogous term specific to musicians was the so-called “playing-related musculoskeletal disorder”.

The first definition of playing-related musculoskeletal disorders (PRMDs) was given in 1998 by Zaza, Charles, and Muszynski. They conducted semi-structured interviews with 27 musicians of a variety of ages, instruments, professional status, and both genders, as well as 3 health care individuals. With the use of the data generated in these interviews, they reached the definition of PRMDs as “pain, weakness, lack of control, numbness, tingling, or other symptoms that interfere with your ability to play your instrument at the level you are accustomed to”. (101, p. 2016) This definition does not include “transient aches or pains”, and it applies to any musician, not just professionals, and to any aetiology of the musculoskeletal disorder. It is the most widely accepted definition in the PAM-related literature today. (102, p. 152, 103)

1.2.1 Prevalence & Risk Factors

The first evaluation of the prevalence of PRMDs was also done by Zaza in 1998, the same year they were first defined. She conducted a systematic review and included data from 7 studies with professional adult musicians and music students. The point prevalence of PRMDs was between 39%-87% in adult musicians and 34%-62% in music students, with the estimated mean prevalence being 65%. The variability of these numbers is explained not just by the lack of a clear definition of PRMDs, but also by the fact that some studies distinguished between levels of severity. Other studies also included mild aches and pains, which, as Zaza stresses in her paper, are not considered PRMDs by the musicians and do not fit her definition. (104)

Another problem with assessing the prevalence of PRMDs is that studies only record either point prevalence (prevalence at the time of the evaluation), 12-month prevalence, or lifetime prevalence, but never multiple outcomes, which makes it difficult to compare studies. (105) Furthermore, many studies only report the prevalence of specific groups, such as musicians of certain ages, (106) in certain geographic areas, (107, 108, 109) playing specific instruments, (103, 110, 111, 112) music students, (113, 114, 115) or amateur musicians. (116)

An extensive systematic review was conducted by Kok et al. (105) in 2015 and published in print in 2016. It featured important inclusion criteria like certain study designs, participants´ age >18, a clearly described prevalence rate as the outcome measure, and publishing in a peer-reviewed journal. Of 957 potentially relevant studies, 17 were included, with 11 of these referring exclusively to professional musicians playing in an orchestra. The articles included were also thoroughly examined and rated on a scale of 0-8 based on their methodological quality. (105)

In 2020, another even more extensive systematic review was published by Rotter et al. (102), though its literature search was conducted in December 2017 and thus no more recent articles are included. It features a very detailed rating system of 14-18 possible points, depending on the study design, and also the possibility of a negative rating value (the “worst” study received -13 points). Of 2074 initially identified articles, 109 were included in the review. The authors state that studies often lacked clearly defined inclusion criteria, checks for major confounders, and sufficient definitions of exposure. Because of these methodological concerns, they do not provide a statement for the overall prevalence of PRMDs (here called “musculoskeletal complaints and disorders”), but express the need for new prospective, long-term cohort studies. (102)

In the following years, several studies and reviews were conducted in different populations and with different instruments. Among these were also large-scale studies, such as Cruder et al. (115) (n=850) and Gembris et al. (106) (n=1,143). (106, 115) Prevalence rates varied between 20% (point prevalence) and 94,8% (12-month prevalence). (96, 103, 107, 108, 116, 117, 118, 119)

Table 1 provides an overview of the prevalence rates of PRMDs reported in studies focusing exclusively on orchestra musicians. It is based on the two reviews mentioned above, as well as studies that have been published on the topic since January 2018. (102, 105) Outcomes are divided into three groups based on the type of prevalence reported.

	Number of Participants (n)	Point prevalence (%)	12-month prevalence (%)	Lifetime prevalence (%)
Fishbein et al. (63)	2212	68		
Engquist et al. (120)	103		52	
Abreu-Ramos and Micheo (121)	75			81
Leaver et al. (122)	243		41	
Paarup et al. (123)	342		73	
Kaufman-Cohen and Ratzon (124)	59		83	
Ackermann et al. (65)	377	50		84
Chimenti et al. (125)	261		93	
Fotiadis et al. (126)	147			82
Steinmetz et al. (127)	408	9		90
Kenny et al. (128)	378	46-56		85-90
Berque et al. (129)	101	37	46	77
Sousa et al. (130)	112	63		
Gasenzer et al. (131)	740	66		
Kok et al. (116)	357		68	
Vastamäki et al. (118)	590	20		
Cygańska et al. (119)	31	52	81	87
Panebianco (108)	79	30		76

Table 1: *Prevalence rates of orchestra musicians as integers in percent from 18 studies.*

The studies listed in Table 1 show considerable variability in the number of their participants, ranging from 31 in Cygańska et al. (119) to 2212 in Fishbein et al. (63). Among the prevalence outcomes, eleven studies provided point prevalence rates, with values between 9% and 68%. The 12-month prevalence is reported in eight studies and lies between 41% and 93%; and the lifetime prevalence, which is also reported in eight studies, lies between 76% and 90%.

There are also differences in the prevalence rates of PRMDs between men and women and therefore a possible causal association. (67, 132) A cross-sectional study with 342 participants (208 male, 134 female), controlled by a representative cohort of 5436 workers (2731 male, 2705 female), was conducted by Paarup et al. (123) in 2011 to investigate this matter. They screened for musculoskeletal symptoms in nine different anatomic regions (neck, upper and lower back, both shoulders, both elbows, and both hands/wrists). Female musicians showed a higher prevalence of symptoms in every single anatomic region, with significant differences in the upper back, both shoulders and the left hand. Musicians overall also showed a higher prevalence of symptoms than the control cohort of workers. (123)

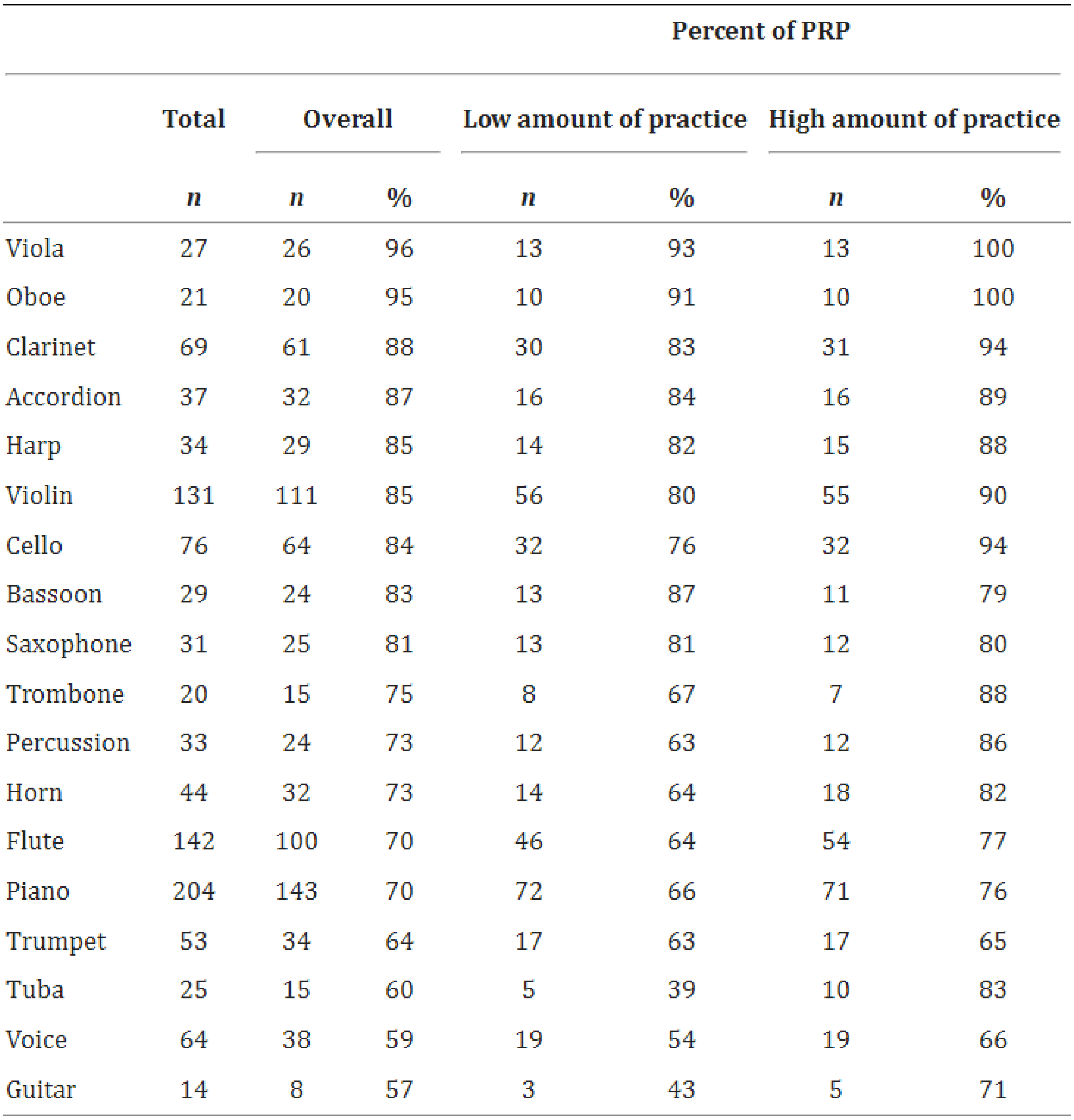
Since then, the findings of Paarup et al. (123) have been backed up by many other studies. (103, 117, 122, 124, 127, 133, 134, 135, 136, 137) Nevertheless, Rotter et al. (102) conclude that there is not yet sufficient qualitative data to provide a statement on the influence of gender on the development of PRMDs. (102) However, in their large-scale study in 2020, Gembris et al. (106) found a significant difference in the prevalence of PRMDs between female (79%) and male (71%) musicians. (106)

Another factor very influential on the development of PRMDs is the instrument played by the musician. Every instrument has unique features and therefore requires a unique posture, breath control, and different muscles, joints, and other ergonomic features to be fulfilled by the musician. Instruments for classical music are built according to tradition, in order to resemble those of the past centuries, because the emphasis lies more on sound and less on ergonomic factors and the musicians´ long-term health. (138, 139)

Multiple studies have found that musicians playing string instruments are at significantly higher risk than wind musicians (i.e., players of brass or woodwind instruments). (123, 126, 130, 140) This applies especially to high string players, a term which describes the group of violin and viola together. (123, 131) String players also seem to be more affected by PRMDs than other groups like singing or percussion. (115, 130) One possible explanation would be that the long practice times of violinists and violists are almost entirely spent in asymmetric positions with elevated shoulders and arms. (127)

The prevalence of PRMDs also seems to be strongly correlated with the number of hours of practice, (112, 124, 126, 127) as well as the number of performances in a given time. (141) This would also at least partially explain the risk factor of playing a string instrument, because string players, particularly violinists and violists, start playing their instrument at a younger age and collect more practice hours than players of other instrument groups. (127)

Table 2, taken from Gembris et al. (106), combines the two risk factors "instrument" and "amount of practice". For each specific instrument, the point prevalence of PRMDs (gathered as playing-related pain in this study) is given for all players together. Then, the players are divided into two groups based on their reported practice times and the prevalence is reported for each group separately.



		Percent of PRP					
	Total	**Overall**		**Low amount of practice**		**High amount of practice**	
	n	*n*	%	*n*	%	*n*	%
Viola	27	26	96	13	93	13	100
Oboe	21	20	95	10	91	10	100
Clarinet	69	61	88	30	83	31	94
Accordion	37	32	87	16	84	16	89
Harp	34	29	85	14	82	15	88
Violin	131	111	85	56	80	55	90
Cello	76	64	84	32	76	32	94
Bassoon	29	24	83	13	87	11	79
Saxophone	31	25	81	13	81	12	80
Trombone	20	15	75	8	67	7	88
Percussion	33	24	73	12	63	12	86
Horn	44	32	73	14	64	18	82
Flute	142	100	70	46	64	54	77
Piano	204	143	70	72	66	71	76
Trumpet	53	34	64	17	63	17	65
Tuba	25	15	60	5	39	10	83
Voice	64	38	59	19	54	19	66
Guitar	14	8	57	3	43	5	71

Table 2: *Prevalence of playing-related pain for different instruments and practicing efforts. Source: Gembris et al. Frontiers in Psychology. 2020; 11:564736 (106, p. 7).*

Due to the varying popularity of different instruments among young musicians, there are vastly different numbers of participants (n) in the individual categories: more than 200 pianists on one end of the spectrum face only 14 guitarists on the other end. The mean prevalence was 76%, with the rates of PRMDs ranging from 57% in guitarists to 96% in violists. The other string instruments also have a relatively high prevalence of 85% (violin) and 84% (cello). When considering the two practice groups, the prevalence of the musicians practicing a lot is higher in almost all instruments, the only exceptions being the saxophone and the bassoon. Most instruments have prevalence rates of over 10 percentage points higher than the group with a low amount of practice, including the three with the most participants (piano, flute, and violin) and a maximum difference of 44 percentage points (tuba).

Many other possible risk factors for PRMDs have also been investigated. These include higher age, (103, 106, 121, 126) previous PRMDs or other musculoskeletal injuries, (103, 142, 143) a higher body mass index (BMI), (103, 144) playing in a pit as opposed to a stage, (128) playing multiple instruments, (145) use of excessive force, (146) and psychological problems like stress, fear of unemployment, or depression. (127, 136, 147) Multiple authors have also reported a correlation between music performance anxiety and PRMDs, (122, 127, 134, 136, 143) It may also seem logical that an asymmetric playing posture would be a predictor of PRMDs, as was already suggested, (148) but a study with professional bassists by Woldendorp et al. (149) could not find a significant correlation between work-related postural stress and PRMDs. (149)

As possible protective factors authors have suggested warm-ups before and breaks during a performance, (124, 144) physical fitness, (150) as well as more years of playing the instrument. (140, 144) There was no correlation found for physical exercise, cigarette smoking, influence over or support at work, and different anatomical features like tendon anomalies or hypermobility of joints. (122, 124, 143)

Among these factors, some cannot be altered by the musicians (e.g. age), while others like warming up and taking breaks can be modified rather easily by the musicians and could therefore be relevant for treatment and prevention strategies. (132) Although many studies have been conducted, there is still not enough data to draw meaningful conclusions about individual risk or protective factors. Without studies using a prospective design, it is also impossible to make statements regarding the causality between these factors and PRMDs. (102, 143)

Table 3 divides all factors with a potential association with PRMDs into three categories: “possible risk factors” encompasses those with reported correlation in multiple and/or larger studies, “factors of unclear status” those with less or conflicting information, and “possible protective factors” those for which the possibility of a protective effect has been stated.

Possible risk factors	Factors of unclear status	Possible protective factors
Gender	BMI	Warm-ups
Instrument	Playing posture	Breaks during practice
Amount of practice	Playing environment	Physical fitness
Age	Playing multiple instruments	Years of playing
History of PRMD	Use of excessive force	
Performance anxiety	Work stress	
	Fear of unemployment	
	Depression	

Table 3: *Factors possibly associated with the development of PRMDs.*

1.2.2 Clinical Manifestations

The complexity of the human musculoskeletal system allows it to fulfil many different tasks over long periods of time. It is essential for people´s mobility, their ability to work, and to take part in other activities of daily life. (151) Playing an instrument on a professional level is one of the most demanding neuromuscular tasks and such exertion on a regular basis can cause a wide variety of problems for the musculoskeletal system. The diverse aetiologies of PRMDs are believed to be multifactorial, but in the majority of cases the main complaint of the musicians is pain, which is also usually the first and final symptom they encounter. (103, 146, 152)

The location of perceived pain is shown in Figure 1, for which Cruder et al. (153) investigated 340 music students. (153) They used the Nordic Musculoskeletal Questionnaire (NMQ, also known as Standardized Nordic questionnaire), which was initially published in 1987 and is the most widely used questionnaire for evaluating the location and severity of all musculoskeletal symptoms today. (154, 155, 156) The area and color of the circles represent the frequency of pain for each of the anatomical regions of the NMQ (bigger and darker red means more frequent) and they are also described via a bar chart.

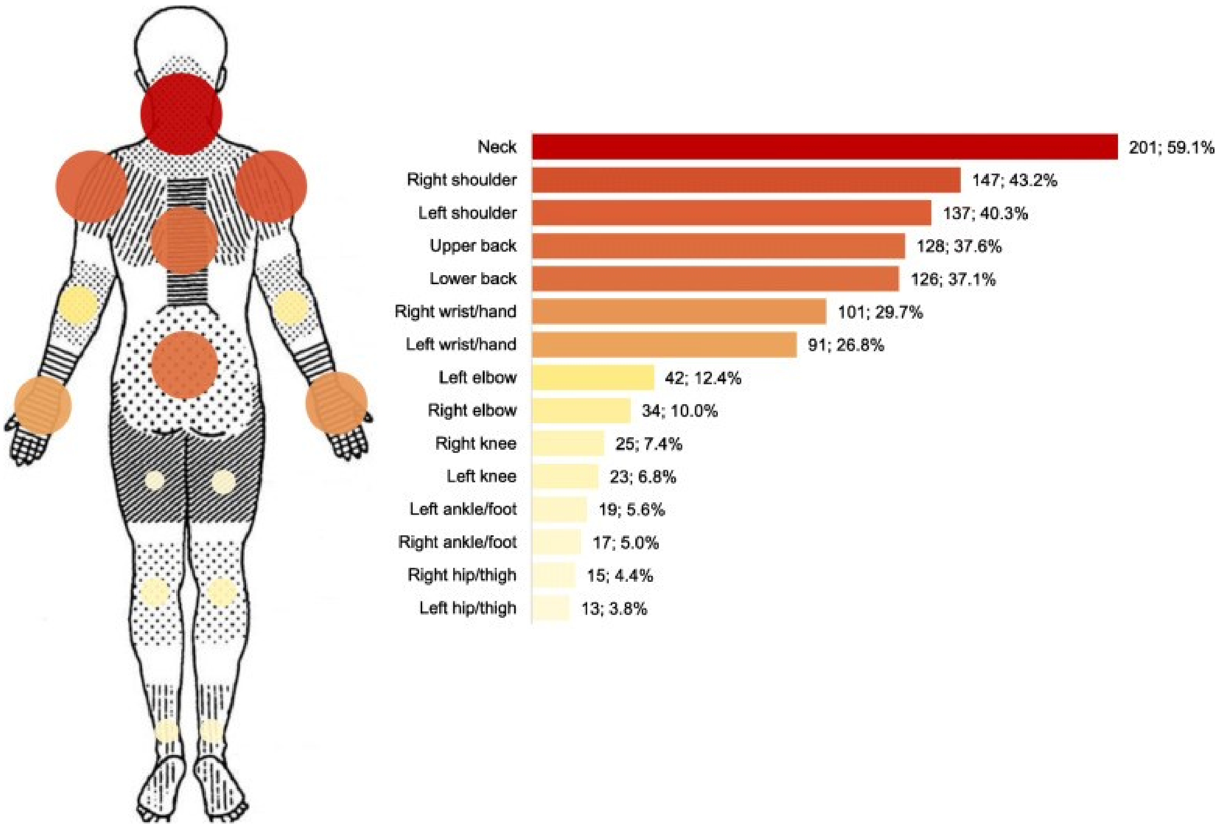


Figure 1: *Distribution of musculoskeletal pain location among music students. Source: Cruder et al. BMC Musculoskeletal Disorders. 2021; 22(1):184 (153, p. 6).*

The most frequently affected area was the neck with 59.1%, ahead by over 15 percentage points over the following areas, which were the shoulders (43.2% on the right, 40.3% on the left) and the upper (37.6%) and lower back (37.1%). The upper extremity (wrist/hand and elbow) showed moderate frequency, whereas the lower extremity (hip/thigh, knee, and ankle/foot) were almost completely unaffected, with well under 10% in every region. When comparing the left and right side, the differences are minimal and suggest that both sides are equally befallen by PRMDs. It should be noted, however, that players of some specific instruments have pain predominantly on one side due to their technique (e.g. percussionists in the left, but not the right elbow). (123) The study of Gembris et al. (106) found similar results with a sample size of n=1,110 participants and also added fingers (39%), mouth/lips (28%), and head (17%) as anatomical regions. (106)

But PRMDs manifest themselves through more symptoms than just pain, causing weakness, numbness, tingling, and, most importantly, functional disabilities, which can become very severe. (101, 152, 157) These symptoms lead to sleep disturbances and an impairment in activities of daily life and especially work, which can pose psychological, social and financial problems for the musicians. (101, 123, 158) In the following paragraphs, some of the diseases that are classified as PRMDs when caused by and impairing playing an instrument will be introduced.

Diseases of the spine

The neck and back is one of the primary locations of musicians´ pain, as described above, and also in the general population, where neck pain is the fourth most common and lower back pain the most common cause of disability. (159) This pain originates from the spine, which owes its great mobility to the many joints (lat. articulationes zygapophyseales) and discs (lat. discus intervertebralis) between the vertebrae. (160) Although in most cases the aetiology of neck and back pain remains unclear and can therefore only be treated symptomatically (e.g. painkillers, manual therapy or exercise), there is a variety of serious pathologies that can underly these symptoms. (161, 162)

The differential diagnosis of these pathologies, which include traumatic injuries, osteoporosis, myelopathies, metastases, infections or vascular diseases, is done with plain radiographs or, more often, magnetic resonance imaging (MRI). (163) The latter is the most sensitive method for detecting injuries of the soft tissue like radicular syndromes and disc herniations, which are the leading source of lower back pain. (164, 165)

Figure 2 shows a median-sagittal slice through the lumbar spine with the ligaments and the intervertebral discs. (160) The latter are composed of a soft and flexible nucleus pulposus, primarily made of water, on the inside, and a tough anulus fibrosus with many type I collagen fibers on the outside, which contains the nucleus pulposus inside the disc. The functionality of the disc is twofold: on one hand, it serves as a cushion that distributes axial pressure to all parts of the body of the vertebra, on the other hand, it limits the range of motion of the spine as a whole and thereby prevents injuries to the spinal cord. (160)

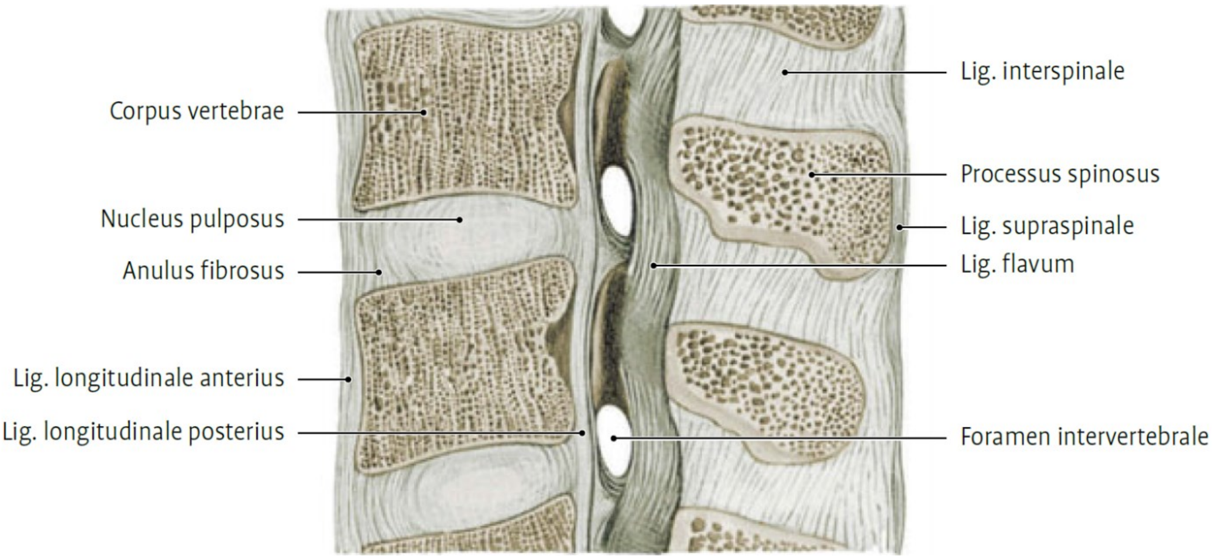


Figure 2: *Median-sagittal slice through the spine with ligaments and intervertebral discs. Source: Streicher and Pretterklieber. In: Waldeyer – Anatomie des Menschen. 2012 (160, p. 126).*

A disc herniation occurs when the nucleus pulposus bulges out of the disc, with or without an intact anulus fibrosus, and compresses parts of the spine or nerve roots. This pressure, coupled with the release of inflammatory factors, can cause massive radicular pain, weakness, and neurological symptoms like paraesthesia and paresis in the areas of the compressed nerve roots. (160, 166, 167)

The first-line treatment is conservative using non-steroidal anti-inflammatory drugs (NSAIDs), epidural or intradiscal corticosteroid injections, physical therapy/exercises, (167, 168, 169) intradiscal ozone therapy, gene therapy, tissue engineering, different approaches of alternative medicine, and a lot more. (168) In rare circumstances an operative lumbar discectomy becomes necessary (e.g. disruption of bladder function or progressive neuromuscular deficits). (168)

Diseases of the shoulder

The shoulder (lat. articulatio glenohumeralis or humeri) is the anatomical joint with the highest mobility, a property which it facilitates through a complex construction of many different ligaments, tendons, bursae, and a labrum. (160) Eleven individual muscles initiate movement in the joint, therefore subjecting it to a lot of use. When playing an instrument, the shoulder is subject to static and dynamic loads, e.g. static load on the left shoulder and static and dynamic loads on the right shoulder in violinists. (170)

Figure 3 from Waldeyer´s textbook and atlas of anatomy (19th edition, 2012) shows the right shoulder joint with its bones and some of its bursae, ligaments, and tendons from a ventral point of view. (160) In order to provide its high mobility, the joint capsule is rather loose, so that the tendons of four muscles and a ligament have to stabilize the joint: the teres minor muscle, the subscapular muscle, the supra- and infraspinatus muscles, and the coracohumeral ligament. These have all grown together to form a rough, rounded, caudally open sheet called the "rotator cuff". (160) The movement of the humerus is limited cranially by the fornix humeri, which consists of the coracoacromial ligament (lat. lig. coracoacromiale) and its two bony insertions, the acromion and the coracoid process (lat. processus coracoideus). Between the head of the humerus and the fornix humeri lie the subacromial bursa (lat. bursa subacromialis), the tendon of the long head of the biceps brachii (lat. caput longum m. bicipitis brachii), and parts of the rotator cuff, in particular the tendon of the supraspinatus muscle (lat. m. supraspinatus). (160)

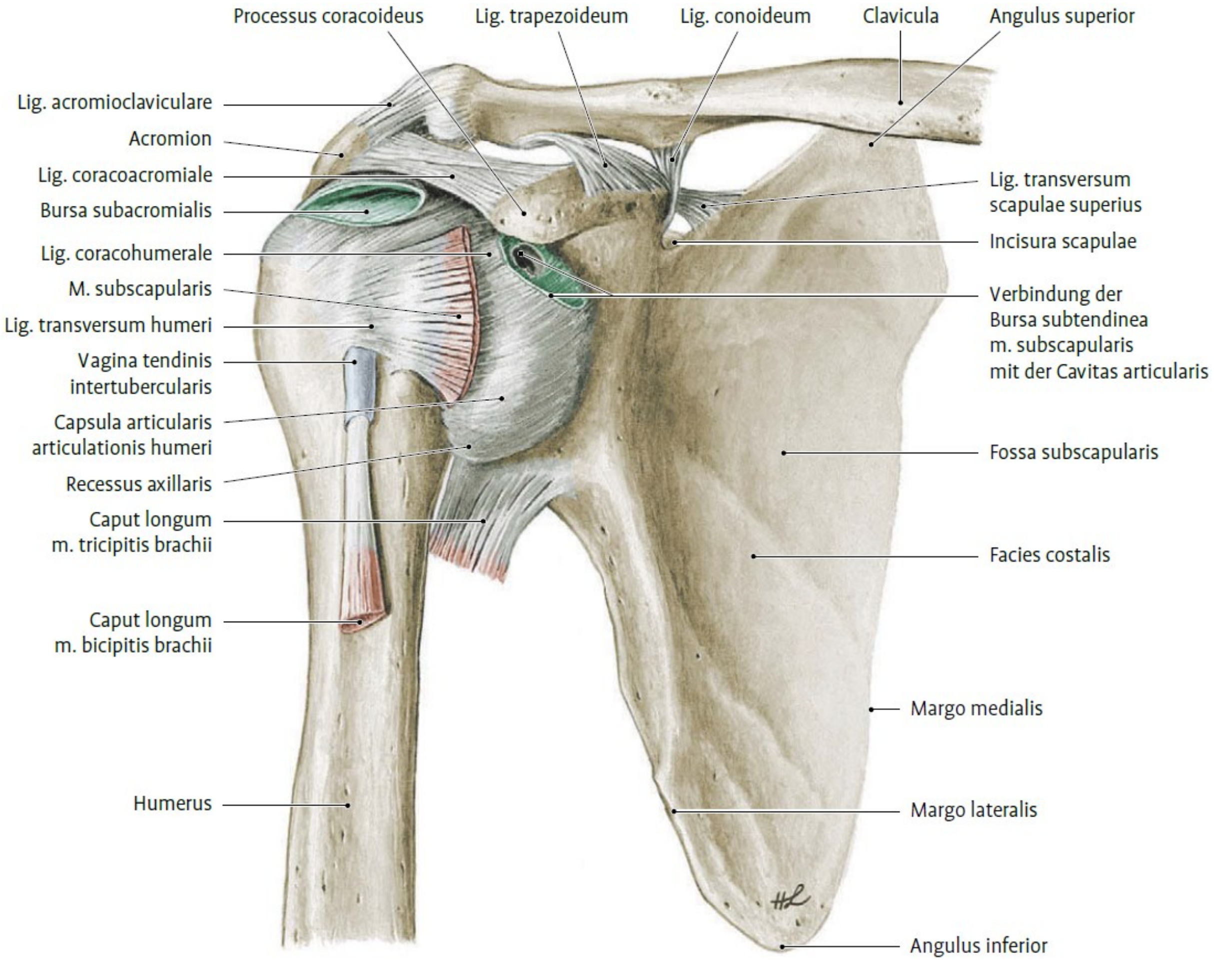


Figure 3: *Ventral view of the right shoulder joint with bursae, ligaments, and tendons. Source: Streicher and Pretterklieber. In: Waldeyer – Anatomie des Menschen. 2012; (160, p. 208).*

The most common cause of shoulder pain in the population is shoulder impingement syndrome or subacromial impingement syndrome (SIS), which was first described by Neer in 1972. (171, 172) It occurs due to entrapment of the anterior soft tissues, especially the tendon of the supraspinatus muscle, between the lesser tuberosity of the humerus and the fornix humeri. The aetiology is either extratendinous (extrinsic), usually damage to the supraspinatus tendon by compression of the rotator cuff between the head of the humerus and coracoacromial structures, or intratendinous (intrinsic) by degenerative processes inside the tendon itself. (173, 174)

Another pathology commonly found in SIS is subacromial bursitis, which commonly occurs together with rotator cuff pathologies such as the aforementioned impingement of the supraspinatus tendon. (175) Inflammatory processes of the subacromial bursa are often found in shoulder impingement syndromes of various aetiologies, but the inflammatory edema can also press onto the supraspinatus tendon, thereby being the cause of the primary extratendinous SIS. (174, 176)

Painful movement of the arm in an angle of about 70°-120° abduction/elevation (the so-called "painful arc") is the cardinal symptom, but also passive movement of the arm above the head and lying on the affected shoulder can cause pain. This leads to sleep disturbances and difficulties to perform specific motions (which are sometimes necessary for instrument playing). (171, 177) The diagnosis primarily relies on the patients´ clinical history and a thorough physical examination. (178) For SIS specifically, several test have been developed, such as the Hawkins-Kennedy test, the Jobe test, the painful arc test, the infraspinatus muscle strength test, and the Neer sign. A combination of these tests together with history-taking and the physical examination yields a diagnostic sensitivity of 90%. (174, 179) If further differential diagnosis is required, e.g. for the detection or exclusion of subacromial bursitis, rotator cuff tendinopathy, tendinosis calcarea, or arthritic changes, imaging techniques are necessary. The methods of choice are ultrasound, conventional MRI, computed tomography (CT), and x-rays. (174, 179, 180)

The treatment of SIS achieves good and very good results in about 80% of patients and, if diagnosed early, there is a good chance of achieving a permanent pain-free state. There are conservative and surgical treatment options and both show equally good outcomes overall. (173, 174) Usually, if there is no major structural damage, patients will initially receive 3-6 months of conservative multimodal therapy. Options include immobilization, manual therapy, physiotherapy, and strengthening and stabilizing exercises, together with pharmacological treatments like NSAIDs and intraarticular corticosteroid injections. (181, 182, 183) If the conservative treatment fails, surgical treatment is the next method of choice. In case of a tear the supraspinatus tendon is repaired and coplaning, acromioplasty, and coracoplasty (among others) to prevent future impingement are considered. As the subacromial bursa is often inflamed, it is usually removed as well. (170, 173, 174, 175)

Another frequent cause of chronic shoulder pain is located in the tendon of the long head of the biceps brachii (LHB), which originates at the supraglenoid tubercle of the scapula and runs through the bicipital groove of the humerus in a synovial sheath. (160, 184) LHB tendinopathies range from tendinitis and tendosynovitis to degenerative tendinosis and are usually associated with other shoulder pathologies like the aforementioned SIS. The aetiology is almost always secondary and can be divided into three categories: trauma, tendon instability, and inflammation. (184, 185, 186)

Patients initially experience anterior shoulder pain that worsens at night or when performing overhead motion, then the resistance to fatigue decreases and functional impairments arise in some cases. (187) The diagnostic procedure is similar to SIS, consisting of a patient history, a physical examination that employs clinical tests, and sometimes a radiographic evaluation with x-rays, ultrasound and MRI. (185) Management of LHB tendinopathies is again very similar to SIS with an initial conservative approach through physical therapy, immobilization, and NSAIDs or, if those prove insufficient, intraarticular corticosteroids. If these methods fail to achieve pain relief, then surgical repair, tenotomy, or tenodesis of the LHB tendon can be performed. (184, 186, 188)

All treatment of the diseases of the shoulder joint should aim to restore the full mobility of the shoulder as quickly as possible, as long-term immobility can lead to adhesive capsulitis, a disease that often occurs together with SIS, e.g. rotator cuff tendinopathy or bursitis. (189) Adhesive capsulitis is characterized by adhesions inside the glenohumeral joint capsule, leading to progressive thickening and contraction. This results in further pain and a loss of active and passive range of motion (ROM), which can last for years and may never entirely disappear. (189, 190, 191)

Diseases of the arm

Pain and dysfunction of the elbow joint (lat. articulatio cubiti) is most commonly caused by lateral epicondylitis, also called the "tennis elbow". It manifests itself as dysfunction and a reduced ROM of the joint, as well as pain that originates from the lateral epicondylus of the radius, where the extensor carpi radialis brevis muscle and other extensors have their origins. (160, 192) In the physical examination, the pain is worsened by extension of the forearm against resistance. Imaging techniques (ultrasonography, MRI, x-rays) are not necessary to make a diagnosis, but can be useful to assess the severity and to rule out differential diagnoses. (193) Currently there is a wide array of both surgical and non-surgical treatment strategies, e.g. injections of botulinum toxin or shockwave therapy, but no therapy has yet been proven to be superior to placebo. (192, 193, 194)

Tendovaginitis stenosans, also termed "de Quervain´s tenosynovitis", was first described by the Swiss surgeon Fritz de Quervain in 1895. (195, 196) The tendon sheaths in question are those of the abductor pollicis longus muscle and the extensor pollicis brevis muscle, which both run in the first dorsal compartment. (160) Heavy use of the wrist causes thickening of the extensor retinaculum and consequently a constriction of the first compartment, resulting in swelling over the radial styloid and radial wrist pain. The pain is exacerbated by actively or passively moving the thumb or the wrist, a fact which is used for diagnosis via Finkelstein´s test. (197, 198, 199) Particularly affected by this disease are clarinetists, oboists, and pianists, with a very famous example of the latter being Robert Schumann. (170, 200) Conservative therapy relies on hand therapy with fabrication of an orthosis for the wrist and NSAIDs or intraarticular corticosteroid injections. If there is no improvement after 3-6 months, surgical decompression of the first dorsal compartment is performed. (197, 201, 202)

Diseases of all joints

Overuse by repetitive motion is the most common cause for development of a musician´s PRMD overall. The "overuse syndrome", which is also well known in sports medicine, is defined by Hunter J.H. Fry as "a condition of pain and loss of function in muscle groups and ligaments through excessive use". (56, p. 572, 57, 59, 203) The damage can be caused acutely or chronically through multiple pathophysiologic mechanisms, which are not yet completely understood in musicians, but studies with athletes have found muscle degeneration with glycogen depletion and lactic acid retention, local edema, cellular infiltrates, and angiofibroblastic tendinosis, among others. (96, 204)

Most overuse syndromes manifest themselves in the musicians´ upper limbs, as this is the area in which repetitive motion occurs most frequently. Symptoms are usually first noticed when there is a sudden increase in the amount of playing (e.g. due to a competition or a new teacher) and occur during and shortly after instrument playing. In early stages musicians have an uncomfortable feeling, especially in the forearm, which later becomes pain, loss of function, weakness, and stiffness in the overused joints, ligaments, and muscles. (57, 96, 205)

Unfortunately, many musicians do not seek medical help, but rather consult their peers or instructors, who unfortunately lack the necessary expertise. They also frequently try self-applied treatment strategies such as resting, stretching, specific exercises, gels or creams. (206) Conservative treatments focus on reducing the workload put on the joint: initially the length of practice segments is reduced or pain-inducing activities avoided entirely, followed by a period of playing with increasing break frequency and improvement of posture coupled with physiotherapy and/or occupational therapy. Nevertheless, only about 28% of musicians report a satisfactory improvement of their symptoms through professional therapy. (56, 96, 206)

1.2.3 Prevention & Treatment

As PRMDs have a high prevalence and often lead to long-term consequences, it is sensible to implement preventive measures, as long as they are cost-effective, based on scientific insights, and cannot cause any damage to the musician. (143) The first proposed preventive measure was by Zaza and Farewell in 1997, who found a significant protective effect of warm-up exercises prior to and breaks during performances (see also chapter 1.2.1). (144)

Since then, some studies on dedicated prevention programmes consisting of education, exercise, or both, have been conducted. (207, 208) Spahn et al. (158) found a positive effect of a combination of lectures and physical exercises on playing-related symptoms, emotional disturbances and anxiety, compared to no prevention program (n=44). (158) Also, López and Martínez found improved body awareness and a decrease of the frequency of injuries of 78% in students who received a theoretical course on prevention of musculoskeletal injuries (n=146). (209) Furthermore, a pilot study with an education workshop conducted by Wolff et al. (210) reported a decrease in pain of 32% in the intervention group and an increase of 8% in controls (although not significant with p=.055, n=57). (210) Zander et al. (211) found a positive effect on psychological health, but not on physical symptoms with a similar prevention program as Spahn et al. (158) (n=247), and Baadjou et al. (212) found a "biopsychological prevention course tailored for musicians" to not be superior to general promotion of physical activity (n=170). (211, 212)

The topics of these courses and exercise programs included education about functional anatomy, physiology and frequent medical problems of musicians, as well as warm-up, strength and endurance exercises and improvement of postural quality, practicing routines, and coping with performance. (150, 212, 213) Unfortunately, these preventive measures are rarely employed and if so, only by a minority of musicians. Furthermore, musicians often recognise the importance of such measures only after the onset of the symptoms of a PRMD, when it is already too late. (214, 215)

The treatment of PRMDs depends on the exact disease at hand and works best when it is individually adapted to the musician and practice with the instrument is incorporated into the therapy regimen. Nevertheless, there are a few therapeutic methods or tools, which are key in the management of PRMDs and therefore often used for treatment. (216, 217) These will be briefly discussed in the following paragraphs.

