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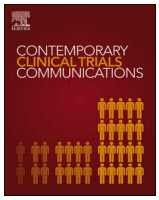

Evaluation of short-term effects of three passive aquatic interventions on chronic non-specific low back pain: Study protocol for a randomized cross-over clinical trial

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ABSTRACT

Background: Low back pain (LBP) is among the most common physical ailments and its chronic manifestation is a leading cause for disability worldwide. LBP is not attributable to a known diagnosis in 85% of the cases and therefore called chronic non-specific LBP (cnLBP). Passive immersion in warm water is commonly claimed to reduce muscular tension and pain, but not yet sufficiently investigated with regard to cnLBP. The current study compares three passive aquatic interventions regarding their effects on cnLBP: floating (resting in a supine immersed position on flotation devices), WATSU (a passive hands-on treatment, in which a practitioner stands in warm water, gently moving and massaging the client), and a Spa session.

Methods: In this randomized cross-over clinical trial, all 24 adult participants with cnLBP will undergo the three interventions in balanced order with a washout-period of at least two weeks in between. Assessments will take place at baseline and follow-up of study and immediately before and after each intervention. Assessments cover the primary outcome self-reported current pain (Visual Analog Scale, range: 0–100 mm), other self-report questionnaires (addressing, e.g., personality traits or -states), and physiological parameters (e.g., measurement of spinal range of motion).

Discussion: The study adds estimates of intervention-specific effect-sizes of widespread passive aquatic interventions to cnLBP. The study also points to potential underlying pain-reducing mechanisms.

Trial registration: The protocol was approved by the Ethics Committee of the Canton Bern (ProjectID: 2018–00461). Trial registration is intended at ClinicalTrials.gov.

1. Introduction

Low back pain (LBP) was reportedly the leading cause for disability worldwide in 2017 [1] and its incidence is increasing [2]. In the Swiss Health Survey 40% of the respondents reported to have experienced LBP in the previous four weeks in 2012 [3], and 43% did so in 2017 [4]. Direct medical costs of LBP were estimated to tie up more than 6% of the total health care spending in Switzerland in 2005 [5]. However, when considering the overall socioeconomic burden of LBP, indirect costs are estimated to exceed direct costs several times over [6,7]. Individuals who chronically suffer pain conditions also tend to be prone to altered pain perception and psychological comorbidities [8,9]. Particularly chronic LBP is not attributable to a known diagnosis in 85% of the patients, and therefore classified "non-specific" (cnLBP) [10]. However, while successful treatment remains challenging, a consensus exists on a biopsychosocial approach in LBP management, leading to respective guidelines recommending, amongst others, behavioral therapy as well as awareness-enhancing interventions [11–14].

The use of warm water to reduce muscular tension and pain was reported over the millennia and finds support in contemporary applications, e.g., during childbirth [15]. Pain reduction by immersion in warm water was reported in animal models [16]. Contributing factors to reduction of pain during immersion in warm water could be, e.g., increased blood flow and thus improved oxygenation of tissues [17] or activation of c-tactile fibers by bypassing warm water [18]. Nevertheless, the evidence on specific passive warm-water treatments in cnLBP is still sparse. Several trials report that Flotation REST (resting in a supine immersed position in salt water) was effective in acute and chronic pain conditions [19–23]. Pain relief was the most frequently investigated

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Abbreviations

5D-ASC	5-Dimensional Altered States of Consciousness Rating Scale
ANOVA	Analysis of Variance
BFH/BUAS	Berner Fachhochschule/Bern University of Applied Sciences
CEC	Ethics Committee of the Canton Bern
CEQ	Credibility Expectancy Questionnaire
cnLBP	Chronic non-specific Low Back Pain
CRF	Case Report Form
DSF	Deutscher Schmerzfragebogen/German Pain Questionnaire
ECR-R	Experiences in Close Relationships – Revised
FESV	Fragebogen zur Erfassung der Schmerzverarbeitung/ German Pain Coping Questionnaire
Flotation REST	Restricted Environmental Stimulation Therapy
FMI	Freiburg Mindfulness Inventory
FreBaQ	Fremantle Back Awareness Questionnaire
HRV	Heart Rate Variability
iDI	Internet-suitable Disability Index
ITT	Intention to Treat
L1	First lumbar vertebra
LADL-Q	Limitations in Activity of Daily Living – Questionnaire
LBP	Low Back Pain
MCD	Movement Control Dysfunction
MDMQ	Multidimensional Mood Questionnaire
NEO-FFI	NEO-Five Factor Inventory
PAIVM	Passive Accessory Intervertebral Movements
PPT	Pressure Pain Threshold
TSD	Post-Traumatic Stress Disorders
Q-Q-Plot	Quantil-Quantil-Diagram
SIJ	Sacroiliac Joint
SLR	Straight Leg Raise-Test
SPSS	Statistical Package for Social Sciences (IBM Software)
TSK-GV	Tampa Scale of Kinesiophobia German Version
VAS	Visual Analog Scale
WATSU	proper name of one of the investigated interventions, portmanteau-word of "water" and "shiatsu" (a Japanese form of bodywork)

effect of WATSU (a passive hands-on treatment, in which a practitioner stands in warm water, gently moving and massaging the client) in a recent systematic review and attributed medium to large effect sizes in the corresponding meta-analysis [24]. In a survey among Swiss practitioners, the use of WATSU during LBP was confirmed by 100% of the respondents [25,26]. Reviews furthermore cautiously report on beneficial effects of Spa therapy in cLBP [27,28].

In the planned randomized cross-over clinical trial, all participants will undergo three interventions – floating, WATSU, and a Spa session – with a washout-period of at least two weeks between two interventions [23]. The main objectives of the investigation are to estimate specific effects of these passive aquatic interventions on cnLBP in an appropriately powered trial that applies strict scientific rigor, and whether the three interventions differ significantly with respect to their immediate effects on cnLBP. In addition, the trial analyses immediate effects on physiological parameters and self-reported interventions effects.

This protocol follows SPIRIT guidelines (Standard Protocol Items: Recommendations for Interventional Trials) [29,30]. It was approved by the Ethics Committee of the Canton Bern (CEC, ProjectID: 2018–00461). A trial registration was prepared for and intended to be published at ClinicalTrials.gov. The project is on hold due to COVID-19.

2. Methods

2.1. Participants

Inclusion criteria for participation in the trial are fluency in spoken as well as written German, to be unacquainted with WATSU, age between 18 and 60 years, cnLBP (lumbar region: first lumbar vertebra (L1) to Sacrum), a pain history of at least 6 months [31,32] as well as constant pain during the last four weeks with a value of minimally 3/10 on a numeric rating scale (= 30/100 mm on VAS), the capability to walk at least one flight of stairs with aids (e.g., a hand rail) but without further assistance, and ability to lie on the back in the water (supported by practitioner or flotation devices) for an hour, or to spend 1 h independently (on their own) in a Spa.

Exclusion criteria are surgery in the concerned area (L1 to sacrum), injury in this area within the past 6 months, and other specific causes for the LBP as identified by the following procedures during first visit: sensory testing (touch detection by ball of cotton) [33,34] and Straight Leg Raising Test (SLR) [35] to rule out lumbar radiculopathy due to disc herniation; testing of muscular strength according procedures suggested by The Medical Research Council to scan for abnormalities that suggest the LBP to be associated to a specific cause [56]. The following muscles will be tested and compared (left/right): iliopsoas muscle, adductor muscles, quadriceps femoris muscle, tibialis anterior muscle, extensor hallucis longus muscle, triceps surae muscle; provocation tests of the SIJ to rule out SIJ pathologies as cause of the pain [36,37]. The following tests will be carried out: Faber provocation SIJ test, Distraction provocation SIJ test, Thigh thrust SIJ provocation test, Gaenslen's provocation SIJ test, Compression provocation SIJ test; Passive Accessory Intervertebral Motion (PAIVM) to rule out joint hypermobility as source of pain [38]; Waddell's testing, a standardized series of physical tests to identify individuals that might profit from additional psychological assessment. Reportedly, individuals who present with positive Waddell signs are at high risk for delayed return to work [39] and in current evaluations, nonorganic somatic components as identified by Waddell's testing seem to be consistent independent predictors in functional capacity evaluation [40,41]. Further criteria for exclusion are other chronic pain areas (e.g., neck pain, fibromyalgia, rheumatism), reported psychiatric illnesses (except: depression, Post Traumatic Stress Disorders (PTSD), and severe stress or burnout without change in medication within the last month), ≥10th week of gestation (by reason of potentially confounding loss of mobility in the lumbar spine due to the embryo's growth), cardiac pacemaker (to avoid interference with Heart Rate Variability (HRV)-measurement), exclusion criteria due to safety in the aquatic environment as acute injuries/fractures, open wounds, or pressure sores, acute skin infections and contagious rashes, acute fever and inflammations (e.g., common cold, urinary tract infections), severe cardiac conditions as well as vascular diseases (including thrombosis), traumatic brain injury or stroke within the last 6 months, seizures, incontinence (unless participant provides and uses incontinence swimwear), damaged eardrum, and frequent shoulder dislocations.

Participants are requested to report their ongoing therapies at baseline, e.g., medication, and changes at each visit. They are asked not to start additional interventions (e.g., other complementary interventions) during their participation in the trial, if not medically necessary. Since participants' adherence to the protocol is limited to direct contacts with the investigators, it is considered fully monitored and no further strategies to improve it will be applied.