It has been known for over 100 years among physicians and in the musicians´ common sense that rest is one of the most important factors in the recovery from playing-related diseases. (31) The duration and frequency of rest breaks is strongly player- and disease-dependent, but in general it has proved efficient to only shorten training time somewhat in mild cases, as complete inactivity leads to a loss of mobility and stiffness in joints and atrophy of the muscles. However, severe injuries that are painful even when not playing the instrument require absolute absence from practice. (216)

After the injury has been healed or at least reached an acceptable state, musicians often disregard the problem and return to normal play. However, in order to prevent the recurrence of the problem, the return to normal performance should be done step by step with increasing playing durations. (217, 218) Table 4, which was originally published in Norris´s book "The Musician´s Survival Manual" in 1993, gives an example of a schedule for returning to normal play after a playing-related injury. (219) It features ten levels that last for 3-7 days each (although individually adjustable), with periods of play and of rest that are adapted depending on the instrument. The duration of the play periods rises steadily from 5 minutes to 50 minutes and the duration of the rest periods decrease from 60 minutes to 10 minutes. (220)

Level	Play	Rest	Play	Rest	Play	Rest	Play	Rest	Play
1	5	60	5						
2	10	50	10						
3	15	40	15	60	5				
4	20	30	20	50	10				
5	30	20	25	40	15	45	5		
6	35	15	35	30	20	35	10		
7	40	10	40	20	25	25	15	50	10
8	50	10	45	15	30	15	25	40	15
9	50	10	50	10	40	10	35	30	20
10	50	10	50	10	50	10	45	20	30
Etc.	Time in minutes; 3-7 days/level; if pain occurs, drop back to previous level until able to progress without pain								

Table 4: *Practice schedule when returning to play after a playing-related injury. Source: Norris R. The musician´s survival manual. St. Louis: ISCOM, 1993. (228, Figure 33)*

Incorrect technique can be responsible for increased static and dynamic loads when playing an instrument and can therefore be a direct cause of a variety of PRMDs. For this reason, the individual technique of a diseased musician and the resulting strain put on the musculoskeletal system should always be evaluated. Static loads (e.g. holding the instrument) can be reduced through harnesses, straps or other stabilizing mechanisms and dynamic loads (e.g. motions with a high frequency or in a certain direction) can be reduced or transferred to other joints through movement-limiting orthoses. (217, 220, 221)

The evaluation and revision of the technique should be done by the therapist together with the music teacher to develop a technique that is optimal not just from a physiological, but also a musical point of view. Beyond the basic technique of an instrument, there is a lot of individual variation possible that can reduce or get rid of the circumstances causing a specific PRMD without hindering the musician´s abilities on the instrument. (217, 220, 221)

Physical therapists specialize in treating musculoskeletal disorders of any origin and therefore play a very important role in the convalescence of musicians with PRMDs. (222) Physiotherapists create an individual treatment plan based on an assessment of the musician. This assessment takes many factors into account, including an extensive past history of the musician and his or her playing, pain and other symptoms, a physical examination with emphasis on posture during performance and without the instrument, and measurements of range of motion and muscle strength. (221, 223)

The treatment plan usually aims for varying degrees of immobilization in the early stages and achieves this goal through orthoses, functional or thermoplastic splints, or therapeutic tape. Then, an exercise regime tailored to the musician is developed with the target to solve any existing postural or other problems, increase range of motion, strengthen the relevant muscles, and improve general fitness. Ergonomic modifications can help with the adaptation of the instrument to the musician and progress can be tracked through biomechanical analysis of the performance, which can also provide important feedback to the musician. (217, 221, 223)

Pharmacological therapy with NSAIDs, with or without a prescription, is a widespread treatment option among musicians. The analgesic and anti-inflammatory effects are perfect for dealing with short-term, mild or moderate pains and aches, but NSAIDs should not be used in the long term. This is due to their negative effects on the gastrointestinal tract and the kidneys, and because they mask the musculoskeletal symptoms, thereby preventing proper treatment of the underlying disease. For severe conditions, corticosteroids can be injected locally as a short-term therapy, but have to be followed up with immobilization, physical therapy, or even surgery. (217, 224, 225) It should be noted that surgical treatments of most PRMDs are only rarely warranted, but have generally shown very good long-term outcomes. (226)

Besides the treatment of PRMDs directly, associated psychosocial factors have to be considered, as these aspects are sometimes even more important to musicians than pure physical health. (227) Musculoskeletal injuries and other problems are often interpreted as a result of bad technique, weakness, or a lack of ability, thus creating a stigmatization of PRMDs among musicians. (7, 10) This, together with fears of losing a job or of being rejected for a new job in favour of other, better competitors, can all cause musicians to continue performing in spite of existing PRMDs without consulting healthcare professionals, thus promoting chronification. (228, 229)

Musicians who cannot perform anymore because of their medical condition often also begin to develop traits of mental illnesses such as eating and substance abuse disorders, anxiety and depression. In these cases, it is paramount that teachers and therapists are aware of the emotional state of the musician and fulfil a supporting and motivating role. The musician should be made aware and understand that these symptoms can be normal reactions to the injury and its implications for everyday life. However, if the symptoms become more severe and develop towards a manifest mental illness, a mental health professional should be consulted as soon as possible. (13, 14, 230)

1.3 Other Playing-related Disorders

Besides the impact on the musculoskeletal system, playing an instrument can also take its toll on other parts of the body, such as the respiratory, cardiopulmonary, sensory, or nervous systems, as well as on the skin and on mental health. Several non-musculoskeletal diseases are significantly more prevalent in musicians than in non-musicians, some of which will be briefly introduced in the following paragraphs.

The most significant association between musicianship and a disease group overall was found for diseases of the larynx and vocal cords, such as chronic laryngitis and voice disturbances, with odds ratios (OR) as high as 6.64 (95% CI: 5.66–7.62) for chronic laryngitis in vocalists. (231) While some of these diseases like vocal fold nodules and polyps almost exclusively occur in singers and brass or wind instrument players, other voice disturbances often occur in string and keyboard players. (232, 233) It is unclear if this observation in string and keyboard players was due to some these instrumentalists singing regularly, as even after removing those that were also vocalists, a significant association remained with both instrument families. (231)

Focal task-specific dystonia (FTSD), the musician´s cramp from the 19th century, is a hyperkinetic movement disorder that can manifest itself as a loss of control in muscles that play a part in extensively trained movements. Its exact pathophysiological mechanisms have not yet been completely clarified, but it is known that an alteration of sensory perception, sensorimotor integration, and reduced inhibition in the central nervous system (CNS) play a role, among others. (66, 234, 235)

FTSD manifests itself as cramps that appear suddenly when specific, well-trained motor tasks, such as playing an instrument, are carried out, and can be divided into two categories based on the location. Musician´s hand dystonia can happen in almost all instruments and usually affects the hand with the more complex task (e.g. flexion in the left hand in violinists, extension in woodwind or brass players). Embouchure dystonia, on the other hand, only happens in brass and woodwind players because of the complex muscular activation needed to produce a sufficient air stream and encompasses abnormal facial, lip, and jaw movements and tremors. (9, 66, 234)

Because the symptoms are intermittent and only arise during performance, FTSD is often misdiagnosed as either an overuse syndrome or a tendon pathology. (236) There are various treatment options, which range from conservative retraining, splint devices, physiotherapy, hand therapy and pharmacological therapies (e.g. botulinum toxin and trihexphenidyl) to even some neurosurgical approaches. (237, 238, 239, 240) Nevertheless, long-term outcomes are rather grim, as FTSD ends the musicians´ careers in many cases despite exploring a variety of treatment options. (235, 237, 241, 242)

Another very common playing-related disease in musicians is noise-induced hearing loss (NIHL) with an OR of 1.36 (95% CI: 1.32–1.39) compared to the general population and accounting for about 11% of all playing-related disorders overall. (231, 243) The prevalence of NIHL varies between instruments, with trumpet players, percussionists, and the left ears of violinists especially affected. (244) It has been known for a long time that prolonged exposure to loud noises causes hearing loss and that workers of any occupation, if faced with exposure, should utilize earmuffs, earplugs, or other hearing protection devices (HPDs). (245, 246) Although these devices are well-accepted and their use is subject to strict standards in most of these professions, there are no regulations mandating use in orchestras and musicians only very rarely use HPDs. (247, 248)

Musicians are at least partially aware that a career in performing music can cause NIHL to the same extent as industrial noises and many musicians are familiar with different types of HPDs. (244, 249) Despite this knowledge, orchestra musicians as well as music students almost never use hearing protection, with study results ranging from "less than 2%" to "maximum 16%", although it should be noted that musicians with manifest hearing disorders tend to use HPDs more frequently than healthy musicians. (248, 249, 250, 251)

The reason for this gap between the knowledge about the risks of noise exposure on one hand and the very infrequent use of protective measures on the other seems to lie in the specific features of the profession, as musicians complain about reduced sound quality and an impaired ability to listen to their colleagues when wearing HPDs. (251, 252) This is also the reason why existing hearing loss makes it even more difficult for the affected musicians to wear hearing protection. (253) Several studies point out the importance of education about the necessity and the proper use of HPDs, in order to resolve perceptional issues and make HPDs a widely used tool in the prevention of musicians´ NIHL. (248, 250)

Interestingly, musicians with hearing loss have a better speech-in-noise perception ability and more robust subcortical encoding of sound than non-musicians, which is likely due to mechanisms of training-induced neuroplasticity. (254, 255) The high exposure to loud noises and the lack of hearing protection does not just cause NIHL, however, as musicians can also suffer from other hearing disorders, such as tinnitus, hyperacusis, diplacusis, and auditory distortions. (250, 256)

The emotional toll that consistently performing at a very high level takes on musicians´ psyches makes them especially predisposed to acquire mental health disorders. A preliminary report of a survey with 2,211 musicians in the UK states that 71.1% of the musicians had experienced anxiety and panic attacks and 68.5% had struggled with depression, and the lifetime prevalence of eating disorders among musicians is estimated by another study to be 32.3%. (13, 257) Furthermore, it is three times more likely for musicians to utilize psychotherapy compared to the general workforce, despite the fact that in many cases they receive treatment very late or not at all. (258) In fact, 52.7% of musicians from the aforementioned report find it difficult to get help for when suffering from mental health disorders. (257)

The most well-known and most researched mental health disorder unique to musicians is music performance anxiety (MPA). The nervousness that comes with having to deliver an elite performance, often in front of large audiences and with high stakes, can generally manifest itself in many different ways, physically as well as mentally. The effects can be positive, e.g. heightened body awareness, better concentration, more enjoyment of playing, and more expressiveness in the performance. (259) However, too much nervousness becomes panic and triggers sympathetic responses in the body, such as a shaky voice, an elevated heart rate, shortness of breath, blushing, sweating, and tremor. These effects can severely limit the musician´s ability to perform properly and/or cause the avoidance of the performance altogether through negative thoughts, e.g. self-doubt or fear of failure. If this happens, the now-pathological nervousness is regarded as MPA. (50, 259, 260)

MPA is one of the most prevalent disorders of musicians overall, with estimated prevalence rates between 15%-25%. (50, 261) In most cases, musicians suffering from MPA are adolescents and young adults, whereas MPA is reported far less frequently by musicians over the age of 45-50 and children. Female musicians are also more likely to be affected than male musicians. However, no correlation between the amount of professional experience and MPA has been found, which is in line with the observation that many famous musicians were affected, among them the cellist Pau (Pablo) Casals and the operatic tenor Enrico Caruso. (50, 262)

As there are systematic variations of the symptoms of MPA among musicians, Spahn et al. (263) recently conducted a study of 532 musicians and concluded that the disorder can further be categorized into three different types. (263) Musicians with Type 1 MPA (49.6%) show few symptoms before, during and after the performance, whereas musicians with Type 2 MPA (27.2%) have more symptoms before and at the beginning of the performance, which then continually decrease towards the end. Both Type 1 and Type 2 exhibit high levels of functional coping and self-efficacy at all times, which are attributes that have been found to positively influence the physical and mental symptoms and therefore the course of MPA. (264, 265) Musicians with Type 3 MPA (23.2%) show lower levels of functional coping and self-efficacy, which leads to their symptoms getting dramatically worse from before and the beginning of the performance towards the end. These are the musicians, who find themselves in an adverse state towards the next performance and Type 3 is therefore rated as “critical” by the authors. (50, 263)

Despite the fact that there is a variety of treatment options for MPA, only a minority of musicians affected seek help, with one study providing an estimate as low as 15%. (266) Over the past decades, psychological approaches have been studied the most extensively and seem to yield the best outcomes. Among these, cognitive behavioural therapy (CBT) is by far the most frequently utilized approach. CBT encompasses multiple different techniques, such as acceptance and commitment therapy, cognitive therapy, systematic desensitization, and virtual reality exposure. All of these methods consistently cured or significantly reduced MPA through a plethora of studies. (50, 267)

Relaxation techniques, such as yoga, meditation, deep breathing or other aerobic exercises have proved to be very useful in controlling the physical symptoms of MPA. Alternatively, the aforementioned beta blockers provide a very effective pharmacological solution for the management of vegetative symptoms, as they were rated as helpful by 93% of surveyed musicians in one study. (268) They should however be used sporadically for only the most important performances, as otherwise the musician´s career becomes dependent on permanent medication. (51) Other therapeutic approaches include psychological counselling, which has been rated as helpful by 60-62% of patients in three different studies, psychoanalytic and psychodynamic therapy, music therapy, hypnotherapeutical interventions, expressive writing interventions, and interventions based on mental imagery. (50, 269, 270, 271, 272)

1.4 Transcranial direct current stimulation

1.4.1 Non-Invasive Brain Stimulation

There is a long tradition in human history of trying to positively modulate cognitive performance beyond physiologically "normal" levels with exogenous methods. The use of pharmacological agents like caffeine and nicotine for this purpose dates back to the Pleistocene more than ten thousand years ago. (273) Although these substances are effective in their own right and enjoy a broad popularity worldwide, historically more recent research has laid its focus on tools that only impact the nervous system in specific parts of the body, i.e., the spinal cord, peripheral nerves, and, of course, the brain itself. (274) The aim is for these tools to be better targeted, thereby gaining effectiveness while simultaneously getting rid of side effects on the rest of the body. The first instances of electrical stimulation of the brain came hand-in-hand with the discovery of electricity itself, but systematic research on the positive effects of various stimulation methods, e.g. deep brain stimulation (DBS) and non-invasive brain stimulation (NIBS), emerged only in the second half of the 20th century. (275, 276, 277, 278, 279, 280)

Non-invasive brain stimulation is a collective term for various methods that employ transcranial electrical currents to alter cortical activity positively or negatively. These methods can be roughly divided into two groups, repetitive transcranial magnetic stimulation (rTMS) and transcranial electric stimulation (tES). The former, rTMS, induces a rapid change of the magnetic field inside the brain through a strong and brief electric current (~8000 A), which in turn triggers action potentials in the stimulated neurons. This technique is useful in the treatment of some neurological and psychiatric disorders, e.g. post-acute motor stroke, pain, and depression. However, multiple drawbacks, e.g. higher technical demands, higher prices, and safety concerns such as induction of seizures, limit its usefulness for many other (non-) medical applications and prevent its domestic use entirely. (280, 281)

On the contrary, tES is very cheap and easy to use, all while being much more safe because the applied currents are ~1-2 mA, which is multiple orders of magnitude smaller than those of rTMS. (282) It should be noted that there is also a variant of tES that employs a stronger current, the so-called "high-intensity tES", but its only application is for intraoperative neuromonitoring, whereas all other protocols in research and clinical practice use low-intensity tES. (283)

The three main methods comprised by tES are transcranial direct current stimulation (tDCS), which employs a constant, one-directional current and is by far the most researched, transcranial alternating current stimulation (tACS), and transcranial random noise stimulation (tRNS). (282, 284, 285)

Applications of low-intensity tES have been researched for a plethora of disorders (see below), as well as for enhancing different aspects of performance in healthy individuals. These include cognitive functions like intelligence and memory, motor functions, moral decision-making, emotional well-being, sleep quality, and anti-aging effects. (280, 286) In recent years, research of NIBS techniques on modulation of memory has experienced a spike in popularity due to the ever increasing number of elderly people in the population, for whom one of the primary struggles is an age-related decline of cognitive ability. (280, 287)

1.4.2 Transcranial Direct Current Stimulation

Transcranial direct current stimulation (tDCS) is a NIBS technique, which can be used to modulate corticospinal excitability and neural plasticity via a weak electric current. This current, typically an amplitude of 1-2 mA, is delivered to the brain by two or more electrodes, made of metal or conductive rubber, that are placed on the scalp. (288, 289, 290) Between the electrode and the scalp is a contact medium, which is necessary to keep chemicals formed at the electrode away from the skin, but has to be conductive for the current to flow. Most commonly used are sponges soaked in saline or conductive cream applied directly to the electrode. (290, 291) Different methods such as plastic casings make sure that the area of the scalp touching the electrode stays consistent among subjects, therefore ensuring reproducibility. (290)

Unlike rTMS, the electric current in tDCS is not considered strong enough to trigger action potentials in the stimulated neurons (see above). Instead, the purpose of tDCS is to alter the threshold for action potentials, depending on the stimulation program. (289, 292, 293) The applied current is either positive (anodal stimulation) or negative (cathodal stimulation), which alters cortical excitability positively (facilitating depolarization, anodal) or negatively (facilitating hyperpolarization, cathodal). (288, 289) Although this rule is generally true for the primary motor cortex (M1), stimulation is also used in many other areas, such as the dorsolateral prefrontal cortex (DLPFC), the primary visual cortex (V1), the right temporal cortex, and the supplementary motor area (SMA). (294, 295, 296) In the cerebellum, anodal tDCS has been shown to increase cerebellar brain inhibition, which, put simply, is inhibition of the M1 by the cerebellar cortex, whereas cathodal stimulation had the opposite effect. (297)

Furthermore, it has been shown that tDCS has an effect on GABAergic function, intracellular calcium concentrations, glial activation, and synaptic plasticity in the M1 when combined with induction of long term potentiation-(LTP)-like mechanisms. (298, 299, 300, 301) LTP describes the long-lasting strengthening of synaptic transmission between neurons induced by activity of the involved synapses, which happens for example through learning or training. This all means that LTP and therefore synaptic plasticity, is amplified by concurrent, pre- or post-training tDCS. (302, 303, 304) Because learning and memory are thought to be a result of enhanced synaptic plasticity, it is argued that stimulation paired with training leads to better task-specific skill improvements than training alone. (305, 306, 307)

The effects of tDCS on motor learning have been studied extensively, with the most frequently investigated region being the M1. Several studies have found significant enhancements of both online (during training) and offline (between training sessions) skill improvement. (308, 309, 310) The improvement of motor skill learning via tDCS has also been observed in musicians, although the effects of stimulation seem to correlate negatively with the level of skill already acquired. (311, 312) Furthermore, tDCS of the M1 has been shown to positively alter musical creativity and the quality of improvised musical performance, as well as tactile discrimination. (313, 314)

Multiple meta-analyses have recently reviewed existing studies to assess the safety of tDCS in humans. Using a high-definition rat model, brain damage has been predicted to occur at current densities of 6.3-17A/m^2, which is substantially higher than in currently applied stimulation protocols (0.3-0.8A/m^2). (309, 315) The application of these protocols have not produced any serious adverse effects in 32.000 sessions and 1000 subjects. (315) In 2011, Brunoni et al. (316) analysed 209 studies (almost 4000 subjects) and found the frequency of mild adverse effects (itching, tingling, headache, burning sensation, discomfort) to be comparable with sham stimulation (10-40%). (316)

The absence of serious side effects, as well as tDCS being non-invasive, relatively inexpensive and easy to administer makes it a promising tool for therapy in a wide variety of fields. Clinical investigations have been conducted for depression, (317) schizophrenia, (318) addiction, (319) social anxiety disorder, (320) chronic pain, (321) migraine, (322) epilepsy, (323) multiple sclerosis, (324) post-stroke aphasia, (325) and motor rehabilitation. (326) In the USA, tDCS has the status of “investigational”, meaning the FDA has not yet issued an opinion and doctors can only use it “off-label”. In the European Union, Canada, Brazil, Australia and Singapore, however, some tDCS products have been approved for the treatment of chronic pain and neuropsychiatric disorders.

1.5 Monitoring Methods

Concurrently with the development of new technologies like tDCS in research and clinical practice, it was necessary to find methods which could help show, evaluate, and/or measure the effects produced by these new technologies in clinical trials. For this purpose, a wide variety of already existing tools have been applied in research and many new technologies have been developed. Some of these methods of monitoring outcomes will be briefly introduced in the next two chapters.

1.5.1 Monitoring of Neural Activity

The aforementioned NIBS technique rTMS is not just useful as an intervention, but also for measuring changes in cortical excitability. This is because the current produced by rTMS is strong enough to generate action potentials in the stimulated neurons, called *motor evoked potentials* (MEP). The size of these MEPs, which can be recorded even in very small muscles using EMG, reflect the excitability of the corresponding cortical neurons, corticospinal pathways, and spinal motoneurons. (327, 328) As many studies have shown, tDCS can alter the size of MEPs positively or negatively, thus demonstrating its effect on the human brain. (288, 289, 329)

Magnetic resonance imaging (MRI) is a non-invasive imaging technology that uses radiofrequency pulses to excite nuclear spins of protons in strong magnetic fields. If said pulse is taken away, the protons realign with the magnetic field, releasing electromagnetic energy that is specific for various tissues and can be detected with MRI sensors. (330) Structural MRI allows to capture structural properties of the brain and quantify different tissue properties. Blood oxygen level dependent (BOLD) functional MRI (fMRI) gives a quantitative signal depending on the ratio between deoxygenated and oxygenated hemoglobin in a given part of the brain at a given time. As this ratio varies depending on neuronal activity, fluctuations in the signal show which region is active at any specific time. Temporal correlation of these fluctuations between two regions of the brain is a sign for functional connectivity between these regions. (331) BOLD fMRI of the brain has been widely used to compare musicians and non-musicians, finding differences in activity in many regions (332, 333, 334, 335), as well as an overlap with structures responsible for language (336, 337, 338), and shared networks between auditory and motor processing. (339, 340)

Diffusion tensor imaging (DTI) is a type of MRI measuring the anisotropic diffusion of water molecules, which gives information about the microscopic properties of white matter (tracts of myelinated axons). (341, 342) Using this method, several studies of musicians have found an increased number of fibres, increased grey matter volume and lower fractional anisotropy in different parts of the brain, suggesting practice-induced structural adaptation. (343, 344, 345, 346, 347)

Electroencephalography (EEG) is a non-invasive technique to measure the electrical activity of groups of neurons in the cerebral cortex through electrodes applied to the scalp, usually over the entire head. A typical EEG recording contains measurements of postsynaptic potentials between multiple pairs of electrodes, with time on the abscissa and voltage on the ordinate. (348, 349) EEG has been used to study motor performance of skilled musicians (350), with some systems being able to minimize movement artifacts in order to record EEG and the musical performance simultaneously, providing insight into its underlying neural mechanisms. (351, 352, 353, 354) The contamination of measurements by artifacts also has to be taken into account when recording EEG with concurrent tDCS. (355, 356)

Magnetoencephalography (MEG) measures the magnetic induction produced by electrical currents in and between neurons using superconducting quantum interference devices (SQUIDs) in a room magnetically isolated by thick layers of metal. Compared to fMRI, which has a high spatial resolution, the temporal resolution of MEG is far better, allowing for imaging with millisecond precision. (357, 358) It has been used to study auditory and auditory-motor processing, functional connectivity and sensorimotor learning in musicians. (359, 360, 361, 362, 363, 364)

1.5.2 Monitoring of Motor Function

There is a wide variety of tasks for investigating motor function and learning. The most common are sequential finger tapping tasks (SFTT), sequential reaction time tasks (SRTT) and sequential visual isometric pinch force tasks (SVIPT). The SFTT consists of a series of simple actions performed as quickly as possible, i.e., pressing a sequence of different keys on a keyboard. (312, 365, 366) In the SRTT, participants respond as fast as possible to visual cues by pressing a corresponding key. (367, 368, 369) Unlike the first two tasks, the challenge in the SVIPT is to perform the action itself as accurately as possible. Participants apply a force as accurately as possible onto an isometric force transducer by squeezing it with the thumb and index finger, moving a cursor into target zones. (370, 371) In the quite similar visuomotor pinch force task (VPFT), the objective is to keep a bar at the same height as a moving reference. (296) To objectively compare results, some studies implement a skill index, which, depending on its definition, can be computed using various formulas. (309, 312, 370, 371, 372)

Motion capture (mocap) allows for a three-dimensional (3D) analysis of posture and movement using body sensors or cameras. Its ability to accurately monitor even very complex movements like that of the hand makes it very useful for objectively evaluating musicians´ motor strategy, including postural and neuromuscular disorders. (373, 374, 375) When analysing music performance with optoelectronic motion capture systems, many different parameters can be recorded simultaneously, e.g. bow position, bow-violin angle, angles of the anatomical joints (shoulder, elbow and wrist) and their respective derivatives (velocity, acceleration and jerk), as well as the coefficient of variation for all parameters. (374)

Studies have used motion capture techniques for different purposes, such as investigating the impact of tactile feedback on timing accuracy, (376) temporal control and hand movement efficiency, (377) measuring bowing parameters (e.g. velocity), (378) joint investigation of cognitive and motor processes in combination with EEG, (353) and evaluating musicians´ skills as well as helping to diagnose motor disorders. (374, 379) Multiple optoelectronic motion capture systems are commercially available, such as Qualisys, (380) OptiTrack, (381) and BTS SMART-DX. (382)

Figure 4 from Ancillao et al. (374) shows the construction of a virtual three-dimensional biomechanical model of the musician from the infrared markers placed on his or her body while playing. Ancillao et al. (374) recorded the player´s motion using six cameras and small infrared markers and computed their cartesian coordinates, which yielded not just the three-dimensional digital representation, but also made the calculation of the aforementioned parameters possible. (374)

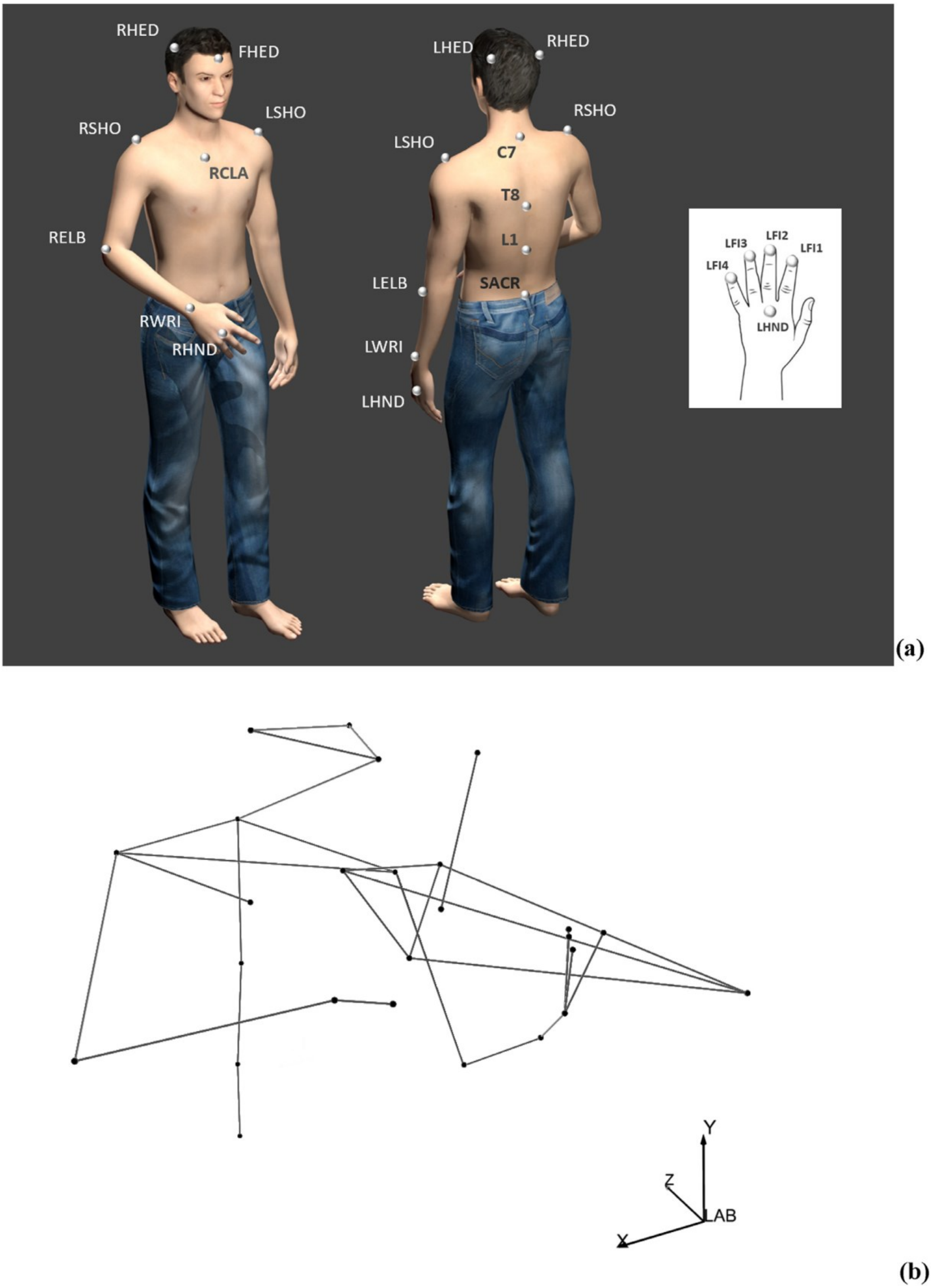


Figure 4: *Construction of a virtual 3D model from infrared markers on the musician´s body. Source: Ancillao et al. Computer Methods and Programs in Biomedicine. 2017;149 (374, p. 22)*

2 Research Questions

This study aims to investigate the feasibility and safety of a therapy regimen consisting of tDCS, physiotherapeutic exercises and psychological coaching. It shall be demonstrated that it is possible to safely and effectively study such a therapy regimen with its potential to enhance the retraining or improvement of orchestra musicians´ motor patterns, thereby alleviating the pain caused by PRMDs or preventing the development of PRMDs entirely. Also, the usefulness of this therapy regimen to gain insight into the pathophysiological neuromuscular mechanisms underlying PRMDs shall be validated. Furthermore, the applicability of imaging techniques and motion capture methods to measure different aspects of musicians´ playing will be evaluated. These measurements could then be able to complement/support the before- and after-treatment subjective perception by the musicians, for which a questionnaire will also be tested. To achieve these goals, pilot trials of the individual methods used for the therapy regimen as well as the evaluation tools will be conducted.

2.1 Primary Hypothesis

Transcranial direct current stimulation (tDCS) combined with a physical therapy and psychological coaching program can be used safely and effectively to study its influence on instrument playing and practicing ability of professional musicians in a larger sample, either in the recovering process of musculoskeletal injuries/disorders or in the regular instrumental training process.

2.2 Secondary Hypothesis

Medical imaging techniques and motion capture methods can be implemented safely and effectively to evaluate their usefulness in measuring and validating improvements of playing and practicing abilities of orchestra musicians in a larger sample.

3 Materials & Methods

3.1 Halo Sport 2

3.1.1 General information

Halo Sport was a commercially available tDCS device produced and marketed by Halo Neuroscience (San Francisco, USA), which is now owned by Flow Neuroscience (Malmö, Sweden). (383, 384, 385, 386) Possible stimulation types include tDCS, tACS, and sham stimulation with an amplitude range of ±2.2 mA and a frequency of up to 600 Hz. The output precision is ±10% or ±50 µA, whichever is larger. It is not intended for the treatment of medical conditions, as tDCS has not yet been FDA-approved in the USA (unlike in other parts of the world, see above).

In the Halo Sport 2 model, the tDCS technology is built into a pair of audio headphones with adjustable size. The contact between the actual electrodes and the skin is made through little foam nibs pre-loaded with salt so there is a conductive electrolyte when they are soaked in water. The electrodes (including the foam) are fixed inside a removable strap on the side of the headband facing the scalp and, when put on, lie directly above the primary motor cortex. The exact positions (using the 10-20 system) are CZ for the anodal electrode, with a size of 24cm2 (6cm x 4cm), and C5/C6 for the anodal electrodes, with a size of 16cm2 (4cm x 4cm).

Figure 5 from the owner´s guide of Halo Sport 2 depicts the locations of some of the key features of the device and shows how the primer band can be inserted into and removed from the headset. On the inside of the headband there is an indentation with a recessed arrow pointing to the left, insuring proper placement of the primer band. The headset has a built-in microphone, USB-C charging port, power button, indicator light and volume/center buttons. A USB-C charging cable for the rechargeable lithium-ion (LiPo) battery is included as well. (387)

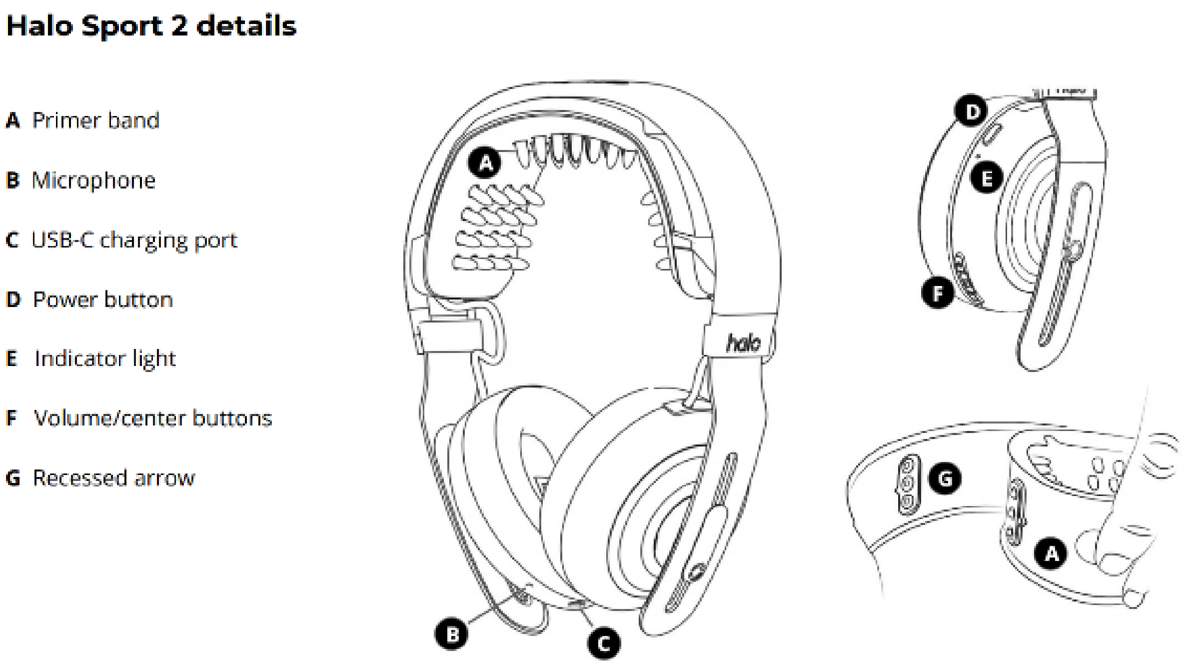


Figure 5: *Details of Halo Sport 2.*

Source: Halo Sport 2 Owner´s Guide. Halo Neuroscience, 2019 (387, p. 4.)

The software for tDCS is provided via a free app that can be downloaded on the App Store (iOS 11 and newer) and on Google Play (Android 6.0 and newer). Using BLE 4.0 ("bluetooth low energy"), Halo Sport can be paired with the smartphone to play music and/or start a neuropriming session (once started, tDCS runs independently and does not rely on a connected phone).

3.1.2 Installation & Handling

When charging Halo Sport 2 using the included USB-C cable, the indicator light will glow yellow, during this period tDCS sessions cannot take place. It takes about 2 ½ hours to fully charge the headset, then the color switches to green and the battery will last for about 15 neuropriming sessions. To pair the Headset with the phone, the Halo Sport app and creation of a free account is required. Before starting a neuropriming session, the foam nibs have to be wet in order to ensure good contact to the scalp. To do this, the primer band is removed from the headband and held under a tap with the nibs facing sideways so the water can run through them easily. The primer band should not be submerged in water completely, as when the sponges are oversaturated, water is pressed out when putting on the headset and covers a random, bigger area of the scalp, therefore altering the location of the current and undermining reproducibility. Then, the primer band is reinserted into the headband by pinching it from the textured circles on the back and aligning the green arrow with the recession in the headset. To check if the primer is positioned correctly, there are alignment lines on the band and headset.

Battery status is displayed on the top right corner on the “home” tab in the app, which also reminds the user to charge before the next session if the battery is very low. If an internal error is detected, the indicator light starts flashing orange. In this case, the headset must be turned off and can be turned back on after 10 seconds. After a tDCS session the headset is turned off and the primer band should be dried.

The headset is turned on by pressing the power button on the right earcup once and put into pairing mode by holding down the center button. When it is ready to pair with the Halo Sport app, the light starts blinking rapidly (twice per second, green if Bluetooth Audio is connected and blue if not). To form a new connection in the app, select “Pair Halo Sport” on the bottom of the “Home Tab” and choose the right model (in this case “Halo Sport 2”). When the connection is being made, the indicator light glows white, once pairing is completed, the light flashes slowly (once every three seconds, green if Bluetooth Audio is connected and blue if not). For tDCS, the headset has to be paired through the app – the audio connection can be established with the phone´s bluetooth settings. Once the connection is established, a neuropriming session can be started. There are three different sessions to choose from: “Legs, Core & Arms”, which focuses on larger muscle groups, and “Hands & Fingers (R) and (L)”, which benefits training of fine motor skill of the hand, e.g. for playing an instrument. Stimulation has a bigger effect on the chosen hand, although both hands are affected regardless.

If the headset and phone are ready for the session with the wet primer band inserted, the headset is put on by spreading it wide and placing the primer band´s nibs directly on the “vertex” top of the head. If positioned correctly, the headset should be vertical when standing up straight. The exact position of the earcups is adjustable through a sliding mechanism, which also ensures good contact to the nibs by tightening the headset to the scalp. While adjusting, the app shows a “contact strength” percentage that indicates the quality of contact and a support button with more information in case there are any issues. When it reaches 100%, the stimulation ramps up and the 20-minute tDCS session begins. Worsened or lost contact during stimulation is indicated via a repeating short low beep, the indicator light flashing yellow and the “adjust your headset” screen reappearing in the app. Once contact is restored, the session resumes automatically. Playing an instrument with a moderate level of body movement is not enough to lose contact in most cases. The session can also be paused at any time and the amplitude of the electric current can be adjusted on a scale of 1-10, with the default being set to 5. The stimulation runs independently and does no longer require contact with the phone. A short high beep signifies the beginning and the end of a neuropriming session.

In the first 30 seconds, the electrical current ramps up until it reaches an intensity of 2.0mA, with the current density being 0.07mA/cm2. For the next 19min, intensity and direction remain constant, until the stimulation is ramped down again in the last 30 seconds. During the sessions, participants complete their training exercises for the entire duration of the sessions. Afterwards, they are encouraged to practice their instrument for until one hour after stimulation has ended (breaks included).

3.2 Physiotherapy

The physiotherapeutic part of this pilot trial was developed in cooperation with Ao.Univ.Prof. Dr. Gerold Ebenbichler, Research Associate Professor and Senior Clinical Specialist, Medical University and General Hospital of Vienna, Christina Knosp, MSc (Physiotherapist), and Ricarda-Samantha Roiger-Simek, MSc (Physiotherapist). The author expresses his sincere gratitude for their contributions.

The aim of physiotherapy is to identify and correct pathological postures and neuromuscular dysfunctions in order to normalize neuromuscular performance. It is known that a non-physiological attitude is a causal or contributing factor for a variety of complaints, including PRMDs. (210, 217, 223) In addition, clinical practice suggests that posture-related myofascial problems of the neck and shoulder girdle are often associated with myofascial disorders of the upper extremities and the hand, with violinists being particularly affected. (388)

A corrected posture on the other hand comes with many benefits, such as alleviation of pain and other musculoskeletal symptoms, more energy-efficient use of the movement system, as well as an improved tone regulation in the pars descendens of the trapezius muscle. It can therefore be assumed that an optimization of physical posture and neuromuscular functions by means of individually adapted physiotherapeutic exercises will lead to less painful and stressful instrument playing and therefore an overall improvement of the musician´s performance on the instrument. (389, 390, 391)

3.3 Coaching

The coaching part of this pilot trial was developed in cooperation with Mag. Nicoletta Margreiter-Neuwirth, Clinical Psychologist and Health Psychologist, General Hospital of Vienna, and Dr. Wolfgang Neuwirth, Clinical Psychologist and Health Psychologist. The author expresses his sincere gratitude for their contributions.

Sufficient training is an important prerequisite for mastering an appearance well. If fear and distraction affect the performance, however, even rigorous practice is not enough. Musicians frequently face tremendous emotional pressure due to their very demanding practice and performance schedule and the need to play difficult pieces perfectly in front of large audiences or at competitions. If they have little to no training in dealing with this mental strain, they struggle to recover from their demanding practice and concert schedule, which is often the case. (8) Coupled with other factors such as perfectionism, strict teachers, and harsh self-criticism, this can result in eating and/or substance use disorders, anxiety and depression, often at a very young age. Therefore, it is necessary for musicians to acquire mental and emotional strength, which allows them to successfully exploit their existing potential in front of the audience. (12, 13, 14, 258)

Cognitive and behavioral therapies (CBT) include education, relaxation exercises, coping skills training, stress management, or assertiveness training. Distorted, maladaptive beliefs are identified and corrected. Behavioural therapy uses thought exercises or real experiences to facilitate symptom reduction and improve functioning. This occurs through learning, through decreased reactivity from repeated exposure to a stimulus, or through other mechanisms.

Individuals for whom CBT works best are generally highly motivated and value a problem-solving approach because therapy requires that the patient learns the skills of self-observation. Patients learn cognitive and behavioral skills and practice them within and outside of the therapy setting. (50, 267, 270, 392)

Psychological factors to be considered are:

- low self-esteem
- personality traits, such as perfectionism or a need to please others
- identity based primarily on performance
- loss of personal control (i.e., expectations determined by coaches and parents)
- increased worry about failure and adult expectations
- overscheduling, extremes of training intensity and time demands
- frequent performances

Individual therapy is the most commonly practiced format, which allows for a confidential interaction between performer and provider, permitting maximal disclosure without fear of others listening or interrupting. The individual adaption of the therapy is done according to the participant´s specific problems and needs and can also be altered based on a variety of neuropsychological parameters that can be collected beforehand. For this purpose, several different neuropsychological tests have been developed (e.g. the verbal learning test, for more information about the specific tests, see chapter 3.5.3). (393, 394, 395, 396, 397)

3.4 Treatment Regimen

The following chapter provides a brief description of the full planned treatment regimen with a duration of 8 weeks and the evaluations done before, concurrently with, and after the treatment. In this pilot study, the trials conducted were separate pilot trials of the individual treatment and evaluation methods and are detailed in chapter 3.5.

The treatment regimen is a program for musicians that consists of tDCS, physiotherapy and psychological coaching. It is divided into two treatment blocks and three evaluation sessions, which take place before, between, and after said treatment blocks. Figure 6 and Table 5 provide an overview of the timeline of the treatment and evaluation periods as well as the duration and the individual methods employed during these periods.

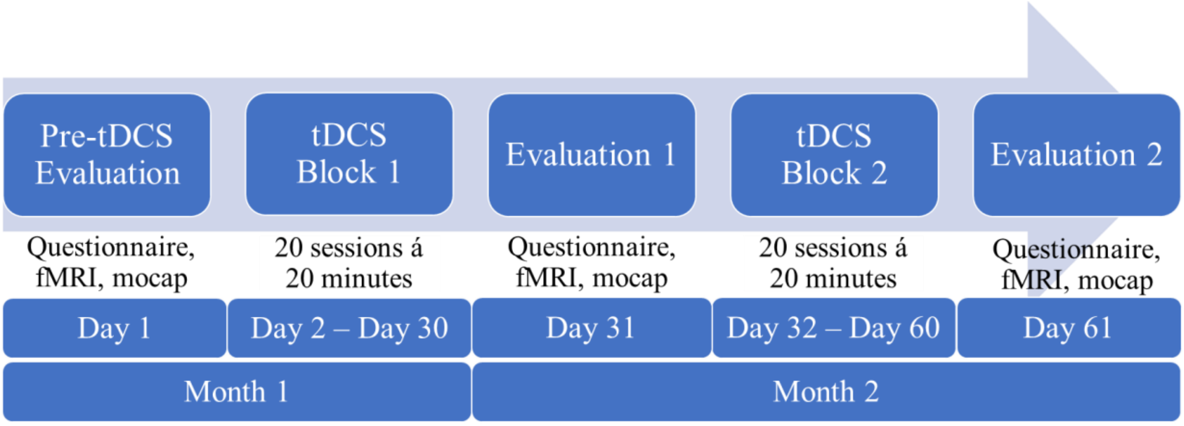


Figure 6: *Timeline of the treatment regimen with evaluation sessions.*

Time	**Program**	**Details**
Day 1	Pre-tDCS evaluation	Pain assessment questionnaire, fMRI acquisition, and 3D Motion capture analysis. ~1.5h.
Day 2-30	tDCS Block 1	20 sessions á 20 minutes of stimulation, 5 days a week, concurrent physio exercises, weekly coaching sessions
Day 31	Evaluation 1	same as pre-tDCS evaluation
Day 32-60	tDCS Block 2	same as tDCS Block 1
Day 61	Evaluation 2	same as pre-tDCS evaluation
After Day 61	Post-study period	No specific post-study treatment, but safety surveillance and ongoing technical support

Table 5: *Study phases with duration and descriptions.*

In the two treatment blocks, the participants will receive 20-minute sessions of tDCS to the primary motor cortex delivered by the Halo Sport 2 device. In total, there are 20 sessions each per block, with every participant receiving real and sham stimulation in one of the blocks. Both blocks have a duration of one month, with five sessions per week. The two days without stimulation are not determined and can be chosen by the participant every week, albeit not consecutively. As handling is relatively simple and requires little experience (see chapter 3.1), these sessions can be self-administered at home.

Concurrently with each of the tDCS sessions, the participants also carry out an 8-week physiotherapeutic exercise program which contains a short warm-up followed by different strength and coordination exercises that vary from week to week. The exercises are individually adapted for each participant based on an introductory physiotherapeutic assessment, which is done before block 1 of the treatment. This assessment and the exercise program, which was done by the participants of this pilot study for one week, is described in detail in chapter 3.5.2. Furthermore, together with the introductory physiotherapeutic assessment the participants complete a 60-minute psychological test (see chapter 3.5.3) and receive weekly sessions of psychological coaching including CBT and other individually adapted therapies based on the results of the initial test (see chapter 3.3).

The efficacy of the therapy regimen described above is evaluated through a number of endpoints, all of which are acquired at three different points in time: before the beginning of the tDCS treatment, after the first block of tDCS, and after the second block of tDCS.

The primary endpoint is a short questionnaire designed for this study to assess musicians´ pain and physical disabilities, as shown in chapter 3.5.4. It is filled out by the participants at each evaluation session. The secondary endpoint consists of medical imaging (structural/functional MRI and DTI acquisitions) and 3D Motion capturing, which are done as an addition to the questionnaire with each of the three evaluations, with the same protocols being employed each time. Both methods of monitoring potential improvements in the musicians´ performance are also described in detail in chapter 3.5.4.

3.5 Pilot Trials

In the following chapters, the pilot trials of the individual parts of the full therapy and evaluation plan are described.

3.5.1 tDCS

Participants carried out one week of the tDCS schedule with Halo Sport 2 (for more information see chapter 3.1), which amounts to 5 sessions and 2 non-consecutive “rest days” that could be chosen freely.

Before beginning with these sessions, the participants received the device together with a charger in the study initiation visit. Here, they were also provided with information on the basic principles underlying tDCS, the construction, handling, and maintenance of the device, and solutions to common technical problems, such as bad connectivity between the electrodes and the scalp.

The visit was held in a "one-on-one" setting, where the participants could try out the device in practice under the supervision of the instructor and had the possibility to ask plenty of questions. For the documentation of the tDCS sessions, they were also given the "checklist for tDCS and the physiotherapeutic exercises", in short "tDCS checklist" (see chapter 3.5.4). Furthermore, they were provided with a handbook explaining all aspects of the use of Halo Sport 2 and received a phone number, which they could call or text anytime if they encountered problems or adverse events or if they had any other questions.

3.5.2 Physiotherapy

The physiotherapeutic trials of this study can be divided into two parts: firstly, the initial physiotherapeutic evaluation, and secondly, the physiotherapeutic exercises done by concurrently to the tDCS stimulations.

The initial physiotherapeutic evaluation took place before the tDCS trials and consisted of a short individual physiotherapeutic assessment including the following tests:

- modified Upper Quarter Y-Balance Test (mUQYBT). (398) In this task, participants started in push-up position and then pushed a little plastic hat along a defined line in three directions that form a "Y" shape together: laterally (to the left with their right hand and vice versa), 45° upwards, and 45° downwards. One arm pushed the hats, while the other was placed at the intersection of the three lines and held the push-up position. The distances of the hats from the intersection were recorded for three tries per arm and direction.
- Closed Kinetic Chain Upper Extremity Speed Test (CKCUEST). (399, 400) Here, participants started in a push-up position with the hands on two white lines that were 91.44cm (36 inches) apart. Then, they moved one arm to the other alternately as fast as they could, and the number of repetitions within 30 seconds was recorded for three tries.

- One-Arm Line Hopping Test, a modified version of the One-Arm Hop Test. (401) For this test, the participants started in a push-up position again, this time with one hand placed just medially of a white line and the other chosen freely for a comfortable position. Then, the participants "hopped" with their hand from the medial side of the line to the lateral side repeatedly as fast as possible. The number of repetitions within 60 seconds was recorded once for each arm.
- Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH) questionnaire. (402, 403) This is a modified, shorter version of the DASH questionnaire (see also chapter 3.5.4). (404, 405) It consists of a main module, which features eleven questions regarding pain and disability in the upper extremity and two optional side modules with four questions each. These two modules, the "work module" and the "sports/performing arts module", each enquire more specifically regarding these topics. For each of the three modules, the "QuickDASH disability/symptom score" can be calculated using the following formula:

  $$symptom\ score = \left(\frac{sum\ of\ n\ responses}{n} - 1\right) \times 25 \qquad \textit{3.5.2-1}$$

  where n equals the total number of questions/responses of the module. The value of this score lies between 0 (= no disability/symptoms) and 100 (= maximum disability/symptoms). (406, p. 2)

These tests were intended to identify (non-)physiological postures and motion patterns and the results were used to create an individually tailored training program. The purpose of this program was to help participants optimize muscle strength, muscle coordination and muscle endurance, as well as to help them achieve a functional, ergonomic, and physiological posture on the instrument.

The exercise program was carried out independently by the participants each time while using "Halo Sport 2" for 20 minutes, altogether five times in one week. The exercises were based on the exercise program developed for the full 8-week treatment regimen, for which table 6 and table 7 provide an example:

Exercise	Week 1+2	Week 3+4	Week 5+6	Week 7+8
Shoulder, elbow and arm movements while standing	10 times backwards 10 times in opposite directions	10 times backwards 10 times in opposite directions	10 times backwards 10 times in opposite directions	10 times backwards 10 times in opposite directions
Cervical spine rotation + nodding one´s head	5 times each looking to the left, middle and right, 3 times nodding one´s head in the three positions mentioned above while sitting	5 times each looking to the left, middle and right, 3 times nodding one´s head in the three positions mentioned above while standing	5 times each looking to the left, middle and right, 3 times nodding one´s head in the three positions mentioned above while sitting	5 times each looking to the left, middle and right, 3 times nodding one´s head in the three positions mentioned above while standing
Thoracal spine rotation in combination with cervical and lumbar spine rotation (global rotation)	10 times isolated rotation of the thoracal spine, 10 times global rotation	10 times isolated rotation of the thoracal spine, 10 times global rotation	10 times isolated rotation of the thoracal spine, 10 times global rotation	10 times isolated rotation of the thoracal spine, 10 times global rotation
Lumbar spine mobilisation	Lumbar spine mobilisation in all planes (flexion/extension, rotation, lateralflexion) while sitting	Lumbar spine mobilisation in all planes (flexion/extension, rotation, lateralflexion) while standing	Lumbar spine mobilisation in all planes (flexion/extension, rotation, lateralflexion) while sitting	Lumbar spine mobilisation in all planes (flexion/extension, rotation, lateralflexion) while standing
Cervical stabilisers	Quick yes and no movements with the cervical spine alternately while sitting and standing	Quick infinity movements with the cervical spine while lying on ones back in the first week and alternately while standing and sitting in the second week (starting in sitting)	Alternately quick yes, no and infinity movements with the cervical spine alternately while standing and sitting week (starting in sitting)	Alternately Quick yes, no and infinity movements with the cervical spine while standing

Table 6: *Warm-up exercises: All warm-up exercises must be performed at each unit.*

	Exercise	Week 1+2	Week 3+4	Week 5+6	Week 7+8
Block A	*Serratus push (m. serratus anterior)*	Dorsal position *week 1*: in closed chain *week 2*: open chain	Plank position against the wall	Push up position against the wall	4 point kneeling position
	Shoulder shrugs (m. trapezius pars descendens)	*Week 1*: in combination with deep breathing (contract – relax) *Week 2*: with 0.5 kilogram dumbbells	with 1 kilogram dumbbells	with 1.5 kilograms dumbbells	with 2 kilograms dumbbells
	Chopping exercise (Sitting position with 90° flexion of the shoulders; movement: very small and quick movements of the arms)	*Week 1*: while sitting *Week 2*: while standing	While sitting + movement in the transversal plane	While standing + movement in the transversal plane	High Squat position + movement in the transversal plane
Block B	*M. transversus abdominis*	Dorsal position with well positioned legs (approx. 120° knee flexion)	Dorsal position with well positioned legs lifting up one foot from the base 15-20 times – repeat with the other side	Dorsal position with well positioned legs lifting up one foot from the base alternately	seated Good Mornings without weight
	Muscle chain ventral + dorsal PNF D1	With no weight alternately while sitting and standing for every training session	With 0.5 kilogram weight alternately while sitting and standing for every session	With 1 kilogram weight alternately while sitting and standing alternately for every session	With a resistance band alternately while sitting and standing alternately for every session
	Muscle chain ventral + dorsal PNF D2	With no weight alternately while sitting and standing for every session	With 0.5 kilogram weight alternately while sitting and standing for every session	With 1 kilogram weight alternately while sitting and standing for every session	With a resistance band alternately while sitting and standing alternately for every session

Table 7: *Strengthening exercises: Exercises from block A and B are performed alternately.*

For the pilot trials, the participants started simultaneously to the start of the tDCS with a short warm-up, after which a combination of five coordination and strength exercises followed. These were carried out in the lower area of the strength pyramid to promote local muscle endurance. The warm-up exercises were the same for every unit: cervical centering exercise, shoulder-neck movements, and rotations of the spine. The coordination and strength exercises of the main part consisted of exercises for the serratus anterior muscle, the pars descendens of the trapezius muscle, and the small neck muscles. Furthermore, functional proprioceptive neuromuscular facilitation (PNF) exercises for the upper extremity with resistances that affect the entire upper arm, chest and trunk muscles (PNF diagonals D1 and D2) were included. (407) Each exercise was done twice a week, with the participants deciding beforehand which exercises to do on which days. The duration of each daily regimen was approximately 22-25 minutes, so that exercises could be performed during the entire tDCS session.

The implementation of the exercises was practiced with the participants until they could do it safely and independently without supervision. To guarantee adherence to the exercise program, the participants were required to fill out a physiotherapeutic checklist, which also offered the possibility to document any problems with the exercises (see chapter 3.5.4).

3.5.3 Coaching

Concurrently to the initial physiotherapeutic evaluation, which took place before the tDCS session, an initial psychological coaching session was held in which purely neuropsychological parameters of the test person were collected through a 60-minute psychological test. The ability to learn (both right and left hemispherical) as well as the executive functions of cognitive processing speed, planning ability and inhibition (= the ability to suppress an unwanted reaction) were examined.

Due to the nature of CBTs, the individually tailored weekly coaching sessions are very diverse between different musicians and require continuous care and constant adaptation over time to be properly executed. As this would not have been possible within the scope of a pilot trial, and because CBTs are well-established in clinical practice, no such sessions were done for this study.

The first two tests were the Verbal Learning Test (VLT) and the Non-verbal Learning Test (NVLT), both type S2, in which the subject was shown either two-syllable meaningless words or abstract figures, depending on the test type. (397, 408) Some of these pieces of content appeared multiple times and it was the subject´s task to decide for each presented piece of content whether it had already appeared previously or not. Possible responses were “YES”, meaning that the piece of content had appeared previously, and “NO” for the opposite. The test scores were based on the number of correct and incorrect YES-responses and provide an insight into the subject´s learning ability. This could be further specified and compared between the left hemisphere, which preferentially encodes semantic information (VLT score), and the right hemisphere, which preferentially encodes non-semantic information (NVLT score). Moreover, a frailness index between 0 and 1, which characterizes the stability of the learning ability based on the number of Yes/No-response changes per word or figure (0 = maximum stability, 1 = minimum stability), was calculated. (409, 410)

The next test done by the participants was the Langensteinbach version of the Trail Making Test (TMT), type S1, which is comprised of two parts. (411) In part A, the subject had to select the numbers 1-25 in the correct order as fast as possible, while in part B, the subject had to select the numbers 1-13 and the letters A-L alternatingly, i.e., in the order 1-A-2-B-3-C-etc.. The TMT examines different neuropsychological domains, such as attentiveness, visuomotor processing speed, and executive functions like cognitive flexibility and working memory. (412)

The main result was the sum of the working times for all items, measured in seconds. It was calculated separately for part A of the test, which characterizes the subject´s cognitive processing speed, and for part B, which provides information about the subject´s ability to change flexibly between different systems of reference, i.e., numbers and letters. These working times were also “corrected” to purely reflect the sequence of correctly selected items by subtracting the processing times of incorrectly selected items. Additionally, the number of errors in part A and part B of the test was also recorded. To further study the participant´s cognitive flexibility, the difference (Test B – Test A) and the quotient (Test B / Test A) of the standard working times were calculated. These values reflect cognitive flexibility even more precisely in relation to cognitive processing speed. (412)

The penultimate test was the Freiburg version of the Tower of London test (TOL-F), type S3. (413) It records planning ability through a set of tasks, in which the participant has to reorganize colored balls into a given order correctly and within one minute per item by seeing multiple moves ahead. (413) In this test, the participants´ planning ability was chiefly represented by the number of items that were solved within the given minute and with the minimum number of moves necessary. However, there were also several secondary variables, which provide further information on planning ability:

- Number of correctly solved items, regardless of the number of actions necessary
- Number of times the subject reversed their decision

- Number of times the subject selected a blocked ball
- Number of times the subject selected a blocked rod
- Number of times the subject tried to select an impossible position
- Median planning time for 4-action, 5-action, and 6-action tasks (time from the beginning of the task until the beginning of the first action)
- Median execution time for 4-action, 5-action, and 6-action tasks (time from the beginning of the first action until the end of the task)

The last test of the initial coaching session was the Response Inhibition Test (INHIB), type S3. (414) In this test, the participant sees quickly flashing triangles or circles and is instructed to press a button every time a triangle appears, but not when a circle does. This method measures the effectiveness of inhibition of the triggered response, i.e., pressing the button when a shape appears, under certain circumstances, i.e., when the shape is a circle. (414)

The primary outcome parameter of the INHIB was the number of commission errors. This parameter represents the absolute frequency of unsuccessful inhibitions, i.e., the number of times the participant pressed the button when a circle appeared. For the opposite scenario, i.e., omission errors, the number of times the participant did not press the button when a triangle appeared was recorded. Furthermore, the sensitivity index, a composite variable which considers both commission and omission mistakes, was calculated. A higher achieved value for the sensitivity index represents a better performance of the participant. Beside the parameters directly evaluating mistakes, the mean reaction time, and its standard deviation (SD), both in seconds, and the total working time spent on the task were recorded. (414)

All five tests were acquired from Shuhfried GmbH and conducted as described in their respective manuals. (397, 408, 411, 413, 414) The test results were compared with age-appropriate norms. The achieved standard value provided information on whether the performance of the person examined was to be assessed as average, above average, or below average in relation to his age group in the respective functional area and whether there were restrictions in functionality.

3.5.4 Outcomes

Questionnaires

The primary endpoint of this pilot trial, i.e., the proof of concept of studying tDCS, physical therapy, and psychological coaching for a larger sample of musicians, was evaluated through two questionnaires and a checklist. One of the questionnaires collected information about the musicians´ pain situation and one about the safety & adverse events of tDCS, while the checklist documented the successful completion of the tDCS stimulations and the physiotherapeutic exercises, as well as any problems with their application. No separate checklists for the coaching, medical imaging, or motion capture trials were necessary, as these trials were all conducted under the direct supervision of the investigators.

Table 8 shows the "pain assessment questionnaire", which is also the primary endpoint of the 8-week therapy and evaluation plan. Its contents are based on three standardized questionnaires commonly used in clinical practice: the Nordic Musculoskeletal Questionnaire (NMQ), (415) the Disabilities of the Arm, Shoulder and Hand questionnaire (DASH), (404, 405) and the Brief Illness Perception Questionnaire (BIPQ). (416)

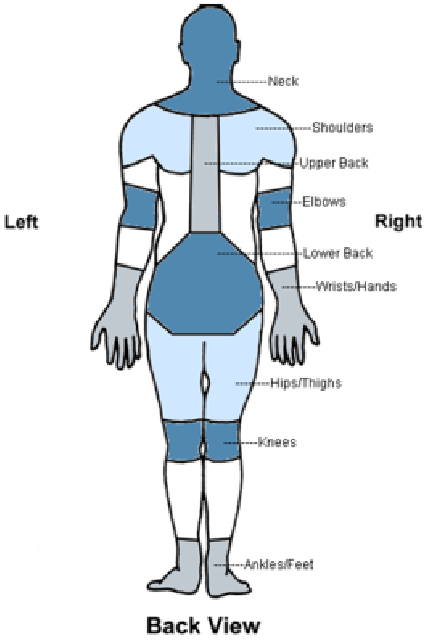
How much PAIN have you had IN THE PAST MONTH?		
On a scale of 0 to 10 (where zero represents "no pain" and 10 represents "severe pain"), please record the number below.		**No pain** **Severe pain**
	**Neck**	0 1 2 3 4 5 6 7 8 9 10
	Shoulders	
	right shoulder	0 1 2 3 4 5 6 7 8 9 10
	left shoulder	0 1 2 3 4 5 6 7 8 9 10
	both shoulders	0 1 2 3 4 5 6 7 8 9 10
	Elbows	
	right elbow	0 1 2 3 4 5 6 7 8 9 10
	left elbow	0 1 2 3 4 5 6 7 8 9 10
	both elbows	0 1 2 3 4 5 6 7 8 9 10
	Wrists/Hands	
	right wrist/hand	0 1 2 3 4 5 6 7 8 9 10
	left wrist/hand	0 1 2 3 4 5 6 7 8 9 10
	both wrists/hands	0 1 2 3 4 5 6 7 8 9 10
	Upper Back	0 1 2 3 4 5 6 7 8 9 10
	Lower Back	0 1 2 3 4 5 6 7 8 9 10
	One or Both Hips/Thighs	0 1 2 3 4 5 6 7 8 9 10
	One or Both Knees	0 1 2 3 4 5 6 7 8 9 10
Please describe your physical ability in the past week. **Did you have any difficulty…**		**No difficulty** **Unable**
… using your usual technique for playing your instrument?		0 1 2 3 4 5 6 7 8 9 10
… playing your musical instrument because of arm or shoulder pain?		0 1 2 3 4 5 6 7 8 9 10
… playing your musical instrument as well as you would like?		0 1 2 3 4 5 6 7 8 9 10
… completing all of your practice exercises in the scheduled time?		0 1 2 3 4 5 6 7 8 9 10

Table 8: *Pain assessment questionnaire.*

Table 9 shows the safety questionnaire, which documents problems with the functionality of the Halo Sport 2 device, as well as any adverse effects in conjunction with the tDCS stimulation sessions, which could occur either during, between or after the sessions. It was filled out by the participants after the week of sessions with Halo Sport 2 at the end of the pilot trials.

	Yes	No
When using Halo Sport 2, the device or software did not work as explained to me and/or I had trouble with the setup or handling of the device. If yes, which: ____	☐	☐
When using Halo Sport 2, I experienced unfavourable/discomforting effects. If yes, which: ____	☐	☐
During the therapy, I experienced unfavourable/discomforting effects that may be related to the use of Halo Sport 2. If yes, which: ____	☐	☐
Unfavourable effects of Halo Sport 2 were an impairment for me in daily life. If yes, which: ____	☐	☐
During the therapy, the symptoms of a disease I already had became more frequent or more severe. If yes, which: ____	☐	☐

Table 9: *tDCS safety questionnaire.*

Table 10 shows the “tDCS checklist” that was filled out by the participants during the week of the pilot trials. For each session of tDCS combined with physiotherapeutic exercises, the participants documented the successful completion of the required exercises, as well as if there were any problems with either the tDCS-device or the exercises during the session. In case there were problems, they were specified by the participants in the spaces provided. For a better understanding and to explicitly include adverse effects, the participants also received the following statement together with the checklist:

“Note: „Problems“ applies to everything related to the application of tDCS or the exercises, this includes for example difficulties with understanding/carrying out the tasks, as well as adverse events that arise in conjunction to the tasks. These include itching, tingling, redness, headache, a mild burning sensation, discomfort, nausea, nervousness, hairy scalp pain, and fatigue.”

Date	**tDCS**	**Physio-exercises**
Day 1:	Completed: yes ☐ no ☐ Problems: yes ☐ no ☐ If yes, which:	Completed: yes ☐ no ☐ Problems: yes ☐ no ☐ If yes, which:
Day 2:	Completed: yes ☐ no ☐ Problems: yes ☐ no ☐ If yes, which:	Completed: yes ☐ no ☐ Problems: yes ☐ no ☐ If yes, which:
Day 3:	Completed: yes ☐ no ☐ Problems: yes ☐ no ☐ If yes, which:	Completed: yes ☐ no ☐ Problems: yes ☐ no ☐ If yes, which:
Day 4:	Completed: yes ☐ no ☐ Problems: yes ☐ no ☐ If yes, which:	Completed: yes ☐ no ☐ Problems: yes ☐ no ☐ If yes, which:
Day 5:	Completed: yes ☐ no ☐ Problems: yes ☐ no ☐ If yes, which:	Completed: yes ☐ no ☐ Problems: yes ☐ no ☐ If yes, which:

Table 10: *Checklist for tDCS and the physiotherapeutic exercises.*

Medical Imaging Protocol

The medical imaging (MI) protocol was developed and conducted in cooperation with Assoc. Prof. PD Dr. Gregor Kasprian, MBA, Department of Biomedical Imaging and Image-guided Therapy, Medical University and General Hospital of Vienna, Dipl.-Ing. BSc Karl-Heinz Nenning, Department of Biomedical Imaging and Image-guided Therapy, Medical University and General Hospital of Vienna, and Dr. Victor Schmidbauer, Department of Biomedical Imaging and Image-guided Therapy, Medical University and General Hospital of Vienna. The author expresses his sincere gratitude for their contributions.

The MI protocol has a total duration of approximately 45 minutes and includes a structural T1 acquisition, DTI, resting-state fMRI and multiple task-based fMRI acquisitions. During the scans, the musician was instructed to lie in the scanner at rest or received different tasks. Figure 7 summarizes the steps of the protocol with their acquisition types and their respective durations.

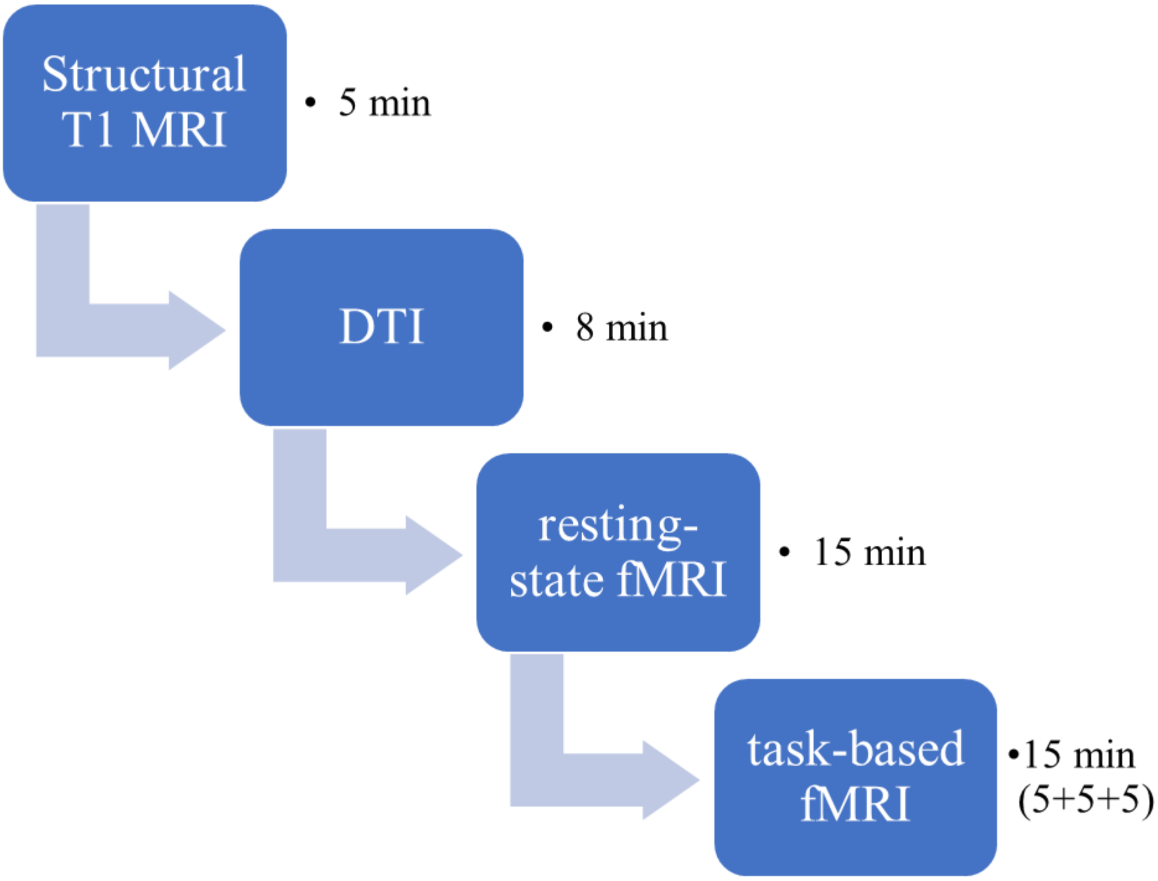


Figure 7: *Medical imaging protocol with acquisition types and durations.*

In detail, the following acquisitions were conducted:

- A standard high resolution structural T1 acquisition of the entire brain with a duration of about 5 minutes, which allows to quantify structural changes in cortical thickness.
- A DTI acquisition with a duration of about 8 minutes, which allows further statements about connectivity between certain parts of the brain.
- A resting state fMRI sequence for about 15 minutes, in which the participant was lying in the scanner at rest and was instructed "not to think of anything in particular". In this state, the intrinsic functional architecture of the brain can be determined best using statistical methods (for more information, see (417, 418, 419)).
- A task-based fMRI acquisition with a duration of 5 minutes, in which the musician was instructed to do mental exercise by pretending to play a given piece of music.
- Another 5-minute task-based fMRI acquisition, with the musician pretending to perform a piece and additionally moving his fingers on a wooden fingerboard as if he was playing.
- A third task-based fMRI acquisition for 5 minutes using alternating blocks of activation and baseline condition for 30 seconds each. During the activation blocks, the participant was instructed to mentally practice challenging exercise techniques, such as the ones found in "School of Violin Technics" by Henry Schradieck (first published in 1899). (420, 421, 422) The behavior in the baseline blocks was the same as in the 15-minute resting-state fMRI sequence.

Functional activity, functional connectivity (based on BOLD fMRI), structural connectivity (based on DTI), and cortical thickness/configuration (based on high-resolution T1-weighted images) patterns were assessed for each task/condition at each evaluation. Single subject analyses and group analyses were performed to detect possible changes of activity, connectivity, or cortical configuration induced by the therapy regimen.

Motion Capture

The motion capture protocol was developed and conducted in cooperation with Emir Benca, PhD, Department of Orthopedics and Trauma-Surgery, Medical University and General Hospital of Vienna. The author expresses his sincere gratitude for his contributions.

For the 3D motion capture analysis, the motion tracking system SMART-E (BTS S.p.A., Milano, Italy) was used to assess the kinematics for an individual musician. The system consists of four cameras, which record the position of light-reflecting markers in 3D space. The angles of the wrist, elbow, and shoulder, as well as their mean absolute deviation, were obtained every 0,008 seconds for two performances (for more information, see chapter 1.5.2). The kinematic data was processed using the system’s own software, Smart Analyzer 1.10. The musical exercises were based on scales and arpeggios and they were played with increasing levels of difficulty, i.e., increasing speeds, with a variety of bowings, articulations and rhythms.

3.6 Presentation of the Results

Due to the small sample size of this proof-of-concept study, the results were presented through a set of descriptions of the individual trials and their outcomes, which were further illustrated using pictures, figures, and tables. As the main purpose of this study was to examine the safety and feasibility of the individual methods, the emphasis was on identifying any misunderstandings, adverse effects, or other problems that occurred in conjunction with the trials. Consequently, all such problems were meticulously recorded and are described in detail in the individual trial results in chapter 4.

First and foremost, an overview of the subject population was provided. This included a description of the participants´ recruitment and descriptive statistical parameters such as age, sex, and instrument played. Also, the population was further characterized regarding the study tasks and time expenditures for each participant.

For the tDCS trials, the experiences of the study initiation visit, the week of stimulation sessions, and the end of study visit were described. The documentation of these trials in the “tDCS checklist”, including any problems that occurred, and the adverse events of tDCS recorded through the “tDCS safety questionnaire” were presented in a separate chapter. Here, they were explained in detail together with the “pain assessment questionnaire” and the findings obtained through these questionnaires were further illustrated with multiple tables.

The results of the physiotherapy trials were split into two thematic parts. In the first part, each of the tests done for the initial physiotherapeutic evaluation was outlined and the parameters measured in these tests were presented in tables. The second part focuses on the exercises done during the tDCS sessions. Here, one participant´s individualized one-week exercise program is also provided to serve as an example.

Similarly to the initial physiotherapeutic evaluation, the results of the initial coaching session were also presented through a description of each individual test, accompanied by tables and graphs of the results achieved by the participants in these tests.

For the medical imaging trials, the events prior to, during, and after the scans were described in detail, followed by an overview of the analyses conducted with the data obtained in these scans for both participants. The experiences of the motion capture trial were described and illustrated with a picture. Then, a sample of the raw data acquired in these measurements was provided and the analysis of the individual joint angles and their absolute deviations was done. Lastly, the 3D reconstructions of the violinist during the motion capture tasks are depicted.

3.7 Ethics

This study was conducted under approval of the ethics committee of the Medical University of Vienna. The project "Transkranielle Gleichstromstimulation (tDCS) und ihre Wirkung auf pathophysiologische Mechanismen zur Besserung von muskuloskelettalen Erkrankungen (PRMD) bei Orchestermusikern." (ethics committee number 1111/2021) was approved by vote on the 26th of May 2021, valid for one year. The validity of the approval was extended for another year, until the 26th of May 2023, by vote of the ethics committee of the Medical University of Vienna on the 17th of May 2022.

For this pilot study in particular, an amendment was issued to specifically include the pilot trials conducted for this diploma thesis on the 9th of September 2022. All three statements of the ethics committee of the Medical University of Vienna can be found in chapter 10.4 of this thesis.

All participants were informed about the purpose and design of the study, possible risks, and adverse events, as well as insurance and data privacy protection matters. The participants were given the opportunity to ask questions regarding any study-related topics and these questions were answered to their satisfaction. They provided their written informed consent in the informed consent form (ICF), of which they also received a copy. The full ICF, which is written in German, can be found in chapter 10.5 of this thesis.

4 Results

4.1 Participants

Participants were recruited from the Orchestra Academy of the Vienna Philharmonic. (423) They were asked for their voluntary participation in an informative “recruitment” e-mail, in which the design and purpose of the study and its individual parts were briefly outlined (see chapter 10.7). In total, seven musicians participated in the study, with each musician completing 1-3 different parts of the study (“study tasks”).

Table 11 shows descriptive statistical parameters of the study participants. The parameters collected were the participants´ age in years, sex, height in cm, weight in kg, BMI, their practiced instrument, the age at which they first started practicing their instrument (Age Instr), and their years of instrument playing (Years Inst). Six of the participants were male, with only one female participant. The instruments played included wind and string instruments; however, no percussionists took part in this study.

Partici-pant No.	Age	Sex	Height	Weight	BMI	Instrument	Age Instr	Years Instr
1	31	M	181	72	22.0	Violin	8	23
2	27	F	170	67	23.2	Violin	5	22
3	20	M	168	59	20.9	Violin	4	16
4	27	M	168	54	19.1	Viola	5	22
5	25	F	171	66	22.6	Flute	5	19
6	25	M	176	75	24.2	Trombone	7	18
7	23	M	185	87	25.4	Trumpet	7	16

Table 11: *Descriptive statistical parameters of study participants.*
(BMI = Body Mass Index, Age Instr = Age of first instrument practicing, Years Instr = Years of instrument playing.)

Table 12 provides an overview of the study tasks done by each participant, as well as their total number of tasks completed. Five of the participants did one of the study tasks each, while participant no. 6 completed the tDCS protocol together with the physio exercises, the introductory physio session, and the coaching session. Participant 7 also did both the introductory physio session and the coaching session, but not the tDCS protocol.

Participant No.	tDCS	Physio	Coaching	MI	Motion	No. of tasks
1				Yes		1
2				Yes		1
3					Yes	1
4	Yes					1
5		Yes				1
6	Yes	Yes	Yes			3
7		Yes	Yes			2

Table 12: *Study tasks completed by each participant.*
(tDCS = transcranial Direct Current Stimulation, MI = Medical Imaging)

For each individual study task, the number of participants enrolled, the number of participants who successfully completed the task, as well as the time expenditure for each participant in minutes is listed below in table 13. A detailed description of the specific tasks is provided in the following chapters.

Study task	**No. enrolled**	**No. completed**	**Time / participant**
tDCS with Halo Sport 2	2	2	100
Physiotherapy	3	3	110-125
Coaching	2	2	60
Medical Imaging	2	2	45
Motion capture	1	1	30

Table 13: *Number of participants and total time (minutes) per study task.*
(tDCS = transcranial Direct Current Stimulation)

4.2 tDCS Trials

In the study initiation visit, the device and its underlying mechanisms, as well as the seven-day schedule were demonstrated and/or discussed thoroughly with both participants having plenty of questions. These questions related to different aspects, such as basic tDCS principles, proper handling of the device, and correct documentation of problems, to name a few. Some of the questions and their answers are provided here as an example:

- "How can an electric current improve learning ability?" To answer this question, the alteration of the threshold for action potentials by the electric current and the concept of neural plasticity were touched on in more detail.
- "How do I ensure that the nibs are soaked in water well enough to achieve good contact?" Answer: "Hold the foam nibs under running water for about one minute and press on them so that they absorb water. If that is not enough, you can submerge the nibs, but not the entire primer band, in water."
- "How do I put on the headset for the tDCS to work best?" Answer: "You should put it on just like a normal headset, but the foam nibs should be the first part that comes into contact with your scalp. Then, adjust the width of the earpieces so that the headset sits as tightly as possible, but is not uncomfortable."

- “When do I mark a session of stimulation or exercises as completed?” Answer: “Mark a tDCS session as completed, if all 20 minutes of the stimulation have been delivered and the app labels the session as “completed”. Mark the exercise program as completed, if you have done all repetitions for of the scheduled exercises.”
- “What exactly counts as a “problem” when filling out the tDCS checklist?” Answer: “Anything that disturbs you during the session whatsoever, or anything that you would attribute the word “problem” to, the more the better. A few examples for problems are provided on the checklist itself.”

All questions were answered to both participants´ satisfaction and no unclear points remained at the end of the study initiation visits. Altogether, the duration of the visits was about 25 minutes for one participant and about 45 minutes for the other, with both participants stating that they were excited to try out the device at the end of the visits.

During the week of stimulations, neither participant called the provided phone number because of any adverse events or other problems. However, one of the participants contacted the instructor per text and asked, what exactly he should focus on when practicing the instrument for one hour after the stimulation to have the most benefit for his playing ability. The instructor answered that it was the most important to focus on the correct execution of the practiced movements, as the tDCS should help with the learning of said movement patterns, which influences long-term playing ability. He also added that only five sessions of stimulation over one week would probably not have a noticeable effect on the participant´s instrument playing.

After the week of stimulations, the participants returned the device and the charger in the “end of study” visit in the same condition that they had received it in. They also handed in their completed “tDCS checklist” and filled out the “pain assessment questionnaire” and the “tDCS safety questionnaire” (see chapter 3.5.4). Both participants stated in their visits that they were very content with the device overall, found it relatively easy to administer, and had a good time during the sessions. When asked if they could in principle imagine doing this stimulation and exercise program continuously for 8 weeks, both answered that they would readily do so. The participants´ answers to the questionnaires and the checklist are presented and discussed in detail in the next chapter.

4.3 Questionnaire Results

In the “checklist for tDCS and the physiotherapeutic exercises”, all 10 tDCS and all 10 physiotherapeutic sessions were reported as successfully completed. In these sessions, the most frequent technical issue documented was electrode connectivity: one participant had problems with achieving a satisfactory connection between the electrode and his skin in two of his sessions, while the other encountered the same problem in one of his sessions (3/10 sessions in total). Due to the lack of connection, the software didn´t allow the participants to start their session or paused the ongoing session until connectivity was restored. As the participants had been informed about this issue and its solution in the study initiation visit, they were able to solve this problem independently by soaking the nibs in water one more time. Thus, they were able to complete these sessions as well without a major disturbance.

More water is usually the solution to connectivity issues, but too much water can also be a problem by itself. One participant reported in a single session that the excess moisture and water drops on his scalp interfered with his concentration while he was doing the physiotherapeutic exercises (1/10 sessions in total). The only other problem with the exercises occurred once and was reported by the same participant in the same session, namely that when he was bending over forwards, the headset would´ve almost fallen off if he hadn´t put it on tight enough (1/10 sessions in total). It is unclear whether the excess moisture in that session made the earpieces and especially the headband more slippery than usual, as both problems were reported together, but not in any other session.

No severe adverse events of tDCS were reported by any participant in any session. However, one participant reported a mild to moderate tingling and/or burning sensation on his scalp during three of his stimulation sessions (3/10 sessions in total).

In total, technical problems or adverse effects were reported in 6/10 sessions. Table 14 provides an overview of the absolute frequency of the specific issues per participant and in total over all 10 sessions.

Issue	Participant 1	Participant 2	Total
Connectivity	2	1	3
Moisture	1	0	1
Falling off	1	0	1
Tingling / Burning	3	0	3

Table 14: *Absolute frequency of issues with tDCS and the physiotherapeutic exercises.*

In the “tDCS safety questionnaire” (see chapter 3.5.4), the participant who experienced connectivity issues twice and tingling/burning three times, answered the first statement with “yes”: “When using Halo Sport 2, the device or software did not work as explained to me and/or I had trouble with the setup or handling of the device.” He further specified that his answer was due to the connectivity issues before and/or during the sessions. Furthermore, the same participant answered the second and third statements with “yes” as well, which were as follows: “When using Halo Sport 2, I experienced unfavourable/discomforting effects.” and “During the therapy, I experienced unfavourable/discomforting effects that may be related to the use of Halo Sport 2.” Both statements were answered with “yes” because of the tingling/burning sensation that the participant had exclusively during the stimulation. He also added that the feeling sometimes travelled to the back of the head.

The other participant answered the first three statements with “no”, and the last two statements were answered with “no” by both participants. These statements were: “Unfavourable effects of Halo Sport 2 were an impairment for me in daily life.” and “During the therapy, the symptoms of a disease I already had became more frequent or more severe.” In total, 3/10 statements were answered with “yes” and the reasons underlying these answers were also documented in the “tDCS checklist” (see above). Table 15 summarizes the findings of the “tDCS safety questionnaire”.

Short statement	**Participant 1**	**Participant 2**
“I had trouble with setup/handling of the device.”	Yes	No
“I had adverse effects when using Halo Sport 2.”	Yes	No
“I had adverse effects during the therapy.”	Yes	No
“Adverse effects were an impairment in daily life.”	No	No
“The symptoms of a disease I had became worse.”	No	No

Table 15: *Answers to the "tDCS safety questionnaire" statements.*

The “pain assessment questionnaire” was filled out by four participants in total, i.e., the two tDCS participants and the two physio participants that did not do the tDCS trials. All participants completed the questionnaire in its entirety.

The reported pain intensities ranged from 0-5 points on a scale of 0-10 points, with the most frequent locations of pain being the neck, the wrist/hand, and the upper and lower back. While pain was reported by 3 of 4 participants in all these regions, there was no region that was described as painful in the last month by all four participants. Table 16 lists the absolute frequency of pain and the average severity (mean ± standard deviation (SD)) in the respective regions.

Body region	Frequency	Severity
Neck	3	2.5 ± 2.1
Shoulders	2	0.9 ± 1.2
Elbows	0	0 ± 0
Wrists/Hands	3	0.6 ± 0.5
Upper Back	3	2.0 ± 1.6
Lower Back	3	2.0 ± 1.2
Hips/Thighs	0	0 ± 0
Knees	1	0.3 ± 0.4

Table 16: *Absolute frequency and mean severity (± SD) of pain in body regions.*

The second part of the questionnaire evaluates the musicians´ physical ability and difficulties with instrument playing and practicing. It consists of the following four questions, to which the answer can again be given on a scale of 0-10 (0 = no difficulty, 10 = unable):

"Did you have any difficulty…
- … using your usual technique for playing your instrument?
- … playing your musical instrument because of arm or shoulder pain?
- … playing your musical instrument as well as you would like?
- … completing all of your practice exercises in the scheduled time?"

The first question was rated with 0/10 by three of the participant and with 4/10 by the fourth. That same participant rated the third question with 4/10 as well, and another participant rated it with 3/10, while the two other participants again responded with 0/10 points. This points towards the existence of factors impairing the perceived playing ability of some of the participants, but it is unclear whether this impairment perceived is due to pain or other factors (e.g., weakness, lack of control, numbness, tingling, subjective discontent, etc.).

The second and fourth questions were rated with 0/10 points by all four participants, suggesting no playing impairment due to arm or shoulder pain, which is in line with the low severity of pain in this (and the other) regions. Also, none of the participants seem to have any issues with completing their practice exercises within their respective time schedules.

4.4 Physiotherapy Trials

In the initial physiotherapeutic evaluations, all three participants completed the mUQYBT, the CKCUEST, and the QuickDASH questionnaire. The one-arm line hopping test was only completed by two of the three participants, as the third suffered from a ganglion cyst on his right wrist. The dynamic weight put on the diseased wrist would have caused pain and possibly worsened the outcome of the condition, which is why this test was omitted for this participant.

After a short set of warm-up exercises, the participants started with the mUQYBT. All three participants understood the exercise and there were no problems during the executions. All participants successfully completed the try-out rounds and all three tries for each arm and each direction. Figure 8 shows a participant doing the mUQYBT, pushing one of the plastic hats in the 45° upwards direction.

Figure 8: *Participant doing the mUQYBT.*
(mUQYBT = modified Upper Quarter Y-Balance Test)

For each of the three tries per direction per arm, the distance of the pushed plastic hat from the intersection of the three lines was measured in centimeters and the arithmetic mean for each direction and arm conducting the movement was calculated. Table 17, table 18, and table 19 list the values obtained in this process.

Furthermore, to better compare the values between participants, their respective arm lengths were measured:

- Participant 1: 84 cm
- Participant 2: 91 cm
- Participant 3: 97 cm

	Lateral		Superior		Inferior	
	right arm	**left arm**	**right arm**	**left arm**	**right arm**	**left arm**
First try	103	95	68	59	101	97
Second try	104	98	63	62	103	101
Third try	103	95	61	65	103	107
Mean ± SD	103	96	64	62	102	102

Table 17: *Distances (cm) achieved by participant 1 in the mUQYBT.*
(mUQYBT = modified Upper Quarter Y-Balance Test)

	Lateral		Superior		Inferior	
	right arm	**left arm**	**right arm**	**left arm**	**right arm**	**left arm**
First try	95	93	65	62	74	74
Second try	102	101	58	63	72	72
Third try	107	103	62	64	75	75
Mean ± SD	101	99	62	63	74	74

Table 18: *Distances (cm) achieved by participant 2 in the mUQYBT.*
(mUQYBT = modified Upper Quarter Y-Balance Test)

	Lateral		**Superior**		**Inferior**	
	right arm	**left arm**	**right arm**	**left arm**	**right arm**	**left arm**
First try	111	97	59	55	97	88
Second try	111	106	60	54	101	82
Third try	110	107	56	82	98	80
Mean	111	103	58	64	99	83

Table 19: *Distances (cm) achieved by participant 3 in the mUQYBT.*
(mUQYBT = modified Upper Quarter Y-Balance Test)

The measured distances in the lateral (96cm-103cm) and superior (58-64cm) directions were roughly equal in general, with the notable exception being the 111cm mean distance that participant 3 achieved in the lateral direction with the right arm. The inferior direction, however, showed bigger differences. Here, participant 1 achieved a mean distance of 102cm with both arms, whereas participant 2 only achieved a mean distance of 74cm, also with both arms.

Taken together, the mean distances achieved per arm were also calculated and are shown together with the participants´ arm lengths in table 20.

	Right arm	**Left arm**	**Arm length**
Participant 1	107	103	84
Participant 2	88	87	91
Participant 3	106	99	97

Table 20: *Mean distances (cm) per arm and arm length in the mUQYBT.*
(mUQYBT = modified Upper Quarter Y-Balance Test)

For the next test, the CKCUEST, the number of repetitions of arm movements within 30 seconds was recorded for three tries. All participants understood the exercise and completed all three tries without any problems. However, one participant had difficulties doing the exercise in the normal push-up position and therefore assumed a position on the knees instead of the feet. Regarding exertion, one of the participants also stated afterwards that this exercise was "physically more demanding" than the mUQYBT due to "the wide grip and the fast movements". Table 21 lists the achieved number of repetitions for each try and the resulting mean for each participant.

	Participant 1	**Participant 2**	**Participant 3**
First try	13	8	10
Second try	16	9	11
Third try	18	10	12
Mean	16	9	11

Table 21: *Number of repetitions achieved in the CKCUEST.*
(CKCUEST = Closed Kinetic Chain Upper Extremity Speed Test)

For the last of the physical tests, the one-arm line hopping test, both participants who completed the exercise started from a push-up position on their knees instead of their feet. For the third it was decided to omit the test, as he suffered from a ganglion on his right wrist, a condition which could have been made worse by the exercise. The participants who did the test had no problems and seemed considerably less exhausted afterwards than after the CKCUEST. The number of repetitions within 60 seconds per arm and the mean number of repetitions for each participant are shown in table 22 (the values for participant 3 are missing, as he did not do this exercise).

	Participant 1	**Participant 2**	**Participant 3**
Right arm	41	25	n.a.
Left arm	52	22	n.a.
Mean	47	10	n.a.

Table 22: *Number of repetitions achieved in the one-arm line hopping test. (Participant 3 did not do this test because of a ganglion in his right wrist.)*

The QuickDASH with all its modules was completed by all three participants and there were no questions during this process. The main module was filled out in English by all participants, whereas the optional modules were filled out in English by only one and in German by the other two. The disability/symptom scores (0-100) of each participant were calculated for each module and are shown in table 23.

	Participant 1	**Participant 2**	**Participant 3**
Main module score	9.1	0	0
Work module score	6.3	0	12.5
PAM module score	6.3	0	12.5

Table 23: *QuickDASH module scores.*
(QuickDASH = Quick Disabilities of the Arm, Shoulder and Hand Questionnaire, PAM = Performing Arts Medicine)

All three participants had very low scores across all QuickDASH modules, indicating that they had few musculoskeletal problems overall. Participant 2 even got a “perfect” score of 0, as he responded to have no disabilities or symptoms in any of the categories whatsoever.

Based on the results of these tests and the QuickDASH, an individual one-week exercise program was developed for the participant who did both the tDCS and the physiotherapeutic study task. The other participant, who only did the tDCS study task, received a more general, non-individualized version of the exercise program.

When the participants received the programs, each exercise was explained, and the proper technique was discussed with the participants. While both participants generally understood most of the exercises rather easily, some technically more challenging exercises were first demonstrated by the physiotherapist and then done by the participants under her supervision. Some minor inaccuracies in the technique of a few exercises remained, which were then corrected by the physiotherapist. At the end of these explanation/demonstration sessions, both participants had no remaining questions and stated that they were aware of their tasks and knew how to execute them.

During the week of exercises, neither participant had any questions about or issues with the program. All exercise sessions were successfully completed and documented in the "checklist for tDCS and the physiotherapeutic exercises" (for more information on the checklist results, see chapter 4.3). The exercise program, which was developed according to the results of the initial physiotherapeutic evaluation, can be found in table 24.

	Exercise	**Description**
Warm-Up Exercises	*Shoulder, elbow, and arm movements while standing*	10 times backwards 10 times in opposite directions
	Cervical spine rotation + nodding one´s head	5 times each looking to the left, middle, and right, 3 times nodding one´s head in the three positions mentioned above while sitting
	Thoracal spine rotation in combination with cervical and lumbar spine rotation (global rotation)	10 times isolated rotation of the thoracal spine, 10 times global rotation
	Lumbar spine mobilisation	Lumbar spine mobilisation while sitting
	Cervical stabilisers	Quick yes and no movements with the cervical spine alternately while sitting and standing
Strengthening Exercises	*Serratus push (m. serratus anterior)*	Dorsal position in closed chain
	Shoulder shrugs (m. trapezius pars descendens)	in combination with deep breathing (contract – relax)
	Chopping exercise (Sitting position with 90° flexion of the shoulders: movement: very small and quick movements of the arms)	while sitting
	M. transversus abdominis	Dorsal position with well positioned legs (approx. 120° knee flexion)
	Muscle chain ventral + dorsal PNF D1	With no weight alternately while sitting and standing for every training session
	Muscle chain ventral + dorsal PNF D2	With no weight alternately while sitting and standing for every session

Table 24: One-week exercise program completed by a participant.

4.5 Coaching Trials

The initial coaching session consisting of different neuropsychological tests was done by two participants. All five tests were done on a computer and explained to the participants in writing on the screen. Neither had any questions regarding their tasks, although the psychologist would have been present in the room to provide further explanations in case they were needed. Both participants completed the tests on their own without any interference from the supervisor or the psychologist.

For four of the five tests, the test language could be adjusted, so that participant 1 could do almost all the tasks in Spanish, his mother tongue. The only exception was the VLT, in which the two-syllable words were based on real German words, which is why it could not be done in any other language. As the mother tongue of participant 2 was German, there was no such issue for his examinations.

The VLT and the NVLT, both type S2, had a duration of 12 minutes altogether (including the time the participants took to read the instructions). For these tests, the sum of correct YES-responses, the sum of incorrect YES-responses, the difference between the two, and the percentile ranks (PRs) for these values compared to a representative age-equivalent sample was calculated. Furthermore, as secondary variables the median of the reaction time in seconds for correct and incorrect YES-responses and the total working time spent on the task (min:sec) were recorded. Also, the frailness index, which provides information about the stability of the learning ability, was calculated for both tests.

Table 25 lists all these parameters for the VLT of both participants, while table 26 does the same for the NVLT, although the medians of the reaction times are omitted in the latter. The numbers in brackets next to the percentile ranks represent their respective 95% confidence intervals (CIs).

	Participant 1		Participant 2	
	Sum	**PR (95% CI)**	**Sum**	**PR (95% CI)**
Correct YES-responses	40	89 (73-96)	39	66 (42-84)
Incorrect YES-responses	21	10 (2-27)	16	24 (8-50)
Difference of correct minus incorrect YES-responses	19	21 (8-42)	23	33 (16-58)
Median of the reaction time for correct YES-responses (s)	0.65		0.97	
Median of the reaction time for incorrect YES-responses (s)	0.84		1.49	
Total working time (min:sec)	01:50		02:08	
Frainlness index	0.00		0.06	

Table 25: *VLT scores of both participants.*

(VLT = Verbal Learning Test, PR = Percentile Rank, CI = Confidence Interval, s = seconds)

	Participant 1		**Participant 2**	
	Sum	**PR (95% CI)**	**Sum**	**PR (95% CI)**
Correct YES-responses	33	49 (24-76)	32	43 (18-69)
Incorrect YES-responses	8	72 (50-88)	10	66 (42-84)
Difference of correct minus incorrect YES-responses	25	82 (54-96)	22	71 (42-92)
Total working time (min:sec)	02:00		04:11	
Frailness index	0.25		0.13	

Table 26: *NVLT scores of both participants.*
(NVLT = Non-Verbal Learning Test, PR = Percentile Rank, CI = Confidence Interval, s = seconds)

The duration of the Langensteinbach version of the TMT, type S1, was approximately 3 minutes. Table 27 displays the working times of parts A and B, as well as the other, secondary variables and all of their respective percentile ranks with their 95% CIs.

	Participant 1		Participant 2	
	Value	**PR (95% CI)**	**Value**	**PR (95% CI)**
Working time part A (s)	17.34	20 (10-38)	9.08	100 (99-100)
Working time part B (s)	20.68	63 (38-82)	15.30	97 (90-99)
Working time part A corrected (s)	17.34	19	9.08	100
Working time part B corrected (s)	19.67	69	15.30	96
Errors part A	0	52	0	52
Errors part B	1	31	0	72
Time difference B-A (s)	3.34	86	6.22	62
Time quotient B/A	1.19	89 (66-98)	1.69	30 (10-62)

Table 27: *TMT scores of both participants.*
(TMT = Trail Making Test, CI = Confidence Interval, s = seconds)

The TOL-F, type S3, lasted for approximately 11 minutes. In Figure 9, a participant is depicted moving a colored ball between two of the rods for one of the tasks requiring a minimum 6 such actions altogether.

Figure 9: *Participant doing the TOL-F.*
(TOL-F = Tower of London – Freiburg Version)

The scores and percentile ranks achieved by the participants for the main variable, “planning ability”, and the secondary variables are listed in Table 28 on the next page.

	Participant 1		Participant 2	
	Value	**PR**	**Value**	**PR**
Planning ability	16	48	21	95
Number of correctly solved items	23	30	23	30
Number of reversed decisions	4	63	4	63
Number of blocked balls selected	0	76	0	76
Number of blocked rods selected	2	49	0	83
Number of impossible positions selected	0	85	0	85
Median planning time of 4-action tasks	2.5	91	7.6	13
Median planning time of 5-action tasks	4.2	85	12.4	15
Median planning time of 6-action tasks	9.5	36	18.0	6
Median execution time of 4-action tasks	4.9	58	3.9	92
Median execution time of 5-action tasks	12.2	24	5.8	81
Median execution time of 6-action tasks	9.5	71	6.5	94

Table 28: *TOL-F scores of both participants.*

(TOL-F = Tower of London – Freiburg Version, PR = Percentile Rank)

Figures 10 and 11 illustrate the percentile ranks achieved by the participants compared to a representative age-equivalent sample.

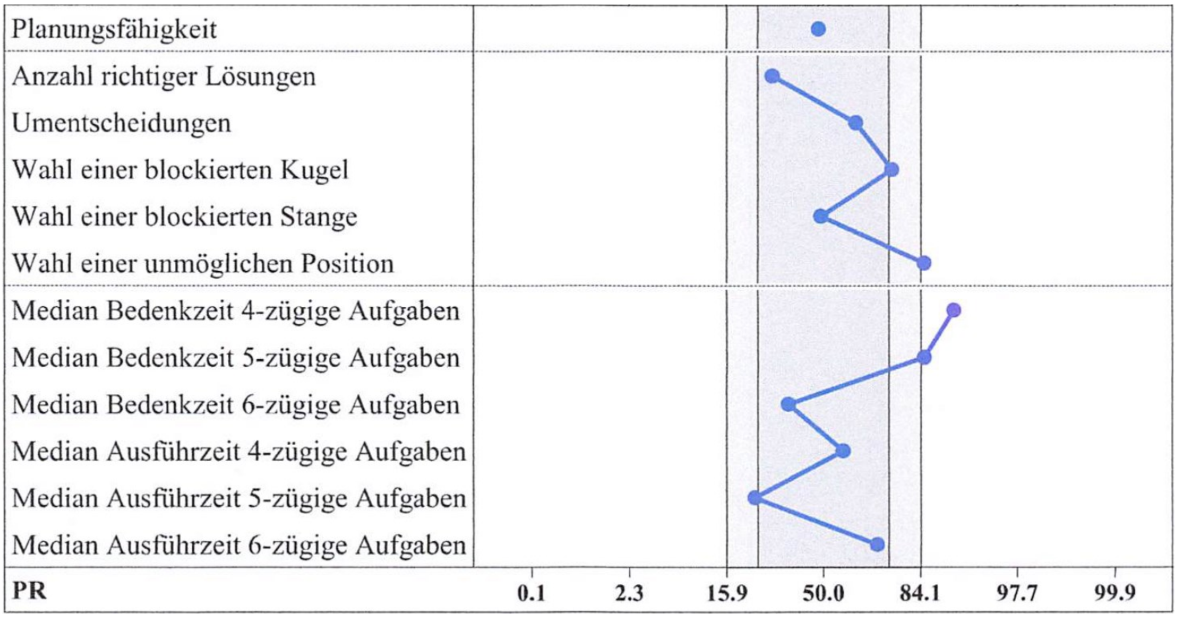


Figure 10: *Percentile ranks achieved by participant 1 in the TOL-F.*
(TOL-F = Tower of London – Freiburg Version)

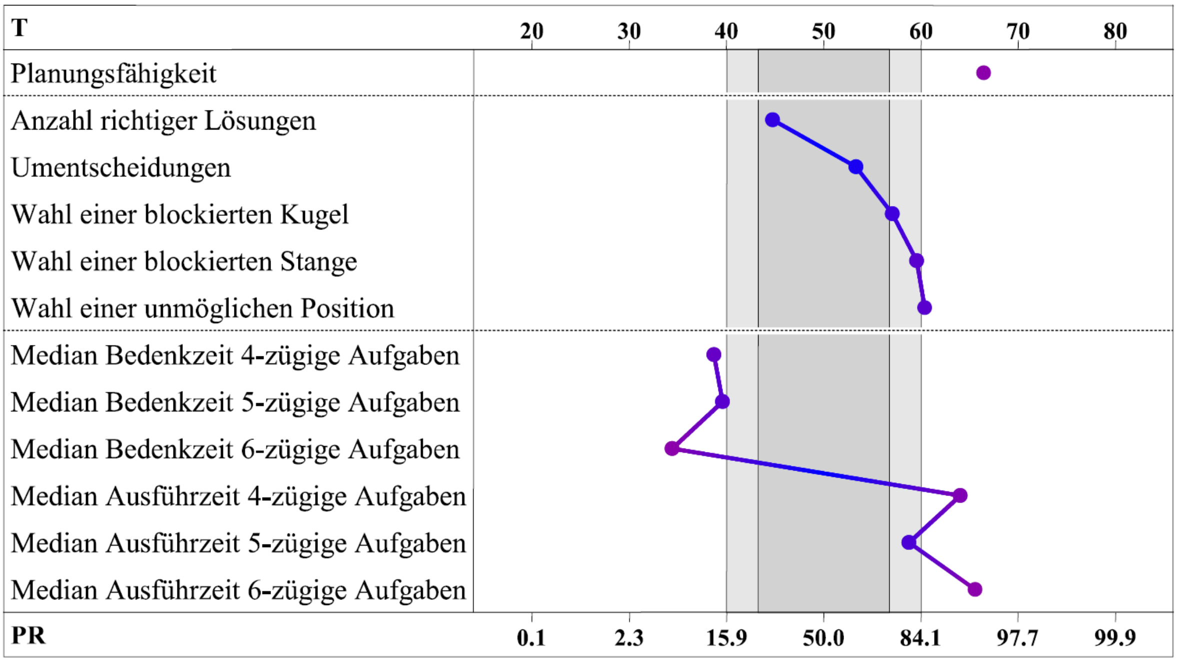


Figure 11: *Percentile ranks achieved by participant 2 in the TOL-F.*
(TOL-F = Tower of London – Freiburg Version)

In the INHIB test, type S3, which had a duration of about 6 minutes, the effectiveness of the participants´ inhibition of triggered responses was evaluated. Table 29 shows all these variables and their percentile ranks with 95% CIs for both participants.

	Participant 1		Participant 2	
	Value	**PR (95% CI)**	**Value**	**PR (95% CI)**
Commission errors	5	75 (46-93)	2	93 (76-99)
Omission errors	3	28 (5-66)	0	86 (54-98)
Sensitivity index	3.430	55 (24-82)	4.310	95 (79-99)
Mean reaction time (s)	0.272	41 (24-62)	0.253	61 (42-79)
Standard deviation of mean reaction time (s)	0.078	54 (18-86)	0.042	93 (69-99)
Total working time	01:51		01:46	

Table 29: *INHIB scores of both participants.*
(INHIB = Response Inhibition, CI = Confidence Interval, s = seconds)

Figure 12 and figure 13 depict graphically the percentile ranks achieved by both participants, as well as their respective 95% CIs.

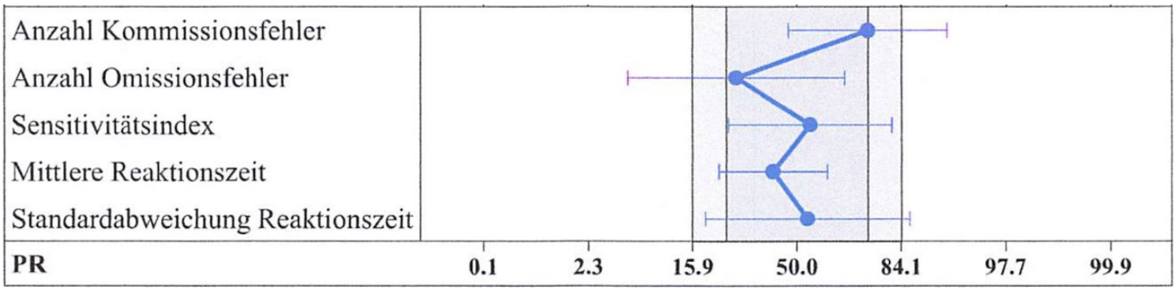


Figure 12: *Percentile ranks with CIs achieved by participant 1 in the INHIB. (INHIB = Response Inhibition, CI = Confidence Interval)*

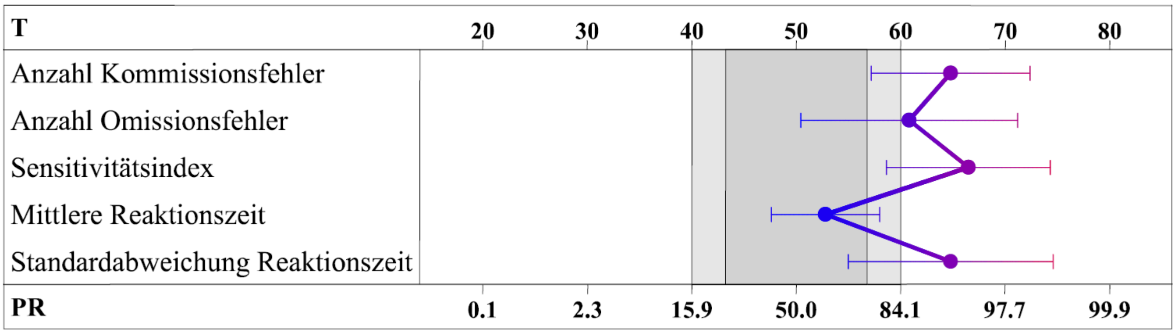


Figure 13: *Percentile ranks with CIs achieved by participant 2 in the INHIB. (INHIB = Response Inhibition, CI = Confidence Interval)*

Immediately following the completion of all these neuropsychological tests, the participants´ results were presented to them by the psychologist and their interpretations were discussed together. Both participants were content with the tasks and the results they achieved, and neither of them seemed particularly worn-out by the tests mentally. One of them also stated that he would be interested in how his results could influence CBTs and both asked what a possible coaching program for musicians would look like.

4.6 Medical Imaging Trials

The medical imaging protocol, as described in detail in chapter 3.5.4, was done by two violinists, both of whom completed the entire protocol. Before beginning with the scans, they were explained the basic principles underlying MRI and DTI, possible adverse effects, and how to react if any problems should occur inside the scanner. Also, both participants were enquired about possible contra-indications to fMRI, which neither of them had. Furthermore, their tasks during the individual acquisitions, as well as the reasoning for implementing them, were discussed in detail. There were a few remaining questions of the participants regarding all these topics, which were all answered to their satisfaction. Lastly, the participants gave a short breakdown of the content, duration, and order of their tasks on their own to ensure that they were ready for the trial.

Inside the scanner, both participants required about 2-3 minutes to figure out how to hold the wooden fingerboard in a way that allowed them to move their fingers comfortably and naturally despite the confined space. This resulted in a brief delay before the beginning of the protocol in both cases.

During the 45 minutes of acquisitions, neither participant stated having any fears or adverse effects and neither discontinued the protocol prematurely, so that all acquisitions could be done in their entirety. Between each of the individual acquisitions, brief communication with the participants was held via the MRI scanner´s speaker system to ensure that everything was all right and the participant knew which part of the protocol was next. During the acquisitions, no communication occurred for two reasons: firstly, to not disturb the participant during his task and secondly, because the sound of the MRI scanner itself was very loud and would therefore have made communication very difficult.

After the trials, both participants stated that they were able to perform all their exercises in the right order without major disturbances. They stated that they were satisfied with the protocol and their ability to perform the tasks inside the MRI scanner. For the virtual tasks, however, both participants reported after the trials, that the loud noises in the MRI scanner were “a little” or “somewhat” distracting and made it difficult to concentrate on the imagined “playing” of the pieces. Also, one of the participants stated that he would have enjoyed more communication during his time inside the scanner.

The following figures show the results of the single subject analyses and the group analyses of both participants´ medical imaging acquisitions. These analyses were conducted by Dipl.-Ing. BSc Karl-Heinz Nenning, Department of Biomedical Imaging and Image-guided Therapy, Medical University and General Hospital of Vienna. They were discussed among the study team and with each participant in the weeks after the trials.

Figure 14 and figure 15 show the first two task-based fMRI acquisitions of both participants. These are the BOLD fMRI scans acquired during the first two 5-minute tasks, in which the participants pretended to play a given piece of music for 5 minutes (pictures on the right) and moved their fingers on a wooden fingerboard (pictures on the left).

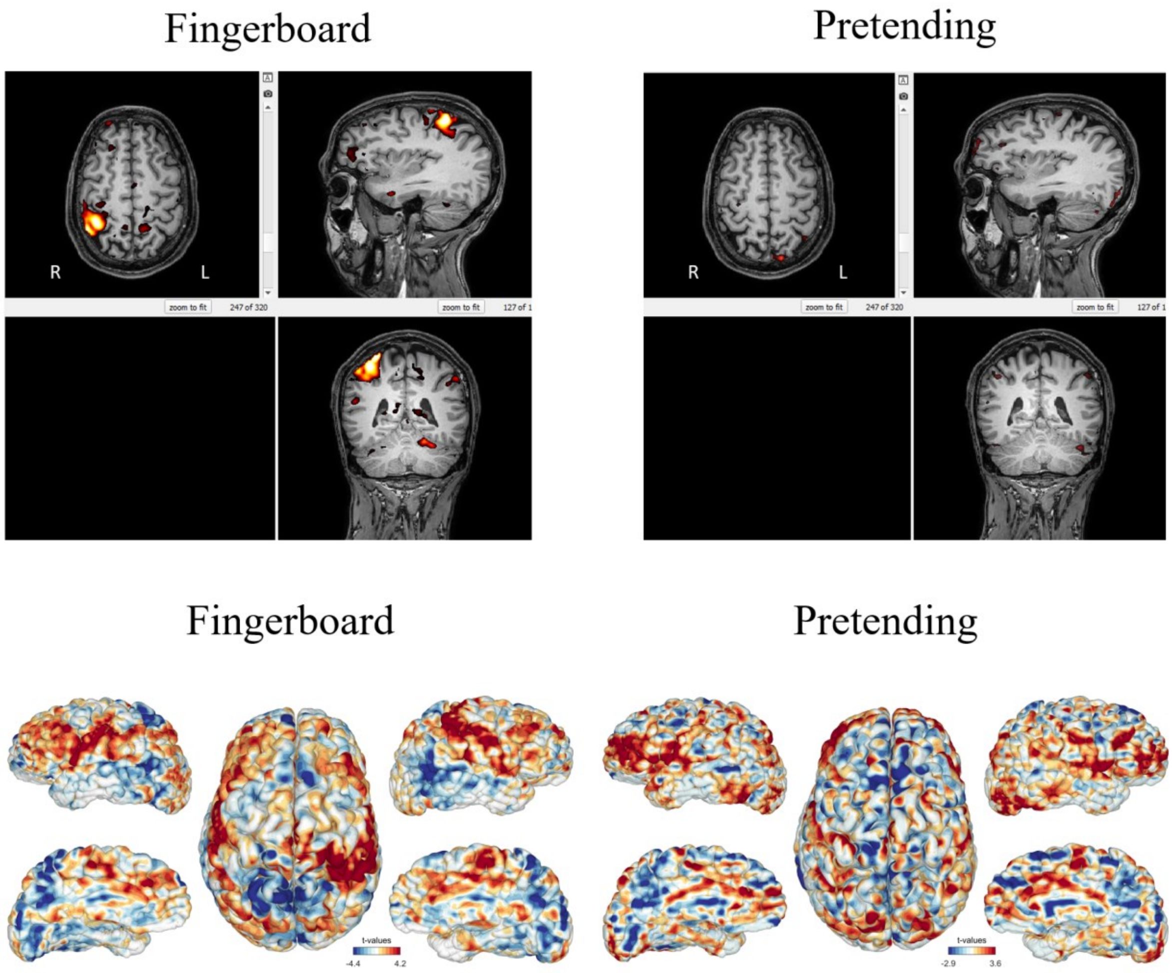


Figure 14: *Task-based BOLD fMRI scans of participant 1.*

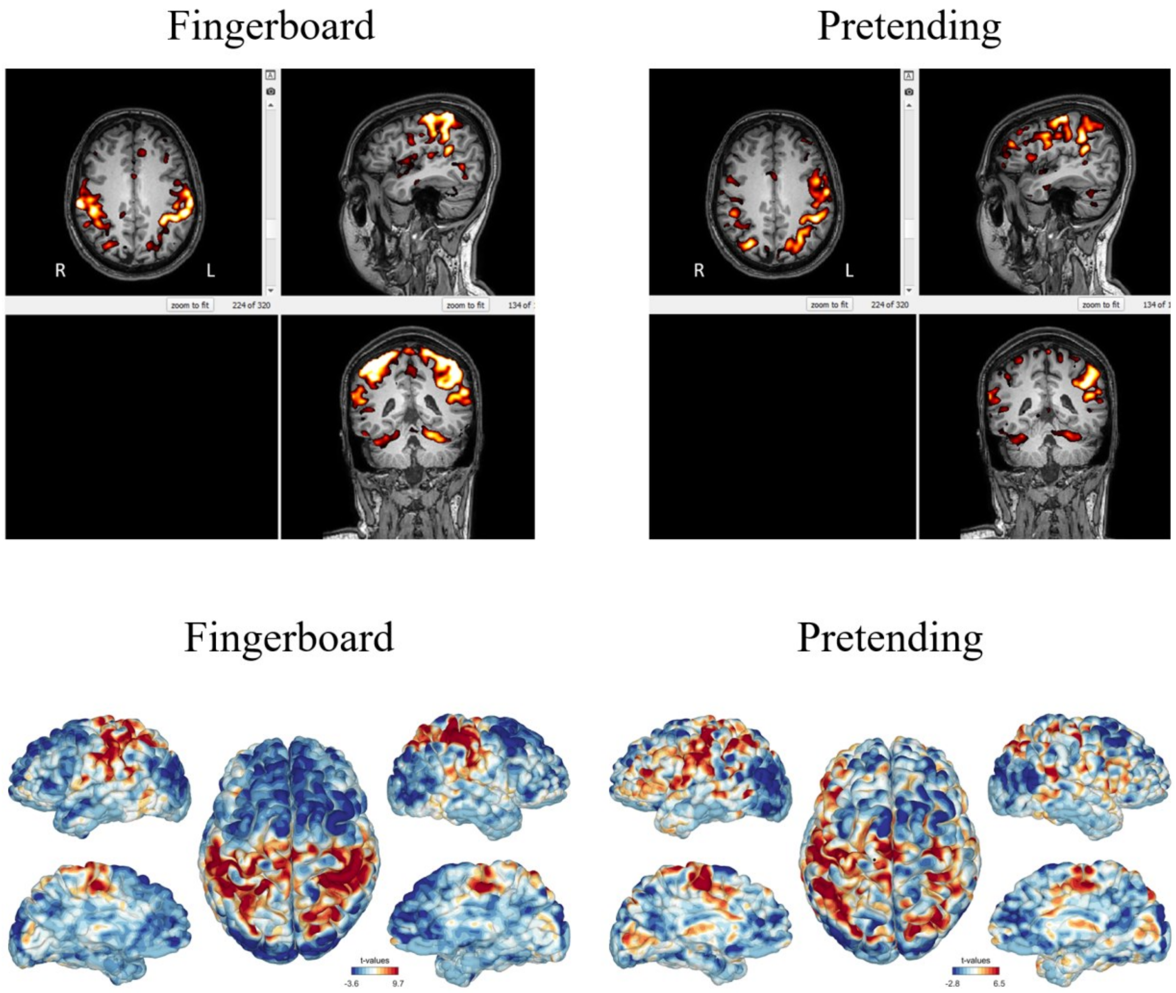


Figure 15: *Task-based BOLD fMRI scans of participant 2.*

Overall, activation patterns can be found in both participants. In the “fingerboard” exercises, participant 1 shows a clear activation of the right M1, specifically in the right hand knob. This activation can be observed even more clearly in participant 2, where the activation of the hand knobs takes place not just in the right M1, but bilaterally.

In the „pretending“ exercise, participant 2 shows a similar activation pattern as in the “fingerboard” task. Here, though, the activation seems to be lateralized more to the left hemisphere. Unfortunately, however, the same patterns cannot be found in participant 1.

For figures 16 and 17, the data acquired in the DTI scans was used to create a tractography, which shows the trajectories and connections of white matter tracts originating from specific areas called “seeds”. Based on the task-based BOLD fMRI results, the areas chosen as seeds were the hand knob of the right M1 and the right SMA.

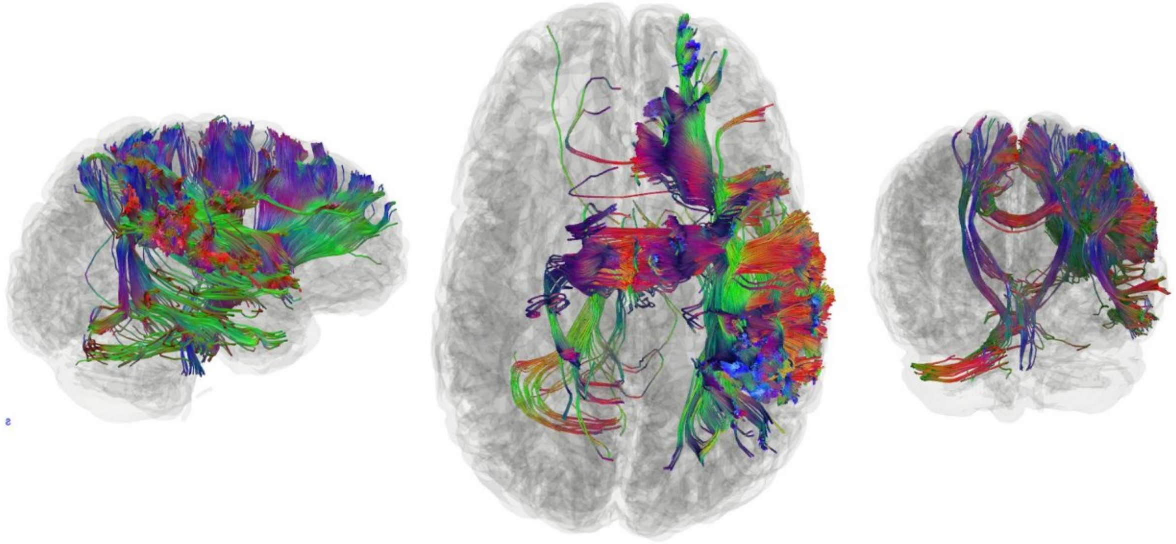


Figure 16: *DTI Tractography of participant 1.*

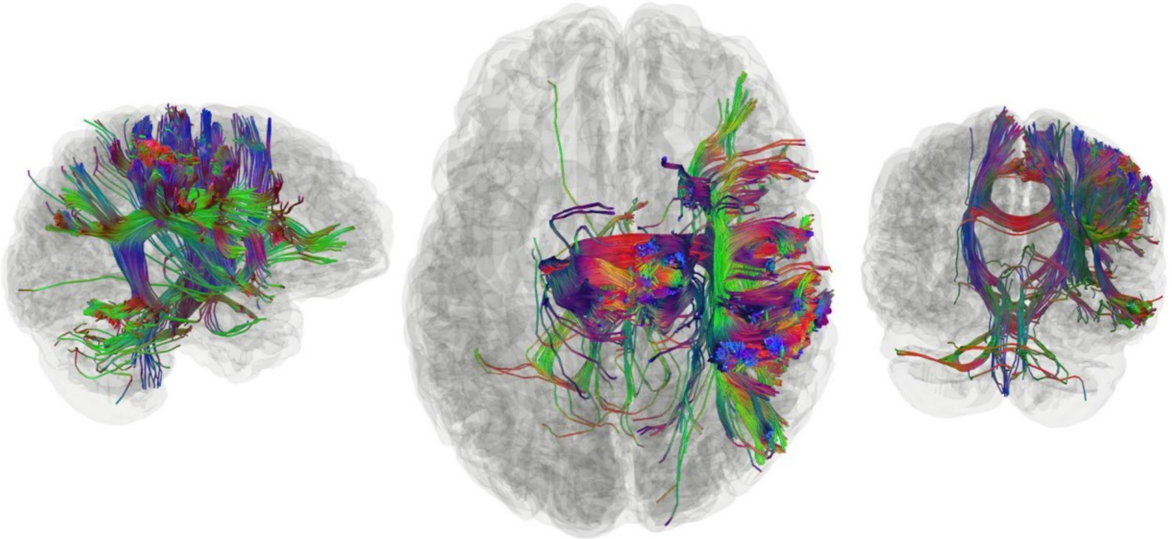


Figure 17: *DTI Tractography of participant 2.*

In both participants, the tracts can be clearly seen originating from the hand knob of the M1 and the right SMA. Furthermore, their course can be followed as far as to the cerebellum, directly illustrating the connectivity between these regions.

4.7 Motion capture trial

In the 3D motion capture analysis, movement of a musician, a violinist, was recorded using light-reflecting, spherical and hemispherical markers. The hemispherical markers had a maximum diameter of about 0.5cm and were fixed directly on the violin. In contrast, the spherical markers with their “stands” had a size of about 2cm x 1cm x 1cm and were fixed on the skin with one-time adhesive strips, which is why the violinist had to perform without wearing clothes on the upper body. As the procedure had been explained to him in advance, there were no problems with the application of all the markers and the shirtless performance.

Figure 18 shows the violin player during performance with the markers on his upper body, the violin, and the bow. The violinist practiced a variety of musical exercises like those found in Schradieck´s “School of Violin Technics”, as well as the prelude from J.S. Bach´s “Violin Partita No.3 in E major”. (420, 421, 422, 424) During the performance, the adhesive strips maintained strong contact with the skin and prevented the markers from falling down. At the same time, the markers were light enough so that the musician had no problems concentrating on the performance. Other problems before, during, or after the process of data acquisition, such as e.g., too low room temperature or adhesive strips remaining on the skin, were not reported by the musician.

Figure 18: *Violin player with markers.*

The position of the markers in a previously defined three-dimensional space was recorded with the motion tracking system SMART-E (BTS S.p.A., Milano, Italy), which consists of four cameras. The system´s own software, Smart Analyzer 1.10 was used to process the acquired kinematic data. The acquired parameters were: wrist angle (°), elbow angle (°), and shoulder angle (°). All three were measured every 0,008 seconds and obtained for two consecutive performances, “play 1” and “play 2”. Table 30 gives a small sample of the raw data acquired for the wrist angle (data for elbow and shoulder angles are displayed analogously).

Wrist angle (°)			
Time (s)	**Play 1**	**Play 2**	**Mean absolute deviation (°)**
0	0.053	0.034	0.019
0.008	0.002	0.02	0.018
0.017	-0.05	-0.07	0.016
0.025	-0.03	-0.13	0.095
0.033	-0.03	-0.11	0.082
0.042	-0.04	-0.09	0.047
0.05	-0.06	-0.15	0.093
0.058	-0.06	-0.16	0.094
0.067	-0.08	-0.16	0.076
0.075	-0.12	-0.19	0.071
0.083	-0.15	-0.21	0.063
0.092	-0.15	-0.23	0.083
0.1	-0.19	-0.29	0.106
0.108	-0.23	-0.33	0.097
0.117	-0.26	-0.32	0.053
0.125	-0.31	-0.25	0.057
0.133	-0.37	-0.26	0.105
0.142	-0.41	-0.24	0.169
0.15	-0.49	-0.27	0.22

Table 30: *Sample of raw data acquired through 3D Motion capture.*

The mean ± SD of the measured parameters across the entire performance was:

- Wrist angle (°): 0.43 ± 8.31
- Elbow angle (°): 12.74 ± 11.91
- Shoulder angle (°): 9.56 ± 7.74

The following three graphs show the respective angles in dependence of playing time (s) for both performances, “play 1” and “play 2”. Figure 19 shows the wrist angle (°), figure 20 the elbow angle (°), and figure 21 the shoulder angle (°). In figure 22, the absolute deviation of each angle (°) is plotted against the playing time (s).

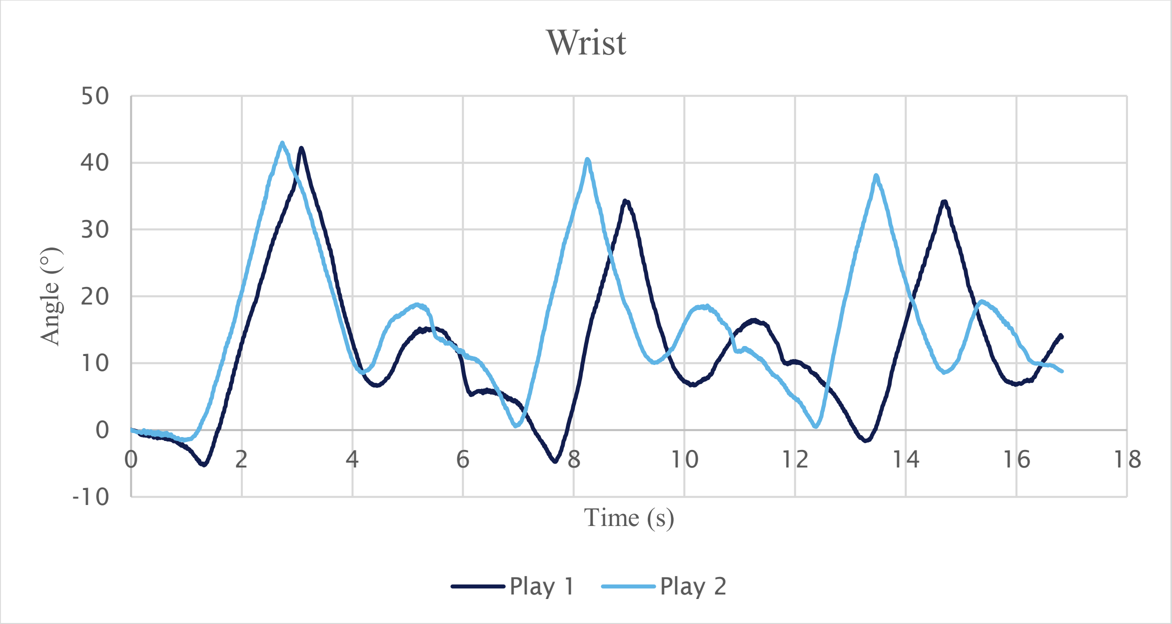


Figure 19: *Wrist angle for two plays.*

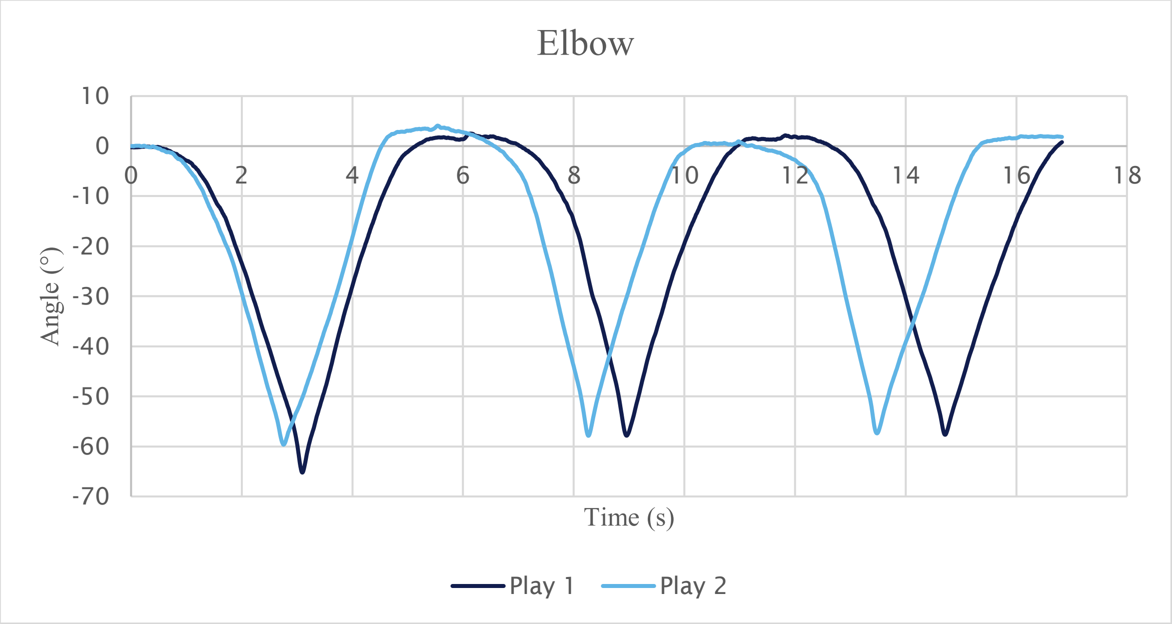


Figure 20: *Elbow angle for two plays.*

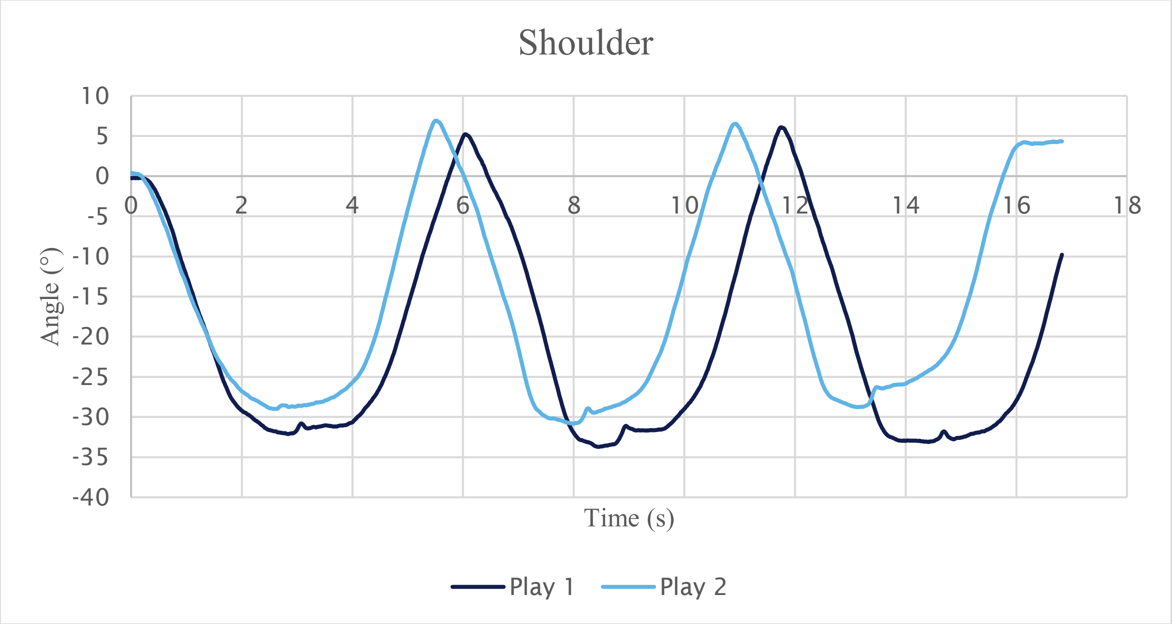


Figure 21: *Shoulder angle for two plays.*

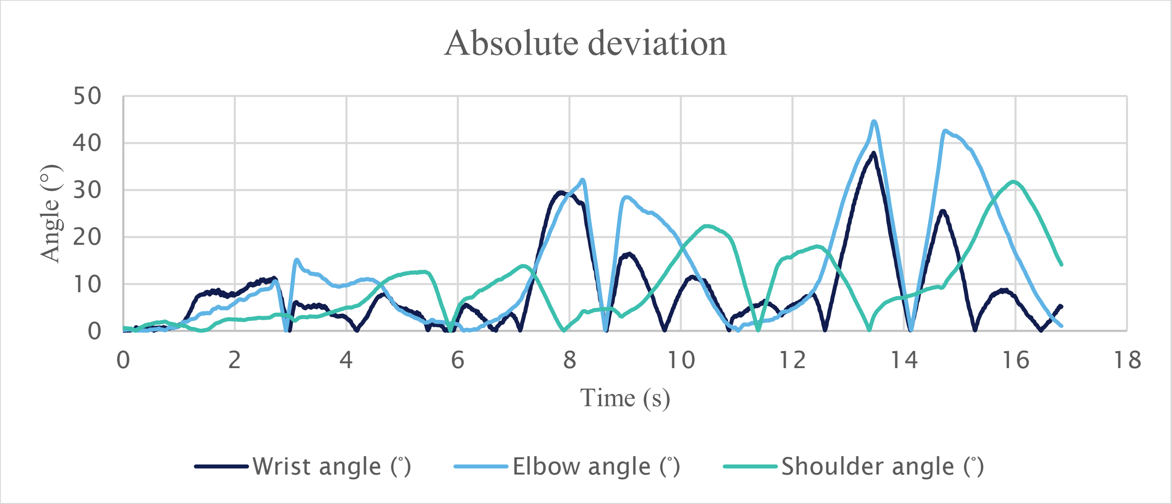


Figure 22: *Absolute deviation for the wrist-, elbow-, and shoulder angle.*

The software Smart Analyzer 1.10 was not just used to process the data, but also to generate a 3D model of the musician´s upper body, the violin, and the bow. This 3D reconstruction of the violinist is depicted below in figure 23 (view from above the musician) and figure 24 (view from in front of the musician).

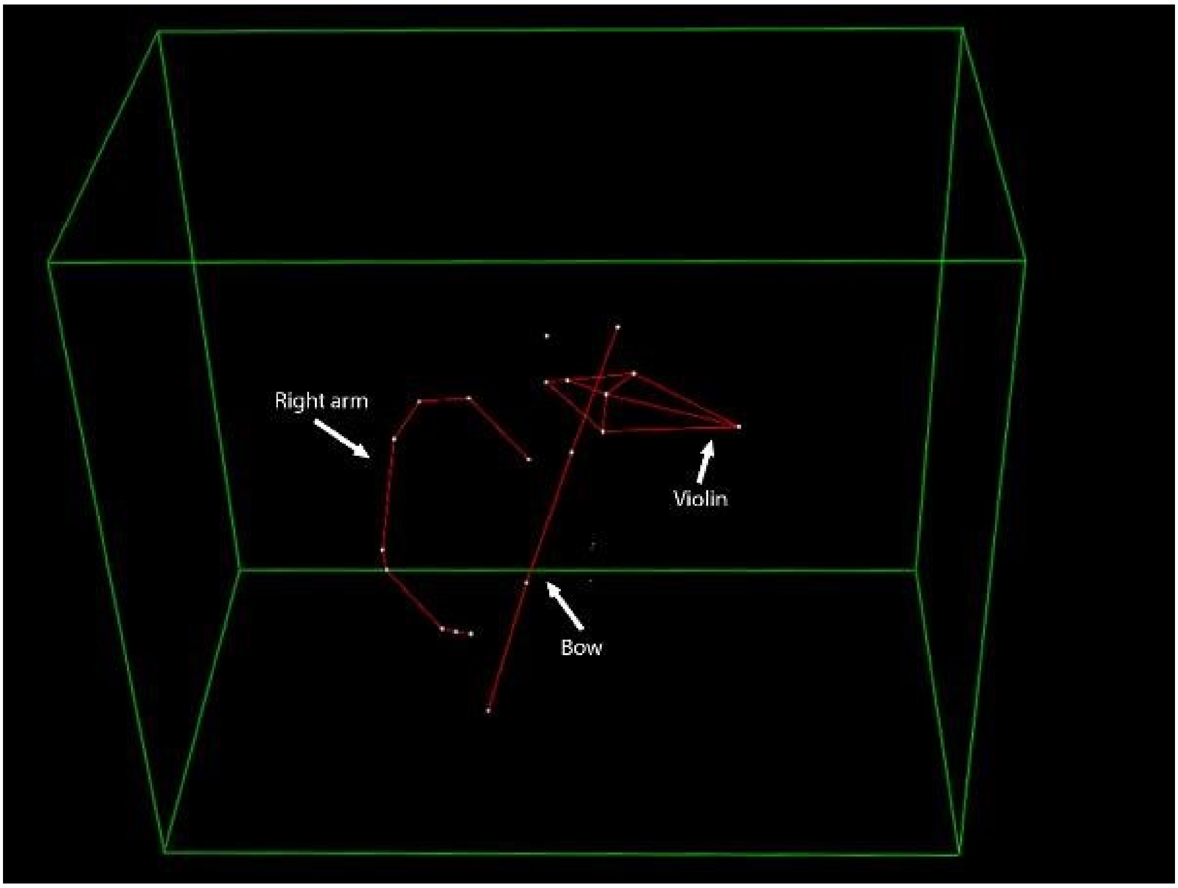


Figure 23: *3D reconstruction (top view).*

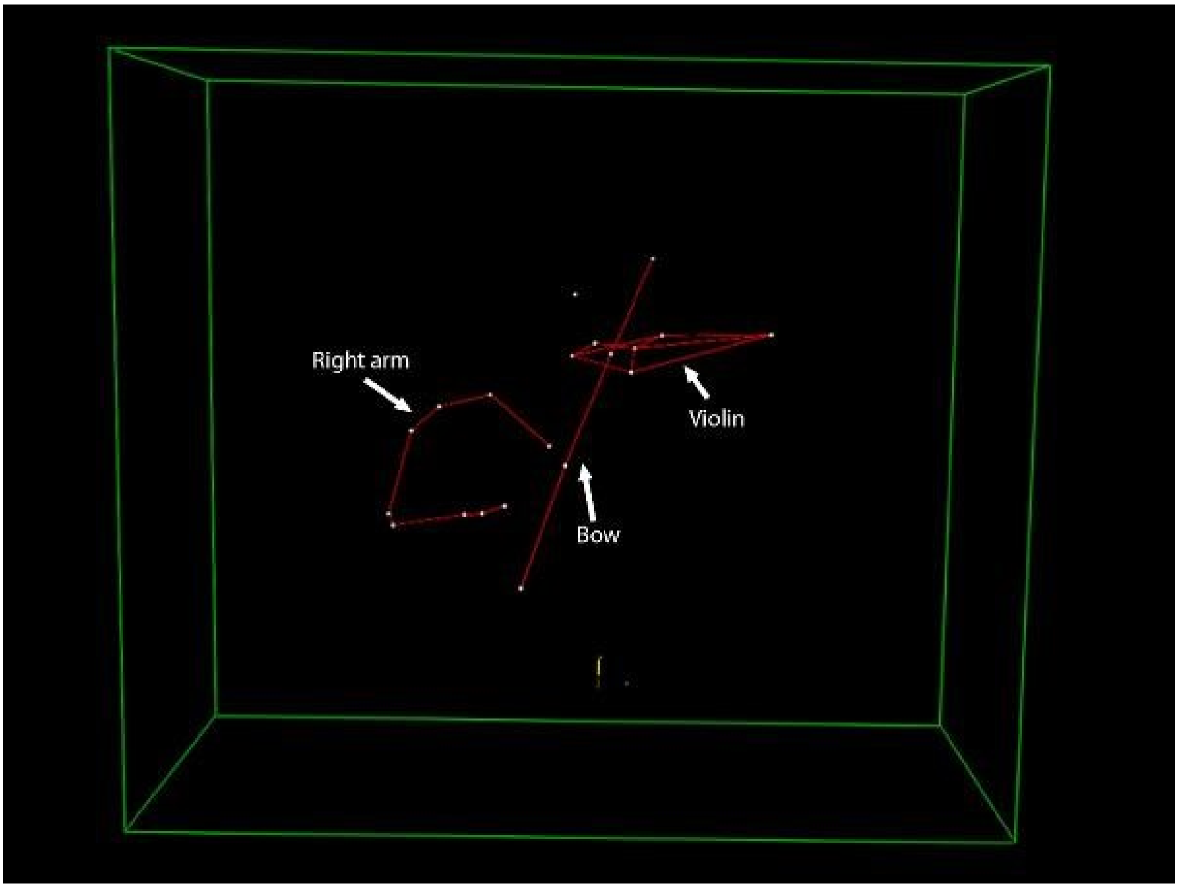


Figure 24: *3D reconstruction (front view).*

5 Discussion

The purpose of this thesis was to provide a proof of concept of a therapy regimen to treat musicians´ playing-related musculoskeletal disorders. To this end, the existing literature on current state-of-the-art diagnosis and treatment of PRMDs was reviewed, as well as the literature on the treatment and monitoring methods that are part of the here-proposed therapy regimen. Then, to demonstrate the safety and feasibility of these methods, pilot trials were conducted with musicians from the Orchestra Academy of the Vienna Philharmonic. (423)

All participants were able to successfully complete the demands of their respective trials in their entirety without any major issues. For the treatment methods, two musicians took part in a one-week program of sessions of transcranial direct current stimulation combined with physiotherapeutic exercises. The "checklist for tDCS and the physiotherapeutic exercises" and the "tDCS safety questionnaire", which were both designed specifically to assess the safety and feasibility of these methods, found the sessions to be safe and easy to conduct overall. Furthermore, the "pain assessment questionnaire" was filled out by four musicians to show its usefulness as the primary endpoint of the proposed regimen.

Three musicians also participated in the initial physiotherapeutic evaluation and two in the initial psychological coaching session, which are both part of the proposed therapy regimen. The two monitoring tools were a medical imaging protocol, which used magnetic resonance imaging and diffusion tensor imaging of the brain and was completed by two musicians, and a three-dimensional motion capture acquisition, which was done by one musician. All these trials were safe and yielded very promising results for their application in a project with a bigger sample size. The findings of the trials and their results are further discussed and compared with other studies in the following paragraphs, and some speculations are made regarding possible implications of this study.

Regarding the tDCS trials, the study initiation visits, the stimulation weeks, and the end of study visits went seamlessly and without any major problems for both participants. The most frequent technical difficulty that both participants faced during the trials (lack of electrode connectivity in 3/10 sessions in total) is a well-known minor issue with the tDCS technology itself. According to the manufacturer, poor connectivity is frequently due to a lack of water saturation of the foam nibs on the inside of the headband. This results in the software not starting the session or, if the session is already underway, pausing the session until sufficient connectivity is restored. This is done by soaking the nibs in water one more time, so that there is enough conductive medium for the electrical current to flow. (387) As the participants were informed about this issue in the study initiation visit, they were able to restore the necessary level of connectivity without assistance and continued these three sessions unimpeded.

The incidence of mild adverse effects in the tDCS trials (3/10 sessions in total) is roughly in line with the results of Brunoni et al. (316), who reported the overall frequency of mild adverse effects to be between 10-40% (see chapter 1.4.2). In that study, the frequency of a tingling sensation was reported at 22.2% vs. 18.3% for real vs. sham stimulation and the frequency of a burning sensation at 8.7% (real) vs. 10% (sham), with no significant difference between real/sham stimulation across almost 4000 subjects. (316) As expected based on the existing literature, there were no severe adverse events in any of the sessions. (282, 315)

In reference to the questionnaires, they were all understood as intended and filled out completely by the participants. The "tDCS checklist" and the "tDCS safety questionnaire" received many valuable and detailed answers in the intended spaces, although in the former they could have been designed even larger to allow for more detailed explanations by the participants.

Also, the third question of the "tDCS safety questionnaire" was written in a way that if the answer to the second statement was "yes", then the answer to the third statement had to be "yes" as well. The reasoning behind the third statement was that it should specifically ask for unfavourable/discomforting effects that occurred during the therapy, but outside of the stimulation sessions themselves. To receive an appropriate response, it should have been formulated more precisely, in order to specifically exclude unfavourable/discomforting effects that occurred during the sessions.

In the "pain assessment questionnaire", the regions in which the participants reported pain most frequently were the neck, the wrist/hand, and the upper and lower back. These are the same regions that are listed as the most prevalent in the pain distribution among music students observed by Cruder et al. (see Figure 1 in chapter 1.2.2). (153) The only exception is the shoulder, which is the third most common location of pain in Cruder et al.´s observation, but is not among the most frequent body regions in this study. Furthermore, the regions in which musicians experienced pain the least often according to Cruder et al. (153), i.e., elbows, knees, and hips/thighs, were also the least frequently reported by the participants in the "pain assessment questionnaire". (153) These results, are also in line with the findings of Gembris et al. (106), albeit with the limited sample size of only four completed "pain assessment questionnaires" in this study. (106)

The initial physiotherapy and coaching sessions all had a pleasant atmosphere, and the participants were all motivated and interested when conducting their tasks. During the initial physiotherapeutic evaluation, it seemed that the closed kinetic chain upper extremity speed test was the most physically demanding exercise for the participants, as one even stated so. As a result, there could have been some exhaustion after this test that then manifested itself in a worse performance in the one-arm line hopping test. This could have also been the reason why both participants had to do this exercise in a push-up position on their knees instead of their feet. Whether all of this was the case remains unclear, but nevertheless, a possible improvement of the protocol could be to swap the two exercises, making the one-arm line hopping test the second and the CKCUEST the final test.

In the coaching session, one of the tests, the verbal learning test, was only available in German. However, the mother tongue of one of the participants was Spanish, which clearly manifested itself in the results of the test. The participant achieved percentile ranks far below average, 10 in the category "Incorrect YES-Responses" and 21 in the category "Difference of correct minus incorrect YES-responses". On the contrary, his results in the non-verbal learning test and the other tests were average or even above average, the only exception being part A of the trail making test. Therefore, the VLT results of this participant were not very meaningful. To circumvent this issue, the VLT could have been either acquired in Spanish or omitted entirely.

As mentioned in the opening paragraph, both the medical imaging and the motion capture trials worked without any major problems. They succeeded in capturing data that may be useful for evaluating the effectiveness of the proposed treatment regimen and in analysing that data in a meaningful way. It should be noted that in the task-based functional magnetic resonance imaging acquisitions, the activation of the primary motor cortex during the "fingerboard" exercise is observed in both participants, unilaterally in one and bilaterally in the other. This activation could be in part due to the use of the hand during this task, but it also occurs in the “pretending” task, where the participants did not execute any physical motion.

In the motion capture trials it was possible to very accurately track the player´s motion and generate a three-dimensional model, similarly to the results of Ancillao et al.. (374) However, due to the smaller scope of this study, only the shoulder, elbow, and wrist angles and their mean absolute deviations were recorded, but not the derivatives of these angles, the bow position, the bow-violin angle, or the coefficients of variation. It is attractive to speculate that this tool could also accurately measure all of the latter variables, but it remains to be seen whether this is the case in practice.

In conclusion, the pilot trials of these treatment and evaluation methods were all conducted as planned and successfully completed without any major issues. All participants were motivated and interested in their tasks and adhered to the protocols that were given to them, which shows the practicability of the schedules. They had many detailed questions regarding these protocols, which were all answered to their satisfaction, so that in the end there were no misunderstandings during any of the trials.

All of this shows that it is possible to safely and effectively study the influence of tDCS combined with a physical therapy and psychological coaching program on instrument playing and practicing ability of professional orchestra musicians in a larger sample. Furthermore, it is possible to safely and effectively implement medical imaging techniques and motion capture methods to evaluate their usefulness in measuring and validating improvements of instrument playing and practicing ability of professional orchestra musicians in a larger sample.

6 Limitations

When interpreting the results, all conclusions regarding the safety and reliability of the many different tools and methods must be drawn very cautiously due to the small sample size (n = 7) of this study. As this was merely a feasibility pilot trial that aimed for a proof of concept, a larger number of participants would have exceeded the scope of this thesis. Nevertheless, all therapeutic parts of the study were conducted at least twice, and only the motion capture trials were done with just one participant. Therefore at least a minimum of reproducibility is achieved, albeit not enough to generalise without being wary of this constraint.

Another limitation of this study also results directly from the sample size and the fact that the different trials were done by different musicians. At least, one participant completed all three trials concerning the therapeutic methods at the same time, which worked very well and addressed the concern that doing all the trials at once could be too demanding to some degree. But still, no participant completed the medical imaging or motion capture trials together with the trials for the therapeutic methods. As there are only three evaluation sessions of the proposed regimen with one month each between them, it is less likely that they will pose an issue for the participants. The much more likely problem could be the steady administration of these sessions for 8 weeks, which could not be done here due to the scope of the study. Still, both participants who did the tDCS trials stated that they would have no problem doing the stimulations for 8 weeks.

This is another reason to treat these results with caution, namely that they are heavily reliant on the musicians´ statements, which are highly influenced by their personal opinions, feelings, and their current mood. This study is focused less on the specific results generated through some of the trials, and more on the fundamental feasibility of conducting the trials in the first place. Therefore, although these statements are not as objective as results obtained through measurements, they are often the most important outcomes.

For these reasons, the safety and feasibility of these methods investigated in this pilot study can be accepted in principle, but this has to be done with a good amount of caution and careful consideration of these limitations.

7 Prospect

As stated previously, this thesis is merely a feasibility pilot study, which is why no statement regarding the efficacy of the investigated tools and methods can be made. Therefore, some interesting questions for future research could be the following:

- Does transcranial direct current stimulation coupled with physiotherapeutic exercises and psychological coaching have a beneficial influence on instrument playing and practicing ability of professional orchestra musicians, either in the recovering process of playing-related musculoskeletal disorders, or in the regular instrumental training process?
- Can improvements of instrument playing and practicing ability of professional orchestra musicians be measured and validated by combining questionnaires with medical imaging techniques and motion capture methods?
- How well can these measurements complement and support the before-treatment and after-treatment subjective perceptions by the musicians obtained through questionnaires?

In this study, all of the therapeutic tools and methods investigated were very successful and showed promising results, indicating their possible usefulness in treating orchestra musicians´ playing-related musculoskeletal disorders. Consequently, the next step would seem to be to conduct a bigger study to determine whether the treatment regimen explored here is not only safe and feasible, but also effective in the treatment and/or prevention of PRMDs. Also, the underlying mechanisms of tDCS and its effect on motor learning in musicians could possibly be elucidated.

Furthermore, both the medical imaging and the motion capture trials worked very well and delivered many promising results. However, the purpose of these pilot trials was again to demonstrate their safety and feasibility, but not to draw conclusions regarding their diagnostic accuracy. To fully make use of these methods in a possible future study, more data could be recorded, such as the parameters that were omitted from the motion capture trials (see chapter 5). Also, more extensive analyses of the more comprehensive data could be done in the future to further expand these methods´ diagnostic potential.

Similarly, the results of the initial physiotherapeutic and coaching sessions could be evaluated in more detail when designing individualised physiotherapeutic exercise plans and coaching strategies for a full 8-week treatment regimen. This was not the purpose of the present study, but it would allow the tests to reach their full utility in helping to develop the best therapy regimen possible for each participant.

It was the aim of this thesis to demonstrate the safety and feasibility of the individual methods of a therapy and evaluation regimen for professional musicians. As this goal has been achieved, it is now time for said regimen to be studied at a larger scale, regarding both the duration of such a project and the number of participants to be enrolled. The groundwork for its realisation has been laid, the necessary steps have been taken, and the proof of concept has been provided. Now, this project is ready to be put into practice.

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9 List of Abbreviations

Abbreviation	**Description**
A	Ampere
AE	Adverse Event
BAPAM	British Association for Performing Arts Medicine
BIPQ	Brief Illness Perception Questionnaire
BMI	Body Mass Index
BMJ	British Medical Journal
BOLD	Blood Oxygen Level Dependent
CEIMArs	Centro Italiano Interdisciplinare di Medicina dell´Arte
CI	Confidence Interval
CKCUEST	Closed Kinetic Chain Upper Extremity Speed Test
cm	Centimeter
CT	Computed Tomography
DASH	Disabilities of the Arm, Shoulder and Hand Questionnaire
DBS	Deep Brain Stimulation
DGfMM	Deutsche Gesellschaft für Musikphysiologie und Musikermedizin
DLPFC	Dorsolateral Prefrontal Cortex
DTI	Diffusion Tensor Imaging
EEG	Electroencephalography
fMRI	functional Magnetic Resonance Imaging

FTSD	Focal Task-specific Dystonia
HPD	Hearing Protection Device
ICF	Informed Consent Form
INHIB	Response Inhibition
kg	Kilogram
lat.	Latin
LHB	Long Head of the Biceps Brachii
Lig.	Ligamentum (latin for “ligament”)
LTP	Long-Term Potentiation
m.	Musculus (latin for “muscle”)
MEG	Magnetoencephalography
MEP	Motor Evoked Potential
MI	Medical Imaging
mocap	Motion Capture
MPA	Music Performance Anxiety
MPPA	Medical Problems of Performing Artists
MRI	Magnetic Resonance Imaging
mUQYBT	modified Upper Quarter Y-Balance Test
M1	Primary Motor Cortex
n	Sample size / absolute frequency (number of cases or participants)
NEJM	New England Journal of Medicine

NIBS	Non-Invasive Brain Stimulation
NIHL	Noise-Induced Hearing Loss
NMQ	Nordic Musculoskeletal Questionnaire
NSAID	Non-Steroidal Anti-Inflammatory Drug
NVDMG	Nederlandse Vereniging voor Dans- en Muziekgeneeskunde
NVLT	Non-Verbal Learning Test
ÖGfMM	Österreichische Gesellschaft für Musik und Medizin
OR	Odds Ratio
PAM	Performing Arts Medicine
PAMA	Performing Arts Medicine Association
PR	Percentile Rank
PRMD	Playing-Related Musculoskeletal Disorder
QuickDASH	Quick Disabilities of the Arm, Shoulder and Hand Questionnaire
ROM	Range of Motion
rTMS	repetitive Transcranial Magnetic Stimulation
s	Second (time unit)
SD	Standard Deviation
SIS	Subacromial impingement syndrome
SFTT	Sequential Finger Tapping Task
SMA	Supplementary Motor Area
SQUID	Superconducting Quantum Interference Device

SRTT	Sequential Reaction Time Task
SVIPT	Sequential Visual Isometric Pinch Force Task
tACS	transcranial Alternating Current Stimulation
tDCS	transcranial Direct Current Stimulation
tES	transcranial Electric Stimulation
TMT-L	Trail Making Test – Langensteinbach Version
TOL-F	Tower of London – Freiburg Version
tRNS	transcranial Random Noise Stimulation
V1	Primary Visual Cortex
VLT	Verbal Learning Test
VPFT	Visuomotor Pinch Force Task
3D	three-dimensional

10 Appendix

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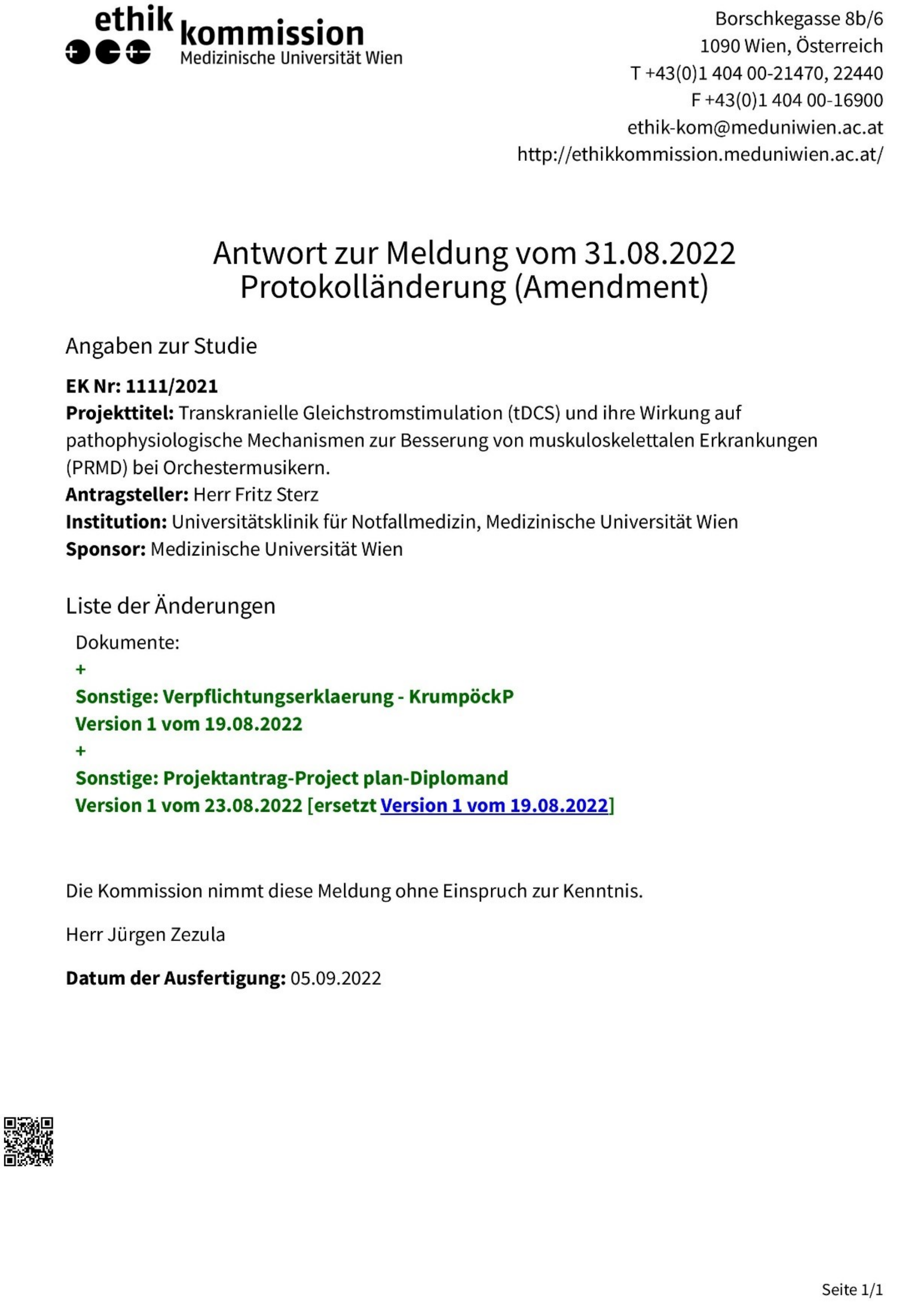
10.4 Positive Vote from the Ethics Committee of the Medical University of Vienna



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Antwort zur Meldung vom 31.08.2022
Protokolländerung (Amendment)

Angaben zur Studie

EK Nr: 1111/2021
Projekttitel: Transkranielle Gleichstromstimulation (tDCS) und ihre Wirkung auf pathophysiologische Mechanismen zur Besserung von muskuloskelettalen Erkrankungen (PRMD) bei Orchestermusikern.
Antragsteller: Herr Fritz Sterz
Institution: Universitätsklinik für Notfallmedizin, Medizinische Universität Wien
Sponsor: Medizinische Universität Wien

Liste der Änderungen

Dokumente:
+
Sonstige: Verpflichtungserklaerung - KrumpöckP
Version 1 vom 19.08.2022
+
Sonstige: Projektantrag-Project plan-Diplomand
Version 1 vom 23.08.2022 [ersetzt Version 1 vom 19.08.2022]

Die Kommission nimmt diese Meldung ohne Einspruch zur Kenntnis.

Herr Jürgen Zezula

Datum der Ausfertigung: 05.09.2022

Seite 1/1

Unterzeichner	Dr. Jürgen Zezula
Datum/Zeit-UTC	2022-09-05T12:03:58Z
Prüfinformation	Informationen zur Prüfung der elektronischen Signatur finden Sie unter: https://www.signaturpruefung.gv.at

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Antwort zur Meldung vom 09.05.2022
Verlängerung der Gültigkeit des Votums

Angaben zur Studie

EK Nr: 1111/2021
Projekttitel: Transkranielle Gleichstromstimulation (tDCS) und ihre Wirkung auf pathophysiologische Mechanismen zur Besserung von muskuloskelettalen Erkrankungen (PRMD) bei Orchestermusikern.
Antragsteller: Herr Fritz Sterz
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Die Ethik-Kommission stimmt dem Antrag auf Verlängerung der Gültigkeit des Votums zu.

Allerdings weist die Ethik-Kommission darauf hin, dass die behördlich vorgeschriebenen Maßnahmen hinsichtlich der COVID-19 Pandemie beachtet werden müssen. Der Prüfer und der Sponsor müssen in ihrem jeweiligen Wirkungskreis unter allfälliger Beachtung von Leitlinien gewährleisten, dass keine zur Bekämpfung der Pandemie benötigten Ressourcen gebunden werden bzw. ausreichend Personal vorhanden ist und die Teilnehmer durch ihre Studienteilnahme keiner zusätzlichen Infektionsgefahr ausgesetzt werden.

Die aktuelle Gültigkeit des Votums endet mit **26.05.2023**

Datum der Ausfertigung: 17.05.2022

Herr Fritz Sterz

Seite 1/1

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EK Nr: 1111/2021
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Sponsor: Medizinische Universität Wien

Teilnehmende Prüfzentren:

Ethik-Kommission	Prüfzentrum	Prüfärztin/arzt
Ethikkommission der Medizinischen Universität Wien	Medizinische Universität Wien, Univ Kl f Notfallmedizin	Herr aUniv. Prof. Dr. med. Fritz Sterz
Ethikkommission der Medizinischen Universität Wien	Med Univ Wien, Universitätsklinik für Radiologie und Nuklearmedizin	Herr Assoc. Prof. Priv.-Doz. Dr. Gregor Kasprian

Die Stellungnahme der Ethik-Kommission erfolgt aufgrund folgender eingereichter Unterlagen:

Conflict of Interest

Name	Version	Datum
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Conflict_of_Interest_Antragsteller_Vers._3_KkasprianG	1.0.0	01.03.2021

Konformitätserklärung

Name	Version	Datum
Certificate-of-CE-Registration-	1	28.01.2021
UMEC ROHS2.0 Compliance DEclaration_HALO SPORT2_210412	1	12.04.2021

Covering Letter

Name	**Version**	**Datum**
2021_01_SterzF_CoverLetter_OM-PNP	1.1.0	04.02.2021

Lebenslauf (CV)

Name	**Version**	**Datum**
CV-Ebenbichler_2020_sig	1.0.1	08.11.2020
2021_01_SterzF_CV	1.0.0	29.01.2021
Lebenslauf Paul Krumpöck	1.0.0	29.01.2021
CV Kasprian final	1.00	01.03.2021

Versicherungsbestätigung

Name	**Version**	**Datum**
VB 47-2021	1	21.05.2021

Gebrauchsanweisung

Name	**Version**	**Datum**
Halo-research-brochure	1.0.0	29.01.2021
Halo+Sport+2+Owner's+Guide	1.0.0	29.01.2021

Sonstige

Name	**Version**	**Datum**
Studierende_Datengeheimnis____6_DSG_und_Verschwiegenheitserkl_V3_Rechtsabteilung_Version_vom_14022019 (1)	1	03.02.2021
10055768 10055769 10055770 10055771 10055775 AppendixP	1	02.04.2021
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10055772 AppendixD(BLE)	1	02.04.2021
10055772_Microchip_BM62_CE 300328 BLE(5.5 Final)	5,5	02.04.2021
10055775 002_Microchip_BM62_EN 300 328 V2.1.1_FHSS-signed	2.1.1	02.04.2021
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Patienteninformation

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ICF_klinische_Studie_gemaess_DSGVO_Vers._1.4.2_vom_5.6.2019	1.0.0	29.01.2021
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Studienprotokoll (Prüfplan)

Name	Version	Datum
Projektantrag OM-PNP_vs100	1.0.0	29.01.2021

Name	**Version**	**Datum**
∃motion makes music_CIP_vs200_marked	2.0	08.04.2021
∃motion makes music_CIP_vs200_unmarked	2.0	08.04.2021
∃motion makes music_CIP_vs300	3.0.0	05.05.2021
∃motion makes music_CIP_vs300_marked	3.0.0	05.05.2021
∃motion makes music_CIP_vs400	4	15.05.2021
∃motion makes music_CIP_vs500	5	21.05.2021

Stellungnahme zum Gutachten

Name	**Version**	**Datum**
response_to_vote-mitteilung_∃motion-makes-music_11112021-2021-03-23-1021468731750000-20210323	1.0.	08.04.2021
∃motion-makes-music_response_to_vote-mitteilung-11112021-2021-04-23-1249559849950000-20210423	1.0.0	05.05.2021
∃motion-makes-music_response_to_vote-mitteilung-11112021-2021-05-12-1002246248850000-20210512	1	15.05.2021
∃motion-makes-music_response_to_vote-mitteilung-11112021-2021-05-12-1002246248850000-20210512	1	21.05.2021

Die Kommission fasst folgenden Beschluss (mit X markiert):

☒	Es besteht kein Einwand gegen die Durchführung der Studie. ACHTUNG: Unter Berücksichtigung der "ICH-Guideline for Good Clinical Practice" gilt dieser Beschluss ein Jahr ab Datum der Ausstellung. Gegebenenfalls hat der Antragsteller eine Verlängerung der Gültigkeit rechtzeitig zu beantragen.

Ergänzende Kommentare der Sitzung am 16.03.2021:

Zum Prüfplan:
Der Studientitel ist zu überarbeiten. Der Studientitel sollte erlauben, die wesentlichen Ziele der Studie nachzuvollziehen.
Die Durchführung der Studie ist strukturierter zu beschreiben. Es sollte für den gesamten Studienablauf übersichtlich dargestellt werden, welche Untersuchungen zu welchen Zeitpunkten stattfinden. Die Darstellung in Form einer Tabelle wird empfohlen.
Die Ein- und Ausschlusskriterien sind für alle Teilnehmer genauer darzustellen. So fehlen z.B. Läsionen des Bewegungsappparates, die bei Musikern relevant sein können, wie z.B. Teilrupturen der Sehnen, Bursitis, Discusprolaps, radikuläre Läsionen, Engpassyndrome etc.

Grundsätzlich sollen sehr viele unterschiedliche Outcomeparameter erhoben werden, die überwiegend sehr aufwendig zu messen sind und nicht validiert sind. Aus Sicht der Ethik-Kommission sollte überdacht werden, sich auf weniger Parameter zu fokusieren. Diesbezüglich sollte auch die Stratifizierung der Randomisierung überdacht werden und versucht werden Kriterien zu wählen, die relevant für die Aussage der Studie sind.
Das Übungsprogramm soll detailliert und systematisch dargestellt werden, inklusive der Anzahl der Wiederholungen und Sets. Es fehlt ein strukturiertes Übungstagebuch.
Es gibt eine Diskrepanz zwischen 1x 15 Minuten Übungen mit Halo Sport 2 an 5 Tagen und 20 Minuten Halosport an 5 Tagen - sind es jetzt 5x 15 Minuten oder 5x 20 Minuten oder beides - dies ist zu klären.
Probanden mit muskulären Problemen bekommen eine Physiotherapie bereits vor Beginn der Studie, die anderen Teilnehmer ohne muskuläre Probleme erst mit Beginn der Studie - das sollte bei der Stratifizierung berücksichtigt werden.
Es wurde ein "Certificate of CE-Registration" eingereicht. Dieses ist aber für eine ‚electrotherapeutic unit‘ und ein ‚Interface‘ der Firma Soterix Medical Inc. in New York. Der Zusammenhang zu Halo Sport 2, Neuroscience (San Francisco, CA, United States of America) ist zu klären.

Das Projekt wird vertagt.

Zur Statistik:
Es sollte angedacht werden, eine Wash-out-Phase zwischen den beiden Blöcken zu etablieren, damit sich Effekte aus Block 1 nicht auf den Block 2 übertragen.
Es ist angegeben, dass nach jeder Kombination von Kovariablen die Randomisierung stratifiziert wird, bei 8 Variablen mit 2-3 Ausprägungen ergäbe das über 500 Strata, dies erscheint nicht machbar, insbesondere, da die Randomisierung mittels versiegelter Briefkuverts erfolgt.
Ein "Emergency unblinding" erfolgt durch Rückfrage an einer "independent institution". Deren durchgängige Erreichbarkeit ist im Studienprotokoll zu ergänzen.
Bei Cross-over-Studien wird meist der Therapieeffekt, der Periodeneffekt und ein ungleicher Carry-over-Effekt geprüft. Will man beim Gruppenvergleich einen möglichen Periodeneffekt herausrechnen, so erfolgt die Analyse durch "passend" gewählte Differenzen und ungepaarte t-Tests. Die Anwendung von "einfachen" gepaarten t-Tests berücksichtigt keinen Periodeneffekt.
Es ist unklar, welcher Test bei der Zwischenauswertung herangezogen wird, da erst die Ergebnisse der ersten Periode zur Verfügung stehen, d.h. es kann nur ungepaart ausgewertet werden?
Grundsätzlich stellt sich die Frage, ob ein Cross-over-Design in der geplanten Untersuchung überhaupt anwendbar ist, da die Teilnehmer kontinuierlich auf ihrem Instrument üben und dadurch die Aussage über die Wirksamkeit der Intervention in der 2. Studienphase beeinflusst wird.

Zum Antrag:
Unter Punkt 2.2 fehlen die Fachgebiete Radiologie, Neurologie, Physikalische Medizin.
Punkt 6: Die studienbezogenen Maßnahmen sind unvollständig ausgefüllt, es fehlen alle Assessment- und Evaluationsmaßnahmen, sowie auch alle Therapiemaßnahmen.
Punkt 7.5: Es fehlen wesentliche Ein- und Ausschlusskriterien.

Angaben zur Biometrie, insbesondere zu den Studienhypothesen, fehlen und sind zu ergänzen.
Der Reiter Versicherung ist zu aktualisieren.

Zur Teilnehmerinformation:
Es fehlen wesentliche Informationen. Erst wenn diese ergänzt wurden, kann das Dokument endgültig beurteilt werden.
Vorläufige Punkte:
Punkt 2: Der Studienablauf ist nachvollziehbar und im Detail zu beschreiben. Derzeit fehlen jegliche Angaben zur Randomisierung und der Sham-Stimulation, zur Verblindung und zum Cross-Over. Die studienbedingten Maßnahmen (Stimulation, physikalische Therapie, MRT, EEG, MEG, Motion-Capture-Analyse, Musikanalyse...) müssen vollständig angeführt und anschaulich beschrieben werden, es muss klar hervorgehen, welche Untersuchungen bei welchen Studienbesuchen in welchen Zeitabständen erfolgen und wie viel Zeit diese Besuche und die einzelnen Untersuchungen in Anspruch nehmen. Anhand der derzeitigen Beschreibung können die potentiellen Teilnehmer nicht informiert einwilligen.
Punkt 8: Ein Versicherungspassus ist zu ergänzen. Es ist der Versicherungspassus aus der Musterinformation für klinische Prüfungen zu verwenden.
Punkt 10: Es wurde versehentlich der Text für klinische Studien verwendet. Erforderlich ist der ausführlichere Passus aus der Musterinformation für klinische Prüfungen. Im Satz beginnend mit "Zusätzlich können..." ist als Sponsor nur die Medizinische Universität Wien anzuführen, nicht die Klinik für Notfallmedizin und auch nicht Herr Professor Sterz.
Punkt 11: Die Aufwandsentschädigung scheint deutlich zu hoch, eine Anpassung bzw. Stellungnahme ist erforderlich.
Es fehlt ein Abschnitt ("Was ist Halo Sport"), in welchem das zu untersuchende Gerät und seine Funktion anschaulich beschrieben wird.
Es ist an passender Stelle zu ergänzen, dass aus rechtlichen Gründen Schwangere und Stillende an dieser klinischen Prüfung gemäß MPG nicht teilnehmen dürfen.

Zur Versicherung: muss nachgereicht werden
Sollte es sich nicht um die Rahmenversicherung der MedUni Wien handeln, sind zusätzlich die Allgemeinen Versicherungsbedingungen für die Personenschadenversicherung (APVA, BPV-A, o.ä genannt), sowie allfällige weitere dem Versicherungsvertrag zugrunde liegende besondere Versicherungsbedingungen vorzulegen.

Andere:
Die Ethik-Kommission geht - rechtlich unverbindlich – davon aus, dass es sich um eine klinische Prüfung gemäß § 40 (3) MPG handelt.
Das Fallbericht-Formular (CRF) ist hochzuladen.
Ein gültiges CE-Zertifikat für das Medizinprodukt Halo Sport 2, Neuroscience (San Francisco, CA, United States of America) ist vorzulegen.

Die Ethik-Kommission ersucht die Antragsteller, bei der Wiedervorlage von geänderten Unterlagen ein Exemplar mit hervorgehobenen Änderungen beizulegen.

Zusätzliche Auflagen:

Die behördlich vorgeschriebenen Maßnahmen hinsichtlich der COVID-19 Pandemie müssen beachtet werden. Der Prüfer und der Sponsor müssen in ihrem jeweiligen Wirkungskreis unter allfälliger Beachtung von Leitlinien gewährleisten, dass keine zur Bekämpfung der Pandemie benötigten Ressourcen gebunden werden bzw. ausreichend Personal vorhanden ist und die Teilnehmer durch ihre Studienteilnahme keiner zusätzlichen Infektionsgefahr ausgesetzt werden.

Hinweis:
Die Ethikkommission verweist auf die allenfalls erforderliche Konsultation der Rechtsabteilung der MedUni Wien, der Datenclearingstelle der MedUni Wien, der Datenschutzbeauftragten der MedUni Wien bzw. des Datenschutzverantwortlichen des AKH sowie auch auf die verpflichtend einzuhaltenden GSP Richtlinien der MedUni Wien und die Vorgaben des Handbuchs für Drittmittelprojekte der MedUni Wien.
Weitere Informationen finden sich unter https://ethikkommission.meduniwien.ac.at/service/weitere-informationen/

Ergänzende Kommentare der Sitzung am 13.04.2021:
Die Antragsteller legen am 08.04.2021 überarbeitete Unterlagen vor, die von der Ethik-Kommission ausführlich diskutiert werden.

Zum Prüfplan:
Die Kommission ersucht um Stellungnahme zu folgenden Punkten:
In der Studie werden alle drei Einflussfaktoren gemeinsam angewendet und untersucht, somit kann auch nur eine Schlussfolgerung über einen kombinierten Effekt gezogen werden. Im Titel wird aber nur auf die Effekte der tDCS hingewiesen.
Als primäre Hypothese (eigentlich drei Hypothesen) wird angeführt, dass die kombinierte Behandlung mittels tDCS, Physiotherapie und Coaching die Bewegungsmuster verbessert, die Lebensqualität verbessert und die Neuorplastizität verändert. Widersprüchlich dazu wird im Protokoll als primärer Outcomeparameter ein Schmerzfragebogen (PRMD) angeführt.
Sollen gleich viele Musiker mit Beschwerden wie Musiker ohne Beschwerden eingeschlossen werden und werden diese getrennt oder im Vergleich zueinander ausgewertet? Bei Musikern ohne Beschwerden scheint der Schmerzfragebogen als primärer Outcomeparameter nicht sinnvoll.
Handelt es sich bei der "Physical, mental, and social well-being evaluation" um einen validierten Fragebogen?

Bei den Einschlusskriterien der Satz ergänzt: "with and without playing-related musculoskeletal diseases (PRMD), if still able to play / perform"; analog dazu sollte bei Ausschlusskriterien "Läsionen des Bewegungsapparates, bei denen aus medizinischer Sicht eine Kontraindikation gegen das Spielen des jeweiligen Instruments besteht" ergänzt werden.
Die Kontraindikationen für die MRT wären bei den Ausschlusskriterienzu zu ergänzen und falls ein z/n ICD oder ein Schrittmacher eine Kontraindikation für die Anwendung der transkraniellen Gleichstromstimulation darstellt, wäre dies anzugeben.
Aus dem Text zum Fragebogen auf Seite 37 geht nicht nicht klar hervor, ob dieser NMQ, DASH

und B-IPQ inkludiert; die Kommission ersucht um Klarstellung.
In der Graphik (Seite 28, “study process”) sollte auch das Coaching inkl. Zeitumfang angegeben werden (bisher nur im Antrag angeführt).
Die "secondary outcomes" sollten auch in Kurzfassung vollständig gelistet sein.

Es wurde seitens der Antragsteller ein CE Zertifikat und Testprotokolle der Firma Microchip für ein Bluetooth Produkt "BM62SPKabcC2" nachgereicht. Es ist aber unklar, was dieses CE Zertifikat mit dem eigentlichen Medizinprodukt zu tun hat. Ein gültiges CE-Zertifikat für das Medizinprodukt Halo Sport 2, Neuroscience (San Francisco, CA, United States of America) ist vorzulegen.

Das Projekt wird vertagt.

Zur Statistik:
Eine Berücksichtigung der vorliegenden PRMDs bei der Stratifizierung der Randomisierung wird empfohlen.
Es sind mehrere Scores als primäre Endpunkte genannt. Wenn mehrere primäre Endpunkte getestet werden sollen, muss eine entsprechende Korrektur für multiples Testen vorgesehen werden. Die Multiplizitätskorrektur muss auch in der Fallzahlplanung berücksichtigt werden. Die vorgeschlagene statistische Analyse für das Cross-over Design ist nach wie vor nicht entsprechend dem üblichen Standard. Siehe etwa Senn, S. S. (2002). Cross-over trials in clinical research (Vol. 5). John Wiley & Sons. für die übliche Vorgangsweise.

Zum Antrag:
Die studienbezogenen Maßnahmen sind vollständig anzugeben (z.B. auch die neuropsychologischen Tests) bzw. sind übereinstimmende Angeben notwendig: Für tDCS bzw. Shamstimulation sind 20 Sitzungen zu 20 Minuten über 4 Wochen, dann nochmals 20 Sitzungen zu 20 Minuten mit der jeweils anderen Modalität vorgesehen. Dazu soll jedes mal laut Protokoll Physiotherapie gemacht werden. Es werden aber nur 10x 60 Minuten Physiotherapie angeführt. Auch die weiteren diagnostischen Assessments wie "Health score" WHO QoL Fragebogen, neurologische Untersuchung, neuropsychologisches Assessment etc. sind nicht angeführt und wären zu ergänzen.
Das als Referenzprodukt angeführte Soterix sollte erklärt/beschrieben werden.

Die Angaben im Antrag sind nach Überarbeitung des Protokolls in Übereinstimmung zu bringen: Zur Zeit ist weder die primäre Hypothese im Antrag (Kombinationstherapie verbessert Bewegungsmuster + Neuroplastizität, PMRD, Lebensqualität) ident mit jener im Protokoll (Kombinationstherapie verbessert Instrumentenspiel und Übungsfähigkeiten bei Musikern mit und ohne PMRD) noch die sekundäre Hypothese (Antrag - "MRT, Bewegungsanalyse und Audioanalyse weisen erfolgreiche Behandlung PMRD nach" vs. Protokoll - "MRT, Bewegungsanalyse und Audioanalyse weisen Verbesserungen beim Musizieren und Üben nach").
Auch bei der Anzahl der Teilnehmer (Protokoll: n = 58 + 6 standby adults; Antrag: n = 60) und den Assessments (Protokoll: über 2 Monate, Tag 1-61; Antrag: Dauer Teilnahme 12 Wochen, aktive Phase 59 Tage) sind einheitliche Angagen erforderlich.

Zur Teilnehmerinformation:
Punkt 2: Der Studienablauf ist unzureichend erklärt, so werden z.B. die Fragebögen und die psychologische Testung nicht erwähnt, das Coaching und die Physiotherapie nicht beschrieben. Auch sollte die Vorgangsweise bei der MRT-Untersuchung anschaulich beschrieben werden. Der gesamte Zeitaufwand für die Studie ist aus der Beschreibung ebenfalls nicht ersichtlich. Es sollte auch bereits hier erwähnt werden, dass die Stimulationen bei den Teilnehmer zu Hause stattfinden. Es ist insgesamt eine übersichtliche Beschreibung des Studienablaufs erforderlich, aus dem vollständig hervorgeht, welche Maßnahmen erfolgen, wie diese vor sich gehen, welchen Zeitaufwand die Studienteilnahme mit sich bringt etc.
Der Begriff "primärer Motorkortex" ist zu erklären. Anstatt "oberkörperfrei spielen" sollte es heißen "mit freiem (unbekleidetem) Oberkörper spielen" oder ähnlich. Es ist nicht erwähnt, wer Zugang zu diesen Videos mit spärlicher Bekleidung hat, ob die Teilnehmer auf diesen Videos zu erkennen sind und was mit diesen Videos nach Auswertung geschieht. Entsprechende Angaben sind zu ergänzen.
Punkt 4: Risiken/ Unannehmlichkeiten der MRT-Untersuchung sind zu ergänzen (ruhiges Liegen, enge Röhre, laute Geräusche).
Punkt 8: Die Versicherungsdaten sind zu ergänzen (Name, Adresse Telefonnummer der Versicherungsgesellschaft, Nummer der Versicherungspolizze).
Punkt 10: Es wurde der Text für klinische Studien verwendet. Erforderlich ist der ausführlichere Datenschutzpassus aus der Musterinformation für klinische Prüfungen.
Punkt 12: Eine Beurteilung der Höhe der Aufwandsentschädigung ist erst möglich, wenn anhand einer entsprechenden Beschreibung ist Punkt 2 klar ist, wie hoch der Zeitaufwand für die Studie tatsächlich ist. Eine Aufwandsentschädigung von 25 € für eine 4-stündige Evaluationssitzung ist allerdings zu wenig. Die hier angeführten Screening.- und End-of.Study-Besuche sind aus der Beschreibung in Punkt 2 nicht ersichtlich.
Punkt 15: Die Information hat (derzeit) insgesamt 8 Seiten, nicht 7 - die Angabe der Seitenzahl im Text ("die insgesamt 7 Seiten umfasst") ist anzupassen.

Zur Versicherung: muss nachgereicht werden
Die Antragsteller werden darauf hingewiesen, dass im Falle von Protokolländerungen die Versicherung zu informieren ist. Bei Fehlen einer automatischen Verlängerung des Versicherungsvertrages ist rechtzeitig eine Versicherungsbestätigung über die Verlängerung vorzulegen.

Andere:
Die Ethik-Kommission ersucht die Antragsteller, bei der Wiedervorlage von geänderten Unterlagen ein Exemplar mit hervorgehobenen Änderungen beizulegen.
Es ist ergänzend ein Cover Letter mit einer Punkt-für-Punkt-Stellungnahme vorzulegen.

Zusätzliche Auflagen:
Die behördlich vorgeschriebenen Maßnahmen hinsichtlich der COVID-19 Pandemie müssen beachtet werden. Der Prüfer und der Sponsor müssen in ihrem jeweiligen Wirkungskreis unter allfälliger Beachtung von Leitlinien gewährleisten, dass keine zur Bekämpfung der Pandemie benötigten Ressourcen gebunden werden bzw. ausreichend Personal vorhanden ist und die

Teilnehmer durch ihre Studienteilnahme keiner zusätzlichen Infektionsgefahr ausgesetzt werden.

Hinweis:
Die Ethikkommission verweist auf die allenfalls erforderliche Konsultation der Rechtsabteilung der MedUni Wien, der Datenclearingstelle der MedUni Wien, der Datenschutzbeauftragten der MedUni Wien bzw. des Datenschutzverantwortlichen des AKH sowie auch auf die verpflichtend einzuhaltenden GSP Richtlinien der MedUni Wien und die Vorgaben des Handbuchs für Drittmittelprojekte der MedUni Wien.
Weitere Informationen finden sich unter https://ethikkommission.meduniwien.ac.at/service/weitere-informationen

Ergänzende Kommentare der Sitzung am 11.05.2021:
Die Antragsteller legen am 5.5.2021 überarbeitete Unterlagen vor.

Zum Antrag:
Die Angaben im Reiter Versicherung sind zu aktualisieren.

Zur Teilnehmerinformation:
Punkt 2: Es sollte explizit angeführt werden, wie lange die Evaluations-Termine jeweils dauern, dies ist aus der derzeitigen Darstellung immer noch schwer zu erkennen.
Punkt 4: Risiken/Unannehmlichkeiten der MRT-Untersuchung sind zu ergänzen (ruhiges Liegen, enge Röhre, laute Geräusche).
Punkt 8: Die Versicherungsdaten sind zu ergänzen (Name, Adresse, Telefonnummer der Versicherungsgesellschaft, Nummer der Versicherungspolizze).
Punkt 12: Es ist derzeit nicht beurteilbar, ob eine Aufwandsentschädigung von 250€ pro Evaluationstermin gerechtfertigt ist (siehe oben).
Punkt 15: Die Information hat (derzeit) insgesamt 9 Seiten, nicht 8 - die Angabe der Seitenzahl im Text ("die insgesamt 8 Seiten umfasst") ist anzupassen. Anstatt "Patient" sollte es heißen "Teilnehmer" o.ä. (kommt mehrmals vor).

Zur Versicherung: muss nachgereicht werden
Sollte es sich nicht um die Rahmenversicherung der MedUni Wien handeln, sind zusätzlich die Allgemeinen Versicherungsbedingungen für die Personenschadenversicherung (APVA, BPV-A, o.ä. genannt) sowie allfällige weitere dem Versicherungsvertrag zugrunde liegende besondere Versicherungsbedingungen vorzulegen.

Die Ethik-Kommission ersucht die Antragsteller, bei der Wiedervorlage von geänderten Unterlagen ein Exemplar mit hervorgehobenen Änderungen beizulegen.

Die Ethik-Kommission geht - rechtlich unverbindlich – davon aus, dass es sich um eine klinische Prüfung gemäß § 40 (3) MPG handelt.

Zusätzliche Auflagen:
Die behördlich vorgeschriebenen Maßnahmen hinsichtlich der COVID-19 Pandemie müssen

beachtet werden. Der Prüfer und der Sponsor müssen in ihrem jeweiligen Wirkungskreis unter allfälliger Beachtung von Leitlinien gewährleisten, dass keine zur Bekämpfung der Pandemie benötigten Ressourcen gebunden werden bzw. ausreichend Personal vorhanden ist und die Teilnehmer durch ihre Studienteilnahme keiner zusätzlichen Infektionsgefahr ausgesetzt werden.

Hinweis:
Die Ethikkommission verweist auf die allenfalls erforderliche Konsultation der Rechtsabteilung der MedUni Wien, der Datenclearingstelle der MedUni Wien, der Datenschutzbeauftragten der MedUni Wien bzw. des Datenschutzverantwortlichen des AKH sowie auch auf die verpflichtend einzuhaltenden GSP Richtlinien der MedUni Wien und die Vorgaben des Handbuchs für Drittmittelprojekte der MedUni Wien.
Weitere Informationen finden sich unter https://ethikkommission.meduniwien.ac.at/service/weitere-informationen/

Ergänzende Kommentare:
Nachtrag vom 26. Mai 2021:
Die Antragsteller legen am 25.05.2021 gültige Versicherungsdokumente (Versicherungsschutz für 58 Studienteilnehmer ab 01.06.2021) sowie am 26.05.2021 überarbeitete Unterlagen vor, die von der Ethik-Kommission akzeptiert werden.
Die Antragsteller werden darauf hingewiesen, dass im Falle von Protokolländerungen die Versicherung zu informieren ist. Bei Fehlen einer automatischen Verlängerung des Versicherungsvertrages ist rechtzeitig eine Versicherungsbestätigung über die Verlängerung vorzulegen.

Zusätzliche Auflagen:
Die behördlich vorgeschriebenen Maßnahmen hinsichtlich der COVID-19 Pandemie müssen beachtet werden. Der Prüfer und der Sponsor müssen in ihrem jeweiligen Wirkungskreis unter allfälliger Beachtung von Leitlinien gewährleisten, dass keine zur Bekämpfung der Pandemie benötigten Ressourcen gebunden werden bzw. ausreichend Personal vorhanden ist und die Teilnehmer durch ihre Studienteilnahme keiner zusätzlichen Infektionsgefahr ausgesetzt werden.

Hinweis:
Die Ethikkommission verweist auf die allenfalls erforderliche Konsultation der Rechtsabteilung der MedUni Wien, der Datenclearingstelle der MedUni Wien, der Datenschutzbeauftragten der MedUni Wien bzw. des Datenschutzverantwortlichen des AKH sowie auch auf die verpflichtend einzuhaltenden GSP Richtlinien der MedUni Wien und die Vorgaben des Handbuchs für Drittmittelprojekte der MedUni Wien.
Weitere Informationen finden sich unter https://ethikkommission.meduniwien.ac.at/service/weitere-informationen/

Die Ethik-Kommission geht - rechtlich unverbindlich - davon aus, dass es sich um eine klinische Prüfung gemäß MPG handelt.

Die aktuelle Mitgliederliste der Ethik-Kommission ist unter folgender Adresse abrufbar:
http://ethikkommission.meduniwien.ac.at/ethik-kommission/mitglieder/

Mitglieder der Ethik-Kommission, die für diesen Tagesordnungspunkt als befangen anzusehen waren und daher laut Geschäftsordnung an der Entscheidungsfindung/Abstimmung nicht teilgenommen haben: **keine**

Dieses Dokument ist für berechtigte Benutzer/innen in digitaler Form unter folgender Adresse abrufbar:
https://ekmeduniwien.at/vote/22536/download/

Unterzeichner	Dr. Jürgen Zezula
Datum/Zeit-UTC	2021-05-26T12:54:56Z
Prüfinformation	Informationen zur Prüfung der elektronischen Signatur finden Sie unter: https://www.signaturpruefung.gv.at

10.5 Informed Consent Form

TeilnehmerInneninformation[1] und Einwilligungserklärung zur Teilnahme an der klinischen Studie im Rahmen einer Diplomarbeit

Prevention and therapy of orchestra musicians´ playing-related musculoskeletal disorders with transcranial direct current stimulation: a pilot study.

Prävention und Therapie von spielinduzierten muskuloskelettalen Beschwerden von Orchestermusikern mit transkranieller Gleichstromstimulation (tDCS): eine Pilotstudie.

Sehr geehrte Teilnehmerin, sehr geehrter Teilnehmer!

Wir laden Sie ein an der oben genannten klinischen Studie teilzunehmen. Die Aufklärung darüber erfolgt in einem ausführlichen ärztlichen Gespräch.

Ihre Teilnahme an dieser klinischen Studie erfolgt freiwillig. Sie können jederzeit ohne Angabe von Gründen aus der Studie ausscheiden. Die Ablehnung der Teilnahme oder ein vorzeitiges Ausscheiden aus dieser Studie hat keine nachteiligen Folgen für Ihre medizinische Betreuung.

Klinische Studien sind notwendig, um verlässliche neue medizinische Forschungsergebnisse zu gewinnen. Unverzichtbare Voraussetzung für die Durchführung einer klinischen Studie ist jedoch, dass Sie Ihr Einverständnis zur Teilnahme an dieser klinischen Studie schriftlich erklären. Bitte lesen Sie den folgenden Text als Ergänzung zum Informationsgespräch mit Ihrem Arzt sorgfältig durch und zögern Sie nicht Fragen zu stellen.

Bitte unterschreiben Sie die Einwilligungserklärung nur

- wenn Sie Art und Ablauf der klinischen Studie vollständig verstanden haben,
- wenn Sie bereit sind, der Teilnahme zuzustimmen und
- wenn Sie sich über Ihre Rechte als Teilnehmer an dieser klinischen Studie im Klaren sind.

Zu dieser klinischen Studie, sowie zur Teilnehmerinformation und Einwilligungserklärung wurde von der zuständigen Ethikkommission eine befürwortende Stellungnahme abgegeben.

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[1] Wegen der besseren Lesbarkeit wird im weiteren Text zum Teil auf die gleichzeitige Verwendung weiblicher und männlicher Personenbegriffe verzichtet. Gemeint und angesprochen sind – sofern zutreffend – immer beide Geschlechter.

1. Was ist der Zweck der klinischen Studie?

Der Zweck dieser klinischen Studie ist, die Durchführbarkeit eines Therapieprogramms durch Musiker anhand von Pilotversuchen zu demonstrieren. Dieses Therapieprogramm besteht aus drei Teilen:

a) Transkranielle Gleichstromstimulation (tDCS)

Diese nicht-invasive und schmerzfreie Elektrostimulation moduliert die Aktivität der Nervenzellen und die Erregbarkeit des Gehirns, wodurch das Erlernen und Umlernen von Bewegungsabläufen erleichtert werden soll. Dies soll wiederum zu einer Verbesserung der Schmerzsituation von Musikern, die an spielinduzierten muskuloskelettalen Beschwerden leiden, führen bzw. das Auftreten solcher Beschwerden bei gesunden Musikern verhindern.

b) Physiotherapeutische Übungen

Ziel der Physiotherapie ist es, neuromuskuläre Fehlfunktionen, die z.B. den spielinduzierten muskuloskelettalen Beschwerden zugrunde liegen, zu erkennen und zu beheben. Physiotherapeutische Übungen sollen eine gesunde und ergonomische Haltung am Instrument fördern, um schmerzfreie und energie-effiziente Bewegungen und dadurch eine Verbesserung des Spielens zu erreichen.

c) Coaching

Psychologisches Coaching soll Musikern helfen, verschiedene Probleme, die durch Schmerzen beim Spielen hervorgerufen sein können oder auch nicht, zu überwinden. Dazu gehören der Umgang mit Stress, Zeitnot, überhöhte Anforderungen, Angst vor Schmerzen beim Spielen. In professionellen Coaching-Sessions wird eine Vielzahl von verschiedenen Methoden angewendet, um diese Ziele zu erreichen. Dazu gehören u.a. Konzentrations- und Entspannungsübungen, Stress-Management-Strategien und Strategien für Angstvermeidung und positives Denken.

2. Wie läuft die klinische Studie ab?

Diese klinischen Pilotversuche werden an der Medizinischen Universität Wien durchgeführt, und es werden ungefähr 5 Personen daran teilnehmen.

Ihre Teilnahme an dieser klinischen Studie wird voraussichtlich eine Woche dauern. Sie beginnt mit einem ersten Besuch, der inkl. Anfahrtszeit ca. 3 Stunden dauern wird. In dieser Session wird ein aus drei Tests bestehendes physiotherapeutisches Assessment durchgeführt und anhand dessen ein Plan von passenden physiotherapeutischen Übungen erstellt. Außerdem wird eine neuro-psychologische Untersuchung vorgenommen, in der u.a. Lernfähigkeit, kognitive Verarbeitungsgeschwindigkeit und Planungsfähigkeit erhoben werden. Weiters erhalten Sie das Gerät „Halo Sport 2“ sowie eine Checkliste zur Dokumentation der Stimulation mit dem Gerät und der Durchführung der physiotherapeutischen Übungen. Die Benutzung von Halo Sport 2 sowie das korrekte Ausfüllen der Checkliste werden Ihnen erklärt und allfällige Fragen beantwortet.

Halo Sport 2 ist ein Gerät, in das die tDCS-Technologie mit einem Amplitudenbereich von ±2,2 mA und einer Frequenz von bis zu 600 Hz in ein Paar Audio-Kopfhörer integriert ist. Der Kontakt zwischen den eigentlichen Elektroden und der Haut erfolgt durch kleine

Schaumfedern direkt über dem primären Motorcortex, also demjenigen Gehirnareal, das zu einem erheblichen Teil an der Steuerung von willkürlichen Bewegungen beteiligt ist.

Die gleichzeitig durchzuführenden physiotherapeutischen Übungen für Schulter, Wirbelsäule und verschiedene Muskeln sollen etwaige motorische Probleme verbessern. Als Feedback für die Physiotherapie und zu Dokumentationszwecken soll das Absolvieren der Übungen in der dafür vorgesehenen tabellarischen Checkliste kurz dokumentiert werden.

Innerhalb von 7 Tagen nach dem ersten Besuch sollen Sie an 5 Tagen der folgenden Woche zu Hause jeweils eine 20-minütige Gleichstromstimulation (tDCS) zusammen mit den vorgeschriebenen physiotherapeutischen Übungen durchführen und anschließend ca. eine Stunde mit Ihrem Instrument üben. Welche Tage Sie auswählen und zu welchen Uhrzeiten Sie die Stimulationen durchführen, dürfen Sie selbst entscheiden.

Schließlich wird es einen Abschlusstermin („end of study visit“) geben, bei dem Sie uns das Gerät „Halo Sport 2“ sowie die ausgefüllte Checkliste zurückgeben und noch zwei kurze Fragebogen ausfüllen sollen. Einer dieser Fragebögen thematisiert Ihre Schmerzsituation beim Spielen, der andere betrifft die Einfachheit und Sicherheit der Anwendung von Halo Sport 2. Dieser Abschlusstermin wird inkl. Anfahrtszeit ca. 2 Stunden dauern.

3. Worin liegt der Nutzen einer Teilnahme an der Klinischen Studie?

Es ist nicht zu erwarten, dass Sie aus Ihrer Teilnahme an dieser klinischen Studie gesundheitlichen Nutzen ziehen werden. Durch Ihre Teilnahme ermöglichen Sie aber die Durchführung einer größer angelegten klinischen Studie mit einer neuen Therapie, das die oben beschriebenen Methoden beinhaltet. Im Rahmen dieser Studie sollen die spielinduzierten Beschwerden vieler Musiker gelindert und das Auftreten neuer Beschwerden verhindert werden. Außerdem sollen wichtige wissenschaftliche Erkenntnisse zur Pathophysiologie der diesen Beschwerden zugrunde liegenden Erkrankungen sowie zu den therapeutischen Methoden (tDCS, Physiotherapie, Coaching) gewonnen werden. Sollte die Studie erfolgreich sein, könnten mit Hilfe dieser neuen Therapie zusätzlich viele weitere Musiker auf der ganzen Welt behandelt werden. Sie leisten somit einen wichtigen Beitrag zum wissenschaftlichen Erkenntnisgewinn und zur Entwicklung einer Behandlung für Erkrankungen von Musikern.

4. Gibt es Risiken, Beschwerden und Begleiterscheinungen?

Es können die im Rahmen dieser klinischen Studie durchgeführten Maßnahmen zu Beschwerden führen. Die Nebenwirkungen der transkraniellen Gleichstromstimulation (tDCS) sind Kopf- und Halsschmerzen, ein kitzelndes, juckendes oder brennendes Gefühl, Hautrötung, Müdigkeit und Konzentrationsprobleme Schwerwiegendere Nebenwirkungen der transkraniellen Gleichstromstimulation sind äußerst unwahrscheinlich und wurden bisher noch nie beobachtet. Es ist nicht zu erwarten, dass durch Physiotherapie oder psychologisches Coaching Beschwerden hervorgerufen werden können.

5. Zusätzliche Einnahme von Arzneimitteln?

Während der Teilnahme an der Studie ist die zusätzliche Einnahme von Arzneimitteln nicht geplant.

Dokumentiert werden im Falle die Einnahme von: SSRI (selektive Serotonin-Wiederaufnahme-Hemmern), Benzodiazepinen, Carbamazepinen, und Arzneimitteln, die mit Rezeptorsystemen im Gehirn interagieren können (Glutamat, Dopamin, etc.).

6. Hat die Teilnahme an der klinischen Studie sonstige Auswirkungen auf die Lebensführung und welche Verpflichtungen ergeben sich daraus?

Bei der Teilnahme an der Studie wird vorausgesetzt, dass Sie eine Woche lang 5 mal eine 20-minütige Session von transkranieller Gleichstromstimulation durchführen, währenddessen die vorgeschriebenen physiotherapeutischen Übungen machen und anschließend eine Stunde lang mit Ihrem Instrument üben. Außerdem wird ein Besuch zu Beginn der Studie mit einer Dauer von ca. 3 Stunden und ein Besuch am Ende der Studie von ca. 2 Stunden vorausgesetzt.

7. Was ist zu tun beim Auftreten von Symptomen, Begleiterscheinungen und/oder Verletzungen?

Sollten im Verlauf der klinischen Studie irgendwelche Symptome, Begleiterscheinungen oder Verletzungen auftreten, müssen Sie diese Ihrem Arzt mitteilen, bei schwerwiegenden Begleiterscheinungen umgehend, ggf. telefonisch (Telefonnummern, etc. siehe unten).

8. Versicherung

Als Teilnehmer an dieser klinischen Studie besteht für Sie der gesetzlich vorgeschriebene verschuldensunabhängige Versicherungsschutz (Personenschadenversicherung gemäß § 47 Medizinproduktegesetz, der alle Schäden abdeckt, die an Ihrem Leben oder Ihrer Gesundheit durch die an Ihnen durchgeführten Maßnahmen der klinischen Studie verursacht werden können, mit Ausnahme von Schäden auf Grund von Veränderungen des Erbmaterials in Zellen der Keimbahn.

Die Versicherung wurde für Sie als Rahmenversicherung der Medizinischen Universität Wien klinischer Studien bei der Zürich Versicherung-Aktiengesellschaft in 1010 Wien, Schwarzenbergplatz 15, Tel.: +43 50 1255-1255, Polizze-Nr. 07229622-2, lfd. Nr. 47/2021, von der Universitätsklinik für Notfallmedizin abgeschlossen. Auf Wunsch können Sie in die Versicherungsunterlagen Einsicht nehmen.

Im Schadensfall können Sie sich direkt an den Versicherer wenden und Ihre Ansprüche selbständig geltend machen. Für den Versicherungsvertrag ist österreichisches Recht anwendbar, die Versicherungsansprüche sind in Österreich einklagbar.

Zur Unterstützung können Sie sich auch an die Patientenanwaltschaft, Patientenvertretung oder Patientenombudsschaft wenden.

Um den Versicherungsschutz nicht zu gefährden

- dürfen Sie sich während der Dauer der klinischen Studie einer anderen medizinischen Behandlung nur im Einvernehmen mit Ihrem behandelnden Prüfarzt unterziehen **(ausgenommen davon sind Notfälle).** Dies gilt auch für die zusätzliche Einnahme von Medikamenten oder die Teilnahme an einer anderen Studie.
- müssen Sie dem behandelnden Studienarzt - oder der oben genannten Versicherungsgesellschaft - eine Gesundheitsschädigung, die als Folge der klinischen Studie eingetreten sein könnte, unverzüglich mitteilen.
- müssen Sie alles Zumutbare tun um Ursache, Hergang und Folgen des Versicherungsfalles aufzuklären und den entstandenen Schaden gering zu halten. Dazu gehört ggf. auch, dass Sie Ihre behandelnden Ärzte ermächtigen, vom Versicherer geforderte Auskünfte zu erteilen.

9. Wann wird die klinische Studie vorzeitig beendet?

Sie können jederzeit auch ohne Angabe von Gründen, Ihre Teilnahmebereitschaft widerrufen und aus der klinischen Studie ausscheiden ohne dass Ihnen dadurch irgendwelche Nachteile für Ihre weitere medizinische Betreuung entstehen.

Ihr Studienarzt wird Sie über alle neuen Erkenntnisse, die in Bezug auf diese klinische Studie bekannt werden, und für Sie wesentlich werden könnten, umgehend informieren. Auf dieser Basis können Sie dann Ihre Entscheidung zur **weiteren** Teilnahme an dieser klinischen Studie neu überdenken.

Es ist aber auch möglich, dass Ihr Studienarzt entscheidet, Ihre Teilnahme an der klinischen Studie vorzeitig zu beenden, ohne vorher Ihr Einverständnis einzuholen. Die Gründe hierfür können sein:

d) Sie können den Erfordernissen der klinischen Studie nicht entsprechen;

e) Ihr Studienarzt hat den Eindruck, dass eine weitere Teilnahme an der klinischen Studie nicht in Ihrem Interesse ist.

10. Datenschutz

Im Rahmen dieser klinischen Studie werden Daten über Sie erhoben und verarbeitet. Es ist grundsätzlich zu unterscheiden zwischen

1) jenen personenbezogenen Daten, anhand derer eine Person direkt identifizierbar ist (z.B. Name, Geburtsdatum, Adresse, Sozialversicherungsnummer, Bildaufnahmen...),
2) pseudonymisierten personenbezogenen Daten, das sind Daten, bei denen alle Informationen, die direkte Rückschlüsse auf die konkrete Person zulassen, entweder entfernt, durch einen Code (z. B. eine Zahl) ersetzt oder (z.B. im Fall von Bildaufnahmen) unkenntlich gemacht werden. Es kann jedoch trotz Einhaltung dieser Maßnahmen nicht vollkommen ausgeschlossen werden, dass es unzulässigerweise zu einer Re-Identifizierung kommt.
3) anonymisierten Daten, bei denen eine Rückführung auf die konkrete Person ausgeschlossen werden kann.

Zugang zu den Daten, anhand derer Sie direkt identifizierbar sind (siehe Punkt 1), haben der Prüfarzt und andere Mitarbeiter des Studienzentrums, die an der klinischen Studie oder Ihrer medizinischen Versorgung mitwirken. Zusätzlich können autorisierte und zur Verschwiegenheit verpflichtete Beauftragte der Medizinischen Universität Wien sowie Beauftragte von in- und/ oder ausländischen Gesundheitsbehörden und jeweils zuständige Ethikkommissionen in diese Daten Einsicht nehmen, soweit dies für die Überprüfung der ordnungsgemäßen Durchführung der klinischen Studie notwendig bzw. vorgeschrieben ist. Sämtliche Personen, die Zugang zu diesen Daten erhalten, unterliegen im Umgang mit den Daten den jeweils geltenden nationalen Datenschutzbestimmungen und/oder der EU-Datenschutz-Grundverordnung (DSGVO).

Der Code, der eine Zuordnung der pseudonymisierten Daten zu Ihrer Person ermöglicht, wird nur an Ihrem Studienzentrum aufbewahrt.

Eine Weitergabe der Daten erfolgt nur in pseudonymisierter oder anonymisierter Form.

Für etwaige Veröffentlichungen werden nur die pseudonymisierten oder anonymisierten Daten verwendet.

Im Rahmen dieser klinischen Studie ist keine Weitergabe von Daten in Länder außerhalb der EU (Drittland) vorgesehen.

Ihre Einwilligung bildet die Rechtsgrundlage für die Verarbeitung Ihrer personenbezogenen Daten. Sie können die Einwilligung zur Erhebung und Verarbeitung Ihrer Daten jederzeit ohne Begründung widerrufen. Nach Ihrem Widerruf werden keine weiteren Daten mehr über Sie erhoben. Die bis zum Widerruf erhobenen Daten können allerdings weiter im Rahmen dieser klinischen Studie verarbeitet werden.

Nach der DSGVO stehen Ihnen grundsätzlich die Rechte auf Auskunft, Berichtigung, Löschung, Einschränkung der Verarbeitung, Datenübertragbarkeit und Widerspruch zu, soweit dies die Ziele der klinischen Studie nicht unmöglich macht oder ernsthaft beeinträchtigt und soweit dem nicht andere gesetzliche Vorschriften widersprechen.

Das gemäß DSGVO vorgesehene Recht auf Löschung Ihrer im Rahmen dieser klinischen Prüfung verarbeiteten Daten steht Ihnen aufgrund von Regelungen nach dem Arzneimittelgesetz und Medizinproduktegesetz nicht zu. Zusätzlich ist bei einer klinischen Prüfung nach dem Arzneimittelgesetz das Recht auf Datenübertragbarkeit außer Kraft gesetzt.

Die voraussichtliche Dauer der klinischen Studie für Sie beträgt eine Woche. Die Dauer der Speicherung Ihrer Daten über das Ende oder den Abbruch der klinischen Studie hinaus ist durch Rechtsvorschriften geregelt.

Falls Sie Fragen zum Umgang mit Ihren Daten in dieser klinischen Studie haben, wenden Sie sich zunächst an Ihren Prüfarzt. Dieser kann Ihr Anliegen ggf. an die Personen, die für den Datenschutz verantwortlich sind, weiterleiten.

Kontaktdaten der Datenschutzbeauftragten der an dieser klinischen Studie beteiligten Institutionen:

Datenschutzbeauftragte/r der MedUni Wien: datenschutz@meduniwien.ac.at

Datenschutzverantwortliche/r des AKH: datenschutz@akhwien.at

Sie haben das Recht, bei der österreichischen Datenschutzbehörde eine Beschwerde über den Umgang mit Ihren Daten einzubringen (www.dsb.gv.at; E-Mail: dsb@dsb.gv.at).

11. Entstehen für die Teilnehmer Kosten? Gibt es einen Kostenersatz oder eine Vergütung?

Durch Ihre Teilnahme an dieser klinischen Studie entstehen für Sie keine zusätzlichen Kosten.

12. Möglichkeit zur Diskussion weiterer Fragen

Für weitere Fragen im Zusammenhang mit dieser klinischen Studie stehen Ihnen Ihr Studienarzt und seine Mitarbeiter gern zur Verfügung. Auch Fragen, die Ihre Rechte als Patient und Teilnehmer an dieser klinischen Studie betreffen, werden Ihnen gerne beantwortet.

Kontaktperson 1:

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PAMA & ASCM Performing Arts Medicine Physician
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13. Sollten andere behandelnde Ärzte von der Teilnahme an der klinischen Studie informiert werden?

Es besteht keine Notwendigkeit, den/die Hausarzt/Hausärztin über die Studie zu informieren.

14. Einwilligungserklärung

Name des Teilnehmers:

Geb.Datum:

Ich erkläre mich bereit, an der klinischen Studie „*Prevention and therapy of orchestra musicians´ playing-related musculoskeletal disorders with transcranial direct current stimulation: a pilot study*“ teilzunehmen. Ich bin darüber aufgeklärt worden, dass ich die Teilnahme ohne nachteilige Folgen, insbesondere für meine medizinische Betreuung, ablehnen kann.

Ich bin von Frau/Herrn (Dr.med.) .... ausführlich und verständlich über die klinische Studie, mögliche Belastungen und Risiken, sowie über Wesen, Bedeutung und Tragweite der klinischen Studie und die sich für mich daraus ergebenden Anforderungen aufgeklärt worden. Ich habe darüber hinaus den Text dieser Patientenaufklärung und Einwilligungserklärung, die insgesamt 8 Seiten umfasst, gelesen. Aufgetretene Fragen wurden mir vom Prüfarzt verständlich und zufriedenstellend beantwortet. Ich hatte ausreichend Zeit, mich zu entscheiden. Ich habe zurzeit keine weiteren Fragen mehr.

Ich werde den ärztlichen Anordnungen, die für die Durchführung der klinischen Studie erforderlich sind, Folge leisten, behalte mir jedoch das Recht vor, meine freiwillige Mitwirkung jederzeit zu beenden, ohne dass mir daraus Nachteile, insbesondere für meine medizinische Betreuung, entstehen.

Ich stimme ausdrücklich zu, dass meine im Rahmen dieser klinischen Studie erhobenen Daten wie im Abschnitt „Datenschutz“ dieses Dokuments beschrieben verarbeitet werden.

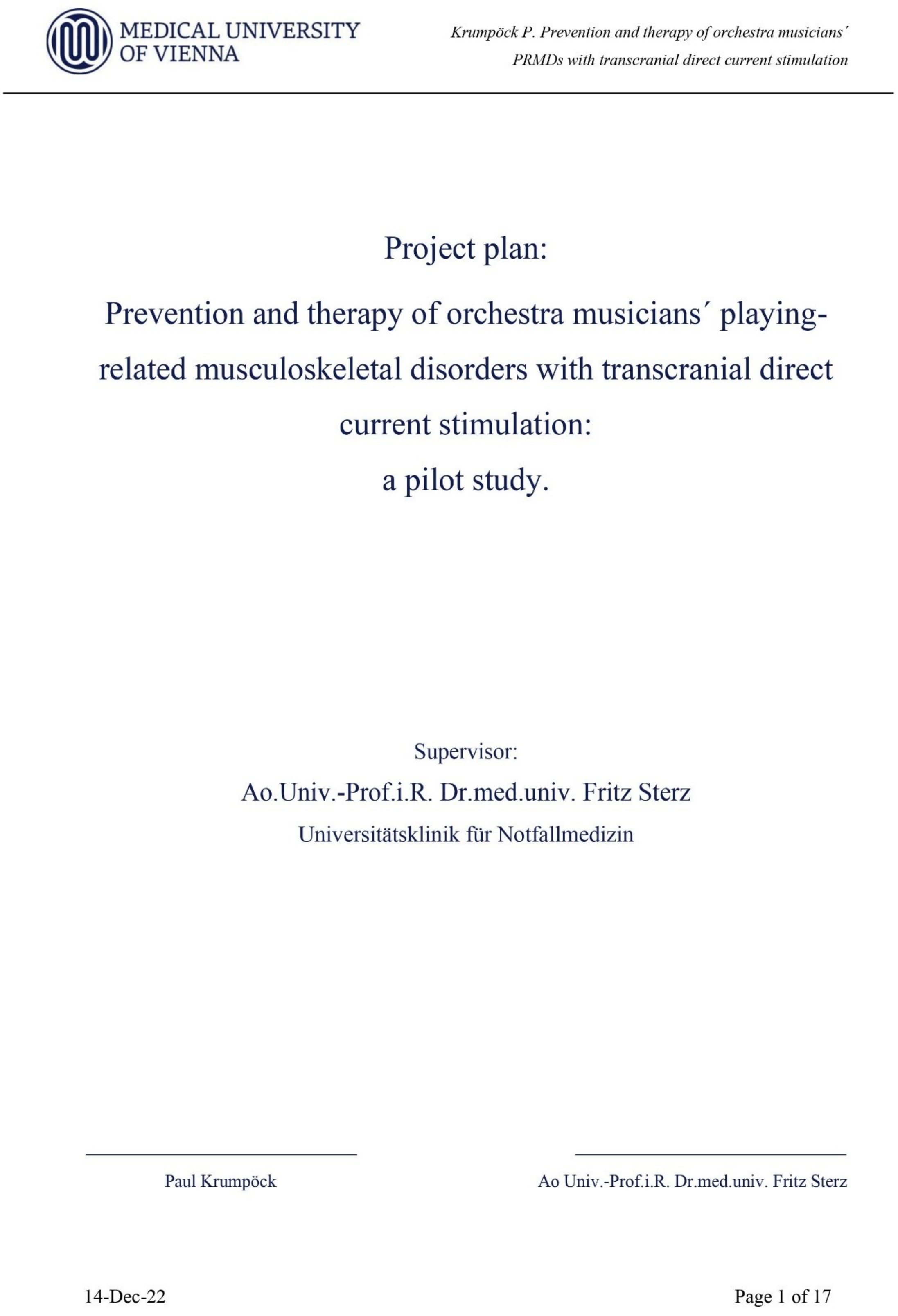
Eine Kopie dieser Patienteninformation und Einwilligungserklärung habe ich erhalten. Das Original verbleibt beim Prüfarzt.

....
(Datum und Unterschrift des Patienten)

....
(Datum, Name und Unterschrift des verantwortlichen Prüfarztes)

(Der Patient erhält eine unterschriebene Kopie der Patienteninformation und Einwilligungserklärung, das Original verbleibt im Studienordner des Prüfarztes.)

10.6 Project plan



Project plan:
Prevention and therapy of orchestra musicians´ playing-related musculoskeletal disorders with transcranial direct current stimulation:
a pilot study.

Supervisor:
Ao.Univ.-Prof.i.R. Dr.med.univ. Fritz Sterz
Universitätsklinik für Notfallmedizin

Paul Krumpöck	Ao Univ.-Prof.i.R. Dr.med.univ. Fritz Sterz

1 Abstract

Thousands of professional orchestra musicians and music students worldwide suffer from playing-related musculoskeletal disorders (PRMDs) without receiving sufficient medical support. Beside sporadic performing arts medicine initiatives there are no medical resources commonly accessible for performers and there is little research on prevention and/or treatment of musicians´ diseases, including PRMDs. There is an urgent need for effective therapeutic tools in order to improve musicians´ health and thus their performance.

A complex motor task such as playing a musical instrument has to be learned through years of practice. It has been shown that musical training alters certain brain areas, especially those related to auditory and sensorimotor networks, through mechanisms of neuroplasticity. Transcranial direct current stimulation (tDCS) is a non-invasive brain stimulation technique, which modulates neural plasticity via a weak electric current. Paired with physiotherapy and training exercises, this could help musicians who suffer from PRMDs with retraining of motor skills in order to alleviate the pain. In addition, it could also help to prevent healthy musicians from incurring PRMDs in the first place.

The aim of this study is to examine the feasibility of a therapeutic program for orchestra musicians´ PRMDs, consisting of regular tDCS sessions together with physiotherapy and coaching. Furthermore, several methods of analysing possible improvement in the musicians´ health and therefore the effectiveness of the therapeutic program (i.e. questionnaires, BOLD fMRI, DTI and 3D motion capture analysis) will also be evaluated. This shall be achieved through pilot trials of the individual methods used for the therapy regimen as well as the evaluation tools.

2 Wider research context

2.1 Orchestra musicians´ performance

There are more than 3,000 classical symphony orchestras worldwide.[1] In 2017, there were approximately 1,600 U.S. orchestras, distributed widely across all 50 states. A total of ~160,000 orchestra musicians, ~40,000 of which are professional, face ~16,700 professional athletes.[2] Orchestra performance activity yields many thousands of concerts, operas and other musical events attracting an audience of more than a billion people each year.[3,4]

Problems related to singing and playing were already described by Ramazzini in the early 1700's, who realized that not just chemicals or physical agents could be responsible for workers´ diseases, but also prolonged postures and repetitive or irregular motions as well as motions that require a lot of effort.[5-7] Nevertheless, work-related musculoskeletal disorders were systematically studied only since the 1970s, and the field of performing arts medicine emerged in the late 1990s.[8] The first definition of playing-related musculoskeletal disorders (PRMDs) was given by Zaza et al. as “any pain, weakness, lack of control, numbness, tingling, or other symptoms that interfere with your ability to play your instrument at the level you are accustomed to”.[9] Since then, multiple studies have been conducted to evaluate the prevalence of PRMDs in amateur and professional musicians with results ranging from 65% to 93%.[10-13] String players are at the highest risk, with the neck and shoulder being the main body parts affected.[14,15] Some studies also evaluated possible risk factors and even some treatment and prevention strategies.[16-18] Prognoses for PRMDs, however, are rather dim, with one study recording a recovery rate of only 26% of patients.[19]

Athletes are limited to about 20 hrs/week of team practice, whereas performing artists often practise well over 40 hrs/week (Performing Arts Medicine Association, PAMA Symposium 2019).[20] Musicians often start playing their instrument at a very young age with strict teachers, competitions and touring to endure and a “no pain, no gain” mindset, which furthers the development of PRMDs.[21] Having little to no training in dealing with physical and emotional strains of high-level performance, musicians often struggle to recover from their demanding practice and concert schedule.[22] Also, they are often reluctant to perform exercises prior to performances or consult healthcare professionals, in order to not be seen as less competent or talented by others,[21] which all leads to PRMDs being ignored and thus untreated.[23,24] Furthermore, perfectionism leads to excessively high performance standards and harsh self-criticism, which can result in eating and/or substance use disorders, anxiety and depression, often at a very young age.[25-27]

Despite the relatively high prevalence and bad outcomes, PRMDs and other disorders linked to performance are still severely underrecognized clinical problems. Beside sporadic performing arts medicine initiatives, e.g. medical consulting hours for musicians, there is no widely accepted medical coaching strategy accessible for performers.[28] Orchestra finances still allow little to no spending on performing arts preventive and curative care, such as playing enhancements, and very little research regarding standard teaching techniques/strategies, ergonomic instruments, physical training, optimal nutrition and mental coaching is available.[29] There is an urgent need for not only effective, but also time- and money-efficient tools and methods, which can help investigate and treat musculoskeletal problems related to instrument playing and further support professional access to occupational care.

2.2 Transcranial direct current stimulation

Transcranial direct current stimulation (tDCS) is a non-invasive brain stimulation (NIBS) technique, which can be used to modulate corticospinal excitability and neural plasticity via a weak electric current.[30] This current is delivered to the brain through electrodes made of metal or conductive rubber that are placed on the scalp,[31-33] with a conductive contact medium (usually sponges soaked in saline or conductive cream) ensuring the current flow.[33,34] Unlike transcranial magnetic stimulation (TMS), the electric current in tDCS is not considered strong enough to trigger action potentials in the stimulated neurons. The purpose of tDCS is to alter the threshold for action potentials, depending on the stimulation program.[32,35,36] The applied current is either positive (anodal stimulation) or negative (cathodal stimulation), which alters cortical excitability positively (facilitating depolarization, anodal) or negatively (facilitating hyperpolarization, cathodal).[31,32] Although this rule is generally true for the primary motor cortex (M1), stimulation is also used in many other areas, such as the dorsolateral prefrontal cortex (DLPFC), the primary visual cortex (V1) and the right temporal cortex.[37] In the cerebellum, anodal tDCS has been shown to increase cerebellar brain inhibition (CBI), whereas cathodal stimulation had the opposite effect.[38] Furthermore, it has been shown that tDCS has an effect on GABAergic function[39,40], intracellular calcium concentrations, glial activation[41] and synaptic plasticity in the M1 when combined with induction of long-term potentiation (LTP)-like mechanisms.[42] This means that LTP and therefore synaptic plasticity, either induced by training or endogenously, is amplified by concurrent, pre- or post-training tDCS.[43] Because learning and memory are thought to be a result of enhanced synaptic plasticity[44], it is argued that stimulation paired with training leads to better task-specific skill improvements than training alone.[45,46] The effects of tDCS on motor learning have been studied extensively, with the most frequently investigated region being the M1. Several studies have found significant enhancements of both online (during training) and offline (between training sessions) skill improvement.[47-49] The improvement of motor skill learning via tDCS has also been observed in musicians, although the effects of stimulation seem to correlate negatively with the level of skill already acquired.[50,51] Furthermore, tDCS of the M1 has been shown to positively alter musical creativity and the quality of improvised musical performance,[52] as well as tactile discrimination.[53]

The absence of serious side effects, as well as tDCS being non-invasive, relatively inexpensive and easy to administer makes it a promising tool for therapy in a wide variety of fields. Clinical investigations have been conducted for depression[54], schizophrenia[55], addiction[56], social anxiety disorder[57], chronic pain[58], migraine[59], epilepsy[60], multiple sclerosis[61], post-stroke aphasia[62] and motor rehabilitation.[63] In the USA, tDCS has the status of "investigational", meaning the FDA has not yet issued an opinion and doctors can only use it "off-label". In the European Union, Canada, Brazil, Australia and Singapore, however, some tDCS products have been approved for the treatment of chronic pain and neuropsychiatric disorders.

2.3 Physiotherapy & Coaching

The aim of physiotherapy is to identify and correct neuromuscular dysfunctions in order to normalize neuromuscular performance. It is known that a non-physiological attitude is a causal or contributing factor for a variety of complaints, including PRMDs.[17,64,65] In addition, clinical practice suggests that myofascial problems of the neck and shoulder girdle are often associated with myofascial disorders of the upper extremities and the hand, with violinists being particularly affected.[66] Individual physiotherapy is intended to create a stable starting position for each participant in order to achieve a functional, ergonomic and physiological posture that can be transferred to the posture on the instrument. As a result, more energy-efficient use of the movement system with an optimization of neuromuscular functions and physical posture lead to less pain during instrument playing and an improvement of the overall performance.[67]

Musicians often face tremendous emotional pressure due to their very demanding practice and performance schedule and the need to play difficult pieces perfectly in front of large audiences or at competitions. Because of this, psychological factors that need to be considered are:

- low self-esteem
- perfectionism or a need to please others
- identity based primarily on performance
- loss of personal control (i.e. performance expectations determined by teachers and parents)
- increased worrying about failure to live up to others´ expectations
- overscheduling, extremes of training intensity and time demands[68]

Psychological coaching is a very useful tool to help musicians overcome these problems and perform better when facing emotional pressure or pain during their performance. Individual therapy is the most commonly practiced format, which allows for a confidential interaction between performer and provider, permitting maximal disclosure without fear of others listening or interrupting.[69,70]

2.4 Monitoring methods

Magnetic Resonance Imaging (MRI) is a non-invasive imaging technology that uses radiofrequency pulses to excite nuclear spins of protons in strong magnetic fields. If said pulse is taken away, the protons realign with the magnetic field, releasing electromagnetic energy that is specific for various tissues and can be detected with MRI sensors.[71] Structural MRI allows to capture structural properties of the brain and quantify different tissue properties. Blood oxygen level dependent (BOLD) functional MRI (fMRI) gives a quantitative signal depending on the ratio between deoxygenated and oxygenated hemoglobin in a given part of the brain at a given time. As this ratio varies depending on neuronal activity, fluctuations in the signal show which region is active at any specific time. Temporal correlation of these fluctuations between two regions of the brain is a sign for functional connectivity between these regions.[72] BOLD fMRI of the brain has been widely used to compare musicians and non-musicians, finding differences in activity in many regions[73-76], as well as an overlap with structures responsible for language[77-79], and shared networks between auditory and motor processing.[80,81]

Diffusion tensor imaging (DTI) is a type of MRI measuring the anisotropic diffusion of water molecules, which gives information about the microscopic properties of white matter (tracts of myelinated axons).[82,83] Using this method, several studies of musicians have found an increased number of fibres, increased grey matter volume and lower fractional anisotropy in different parts of the brain, suggesting practice-induced structural adaptation.[84-88]

Quantitative performance assessment through measurements, instead of qualitative observation, is the method of choice for objectively evaluating musicians´ motor strategy, including postural and neuromuscular disorders. Motion capture allows for a three-dimensional analysis of posture and movement using body sensors or cameras. Its ability to accurately monitor even very complex movements like those of the hand makes it very useful for studying the motor aspect of performance.[89-91] Studies have used motion capture techniques for different purposes, such as investigating the impact of tactile feedback on timing accuracy[92], temporal control and hand movement efficiency[93], measuring bowing parameters (e.g. velocity)[94], joint investigation of cognitive and motor processes in combination with EEG[95], and evaluating musicians´ skills as well as helping to diagnose motor disorders.[90,96] When analysing music performance with optoelectronic motion capture systems, different kinematic parameters can be recorded simultaneously, e.g. bow position, bow-violin angle, angles of the anatomical joints (shoulder, elbow and wrist) and their respective derivatives (velocity, acceleration and jerk), as well as the coefficient of variation (CV) for all parameters.[90]

3 Research questions / Hypotheses / objectives

This study aims to investigate the feasibility and safety of a therapy regimen consisting of tDCS, physiotherapeutic exercises and psychological coaching. It shall be demonstrated that it is possible to safely and effectively study such a therapy regimen with its potential to enhance the retraining or improvement of orchestra musicians´ motor patterns, thereby alleviating the pain caused by PRMDs or preventing the development of PRMDs entirely. Also, the usefulness of this therapy regimen to gain insight into the pathophysiological neuromuscular mechanisms underlying PRMDs shall be validated. Furthermore, the applicability of imaging techniques and motion capture methods to measure different aspects of musicians´ playing will be evaluated. These measurements could then be able to complement/support the before- and after-treatment subjective perception by the musicians, for which a questionnaire will also be tested. To achieve these goals, pilot trials of the individual methods used for the therapy regimen as well as the evaluation tools will be conducted.

Primary hypothesis: Transcranial direct current stimulation (tDCS) combined with a physical therapy and psychological coaching program can be used safely and effectively to study its influence on instrument playing and practicing ability of professional orchestra musicians in a larger sample, either in the recovering process of musculoskeletal injuries/disorders or in the regular instrumental training process.

Secondary hypothesis: Medical imaging techniques and motion capture methods can be implemented safely and effectively to evaluate their usefulness in measuring and validating improvements of instrument playing and practicing ability of professional orchestra musicians in a larger sample.

4 Methods

Each individual part of the therapy regimen and the outcome assessments as described in the following chapters will be tested in pilot trials in order to demonstrate their feasibility.

4.1 Therapy regimen

The treatment will consist of 20-minute sessions of tDCS to the primary motor cortex delivered by the "Halo Sport 2" device. In the Halo Sport 2 model, which was produced by Halo Neuroscience and is now property of Flow Neuroscience,[97,98] the tDCS technology is built into a pair of audio headphones with adjustable size. The contact between the actual electrodes and the skin is made through little foam nibs pre-loaded with salt so there is a conductive electrolyte when they are soaked in water. The electrodes (including the foam) are fixed inside a removable strap on the side of the headband facing the scalp and, when put on, lie directly above the primary motor cortex.

In total, there will be 2 blocks with 20 sessions each, with every participant receiving real and sham stimulation in one of the blocks. Both blocks will have a duration of one month, with five sessions per week. As handling is relatively simple and requires little experience, these 20-minute sessions will be self-administered at home concurrently with the training exercises (see below). The software for tDCS is provided via a free app that can be downloaded on the app store (iOS 11 and newer) and on google play (Android 6.0 and newer).

Participants will receive background information on tDCS and are shown how to use the device and the app by an instructor, who will also answer arising questions. Furthermore, they will be provided with a handbook and a phone number that is available 24 hours a day to call in case there are any problems. The successful administration of each tDCS session will be documented by the musicians on the physiotherapeutic and the safety checklists.

The introductory session of physiotherapy will consist of a short individual physiotherapeutic assessment including the mUQYBT (Modified Upper Quarter Y Balance Test), One-Arm Line Hopping Test, CKCUEST (closed kinetic chain upper extremity speed test), and the Quick DASH (Disabilities of the Arm, Shoulder and Hand), which is intended to identify (non-)physiological postures and motion patterns. The results of the tests will be used to create an individually tailored training program which aims to achieve a functional, ergonomic and physiological posture on the instrument. The exercise program should be carried out independently five times a week while using "Halo Sport 2" for 20 minutes each time. After a short warm-up, the participants optimize muscle strength, muscle coordination and muscle endurance through a variety of exercises. The implementation of these exercises is practiced with the participants until they can do it safely and independently without supervision. Regular weekly check-up sessions are provided in order to increase motivation, clarify problems with the training, or modify certain exercises, if necessary. To guarantee adherence to the exercise program, the participants are required to fill out a physiotherapeutic checklist containing the name of the exercise as well as the number and duration of repetitions.

Before the treatment with tDCS and psychological coaching, purely neuropsychological parameters of the musicians are collected through a 60-minute test. The ability to learn (both right and left hemispherical) as well as the executive functions of cognitive processing speed, planning ability and inhibition (= the ability to suppress an unwanted reaction) are compared with age-appropriate norms, thereby providing information on possible restrictions in functionality in certain areas. Cognitive and behavioural therapies (CBT) will include education, relaxation exercises, coping skills training, stress management or assertiveness training. Distorted, maladaptive beliefs shall be identified and corrected. Behavioural therapy will use thought exercises or real experiences to facilitate symptom reduction, teach self-observation and improve emotional stability.

4.2 Outcomes

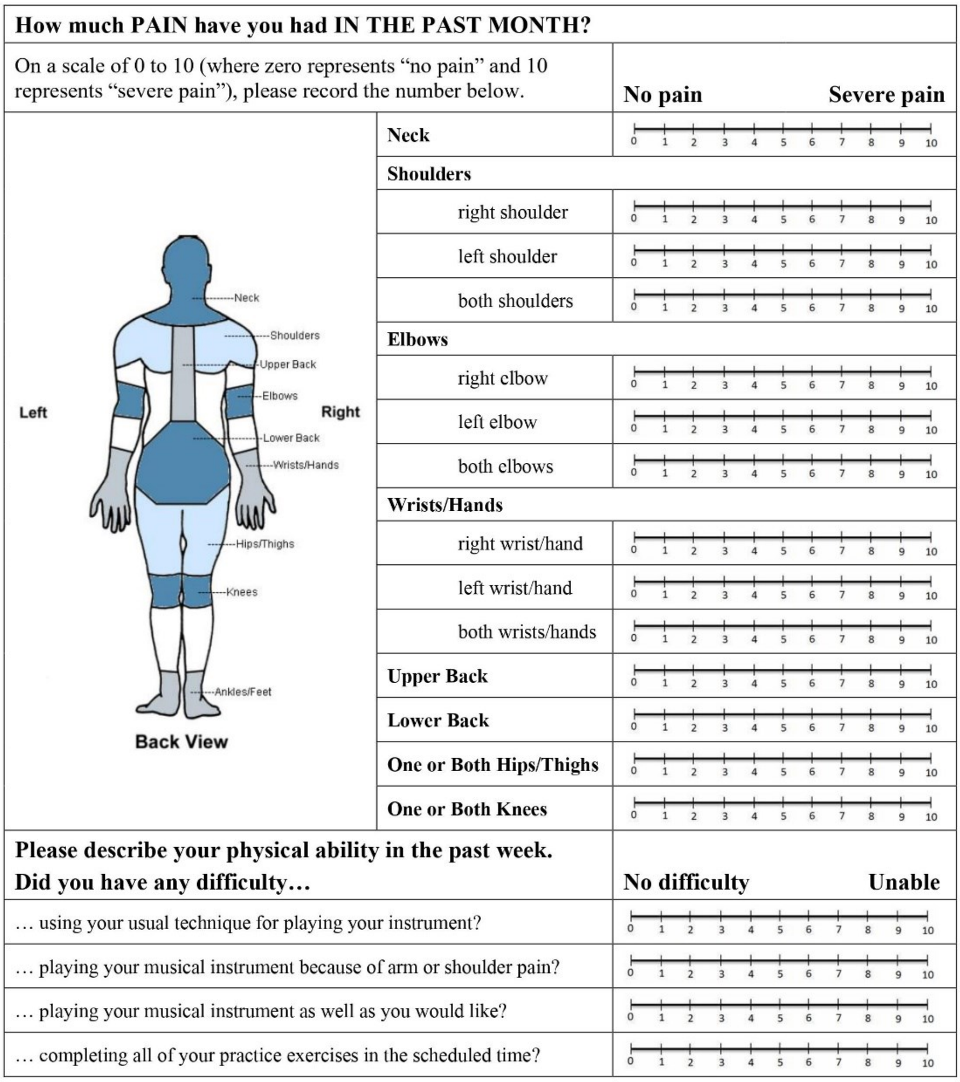
The efficacy of the therapy regimen described above will be evaluated through a number of endpoints, all of which will be acquired at three different points in time: before the beginning of the treatment, after the first block of tDCS and after the second block of tDCS.

The primary endpoint is a short pain assessment questionnaire (see Fig. 1) designed for this study. Its contents are based on three standardized questionnaires commonly used in clinical practice: the Nordic Musculoskeletal Questionnaire (NMQ),[99] the Disabilities of the Arm, Shoulder and Hand questionnaire (DASH),[100,101] and the Brief Illness Perception Questionnaire (BIPQ).[102]

The secondary endpoint will consist of MRI/DTI acquisitions and 3D motion capturing, which will be done as an addition to the questionnaire with each of the three evaluations.

The MRI/DTI protocol has a total duration of approximately 45 minutes and will include a structural T1 acquisition, DTI, resting-state fMRI and multiple task-based fMRI acquisitions. During the protocol, the musicians will receive many different tasks, such as mental exercises by pretending to play a given piece of music, finger movement exercises on a wooden fingerboard as if playing the instrument, and combined exercises. Functional activity, functional connectivity (based on BOLD fMRI), structural connectivity (based on DTI), and cortical thickness/configuration (based on high-resolution T1-weighted images) patterns will be assessed for each task/condition at each evaluation. Single subject analyses and group analyses will be performed to detect possible changes of activity, connectivity or cortical configuration induced by the therapy regimen.

For the 3D Motion Capture analysis, the motion tracking system SMART-E (BTS S.p.A., Milano, Italy) will be used to assess the kinematics for individual musicians. The system consists of four cameras, which record the position of light-reflecting markers in 3D space. The kinematic data will be processed using the system's own software, Smart Analyzer 1.10. The musical exercises will be based on scales and arpeggios and they will be played with increasing levels of difficulty, i.e. increasing speeds with a variety of bowings, articulations and rhythms. The exercises will be the same for all performers, but it will be possible to emphasize certain exercises in order to better adapt each experiment to the requirements of each performer and their particular musculoskeletal problems.



How much PAIN have you had IN THE PAST MONTH?		
On a scale of 0 to 10 (where zero represents "no pain" and 10 represents "severe pain"), please record the number below.		**No pain** **Severe pain**
	Neck	0 1 2 3 4 5 6 7 8 9 10
	Shoulders	
	right shoulder	0 1 2 3 4 5 6 7 8 9 10
	left shoulder	0 1 2 3 4 5 6 7 8 9 10
	both shoulders	0 1 2 3 4 5 6 7 8 9 10
	Elbows	
	right clbow	0 1 2 3 4 5 6 7 8 9 10
	left elbow	0 1 2 3 4 5 6 7 8 9 10
	both elbows	0 1 2 3 4 5 6 7 8 9 10
	Wrists/Hands	
	right wrist/hand	0 1 2 3 4 5 6 7 8 9 10
	left wrist/hand	0 1 2 3 4 5 6 7 8 9 10
	both wrists/hands	0 1 2 3 4 5 6 7 8 9 10
	Upper Back	0 1 2 3 4 5 6 7 8 9 10
	Lower Back	0 1 2 3 4 5 6 7 8 9 10
	One or Both Hips/Thighs	0 1 2 3 4 5 6 7 8 9 10
	One or Both Knees	0 1 2 3 4 5 6 7 8 9 10
Please describe your physical ability in the past week. Did you have any difficulty…		**No difficulty** **Unable**
… using your usual technique for playing your instrument?		0 1 2 3 4 5 6 7 8 9 10
… playing your musical instrument because of arm or shoulder pain?		0 1 2 3 4 5 6 7 8 9 10
… playing your musical instrument as well as you would like?		0 1 2 3 4 5 6 7 8 9 10
… completing all of your practice exercises in the scheduled time?		0 1 2 3 4 5 6 7 8 9 10

Fig. 1: Pain assessment questionnaire.

4.3 Safety & Adverse events

Multiple meta-analyses have recently reviewed existing studies in order to assess the safety of tDCS in humans. Reported mild adverse effects are itching, tingling, redness, headache, a mild burning sensation, discomfort, nausea, nervousness, hairy scalp pain and fatigue. However, no severe adverse events, such as seizures, tissue damage or other injuries, have been reported to date.[103-107] Using a high-definition rat model, brain damage has been predicted to occur at current densities of 6.3-17A/m^2, which is substantially higher than in currently applied stimulation protocols (0.3-0.8A/m^2). The application of these protocols have not produced any serious adverse effects in 33.200 sessions and 1000 subjects.[104] In 2011, Brunoni et al. analysed 209 studies (almost 4000 subjects) and found the frequency of mild adverse events (itching, tingling, headache, burning sensation, discomfort) to be comparable with sham stimulation (10-40%).[108]

If any adverse effects of tDCS should occur, they will be documented adequately and the treatment of the affected participant will be discontinued prematurely, unless absolute safety can be guaranteed. Moreover, the safety of the therapy will be evaluated by the musicians through the following questionnaire:

	Yes	No
When using Halo Sport 2, the device or software did not work as explained to me and/or I had trouble with the setup or handling of the device. If yes, which: ____________________	☐	☐
When using Halo Sport 2, I experienced unfavourable/discomforting effects. If yes, which: ____________________	☐	☐
During the therapy, I experienced unfavourable/discomforting effects that may be related to the use of Halo Sport 2. If yes, which: ____________________	☐	☐
Unfavourable effects of Halo Sport 2 were an impairment for me in daily life. If yes, which: ____________________	☐	☐
During the therapy, the symptoms of a disease I already had became more frequent or more severe. If yes, which: ____________________	☐	☐

Fig. 2: Safety questionnaire

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10.7 Recruitment E-Mail

Liebe Akademistinnen und Akademisten,

einige von euch kennen mich schon, mein Name ist Paul Krumpöck, ich bin Medizinstudent und schreibe meine Diplomarbeit bei Prof. Dr. Sterz. Und genau dafür möchte ich euch um eure Unterstützung bitten – es geht bei meiner Arbeit um einen Pilotversuch zu einem Therapieprogramm für Musiker:innen. Dieser besteht aus drei Teilen, für die ich jeweils Musiker:innen als Probanden suche: eine Session Physiotherapie und eine Session psychologisches Coaching (beide mit dem PhilFit-Team, Zeitaufwand jeweils ~3h inkl. Fahrzeit), außerdem fünf 20-minütige Sessions mit Halo Sport 2 zu Hause vor dem Üben, das ist ein Kopfhörer mit Fähigkeit zur tDCS-Stimulation (https://www.haloneuro.com/products/halo-sport-2).

Es wäre mir eine große Hilfe, wenn ihr euch für einen dieser Teile (Physio, Coaching, Halo Sport) oder auch mehrere Zeit nehmen würdet.

Zur Terminfindung habe ich jeweils ein Doodle mit Zeiten im August (falls jemand nicht in Salzburg ist) und im Oktober erstellt. Wenn ihr an mehreren Terminen Zeit habt, kreuzt bitte auch mehrere an, da die Zeiten noch mit den Physiotherapeutinnen & Coaches koordiniert werden müssen.

Physiotherapie: https://doodle.com/meeting/participate/id/b2RY7Zzb
Coaching: https://doodle.com/meeting/participate/id/dLgKvqXb
Halo Sport (innerhalb einer Woche könnt ihr wann & wo ihr möchtet fünf 20-minütige Sessions machen, im August auch in Salzburg möglich):
https://doodle.com/meeting/participate/id/eX6ZrNWb

Falls ihr Fragen zu meinem Projekt, den einzelnen Versuchen oder den Terminen hab, könnt ihr euch jederzeit sehr gerne unter paul.krumpoeck@meduniwien.ac.at oder +436765763234 bei mir melden.

Vielen Dank für eure Hilfe!

Paul