2.2. Trial setting and intervention description

Individuals who read the flyer describing the trial can in part self-

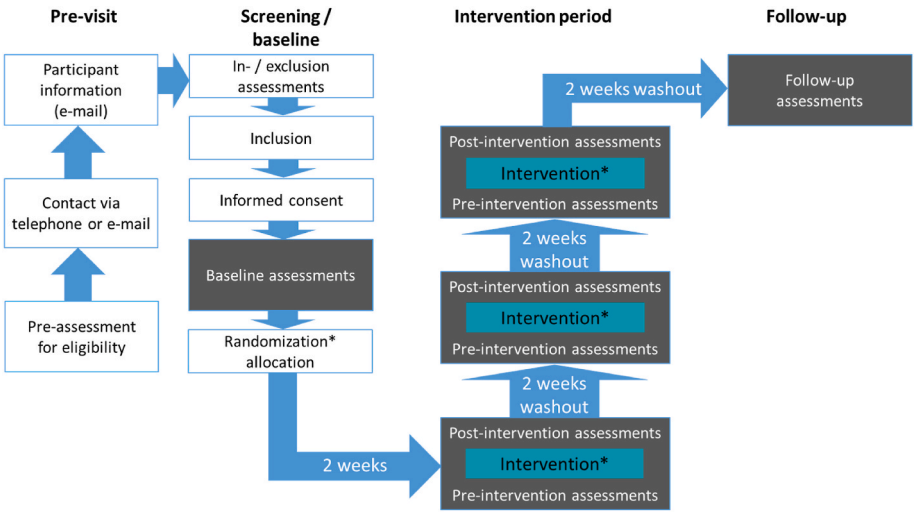

Fig. 1. Illustration of the study flow and activities undertaken at each stage of the trial.
*The order of the interventions (floating, WATSU, Spa session) will be randomized in balanced order.

assess their eligibility for participation even before first contact with the study team via a link to an anonymous electronic self-evaluation form (Microsoft Forms) [42]. A first physical contact for in- and exclusion and baseline assessments, as well as the follow-up assessments, will take place at the Bern Movement Lab of Bern University of Applied Sciences (BUAS). The interventions of this study are planned to be administered in the indoor pool of a public Spa in Switzerland.

An illustration of the stages and activities of the trial is shown in Fig. 1.

On intervention days, participants will first undergo assessments in a secluded room at the Spa and then be accompanied by responsible staff to the pool area, where they take a shower. Before entering the pool, they will be instructed about the planned procedure.

Floating is an adapted form of Flotation Restricted Environmental Stimulation Therapy (REST). In the latter, a client is resting in a supine position on the surface of warm water that is saturated with Epson salts (Mg_2SO_4) [43]. While Flotation REST typically takes place in a closed, soundproof, and unlit container [44], in the planned trial floating will take place in the same pool as the other two interventions for reasons of optimal comparison (e.g., water and air temperatures, humidity). It therefore represents less reduction of environmental stimulation and the participants of the study will be placed on flotation devices to support the head and legs in the water for optimal comfort. These devices will be provided, explained, and applied by a staff member. The participants will be brought into a supine position and instructed to independently interrupt the intervention or to call for assistance whenever they should feel uncomfortable. After 1 h of floating, the waiting staff-member will accompany the participant to a standing position at the side of the pool.

WATSU (also known as water shiatsu) is a passive hands-on treatment, in which a practitioner stands in warm water, gently moving and massaging a client [45]. The practitioners of WATSU who will be treating participants in this trial will have at least five years of practical experience beyond their training. They will briefly take notice of the participant's history, current well-being and general attitudes towards water and physical contact. After entering the pool, a short period will be allowed for acclimatization, before the practitioner will transfer the participant in a supine position and administer a defined movement sequence called "Basic Flow" [45]. Participants will be instructed to interrupt the intervention or to talk to the practitioner whenever they should feel uncomfortable. After 1 h, the practitioner will place the participant at the side of the pool in a standing position. A brief conversation about the experience will complete the WATSU session.

A **Spa session** will function as third intervention to compare the effects of these two interventions with the effects of the Spa-environment and recreational passive immersion per se [46]. It will allow to differentiate between physiological adaptations to immersion [47–50] and treatment-specific effects. Participants will spend the time of the Spa session independently (on their own) and will be instructed to interrupt the intervention or to call for assistance whenever they should feel uncomfortable. After 1 h, the waiting staff-member will ask the participant to leave the pool.

After each intervention, participants will take a shower, towel themself off and change their swimwear as they wish before being accompanied to the post-intervention assessments that again take place in the secluded room.

2.3. Outcomes and their assessment

In the following the primary, secondary and tertiary outcomes of the trial are outlined. Time points of assessment of the outcomes are depicted in Table 1.

2.3.1. Primary outcome

The primary outcome will be self-reported current LBP assessed by VAS (Visual Analog Scale, range: 0–100 mm. 0 = "No pain at all", 100 = "Maximal possible pain"). Assessment will take place at every visit: once at baseline and follow-up, twice on intervention days (pre- and post-intervention). VAS is widely used in clinical assessment and has proven to be reliable for acute and chronic pain; differences between paper pencil and electronic scoring are below clinical relevance [51,52].

2.3.2. Secondary outcomes

These outcomes shall identify changes in preconditions (e.g., change in medication), short-term treatment effects (changes from pre-intervention to post-intervention), completeness of washout/carry-over effects (changes from post-intervention to next visit), and participants' attitudes and review (e.g., expectations, satisfaction).

Physical examination will allow the assessment of physiological parameters as:

- Heart Rate Variability (HRV)

Chronic LBP seems to be strongly tied to psychosocial stressors [53]. HRV is the physiological phenomenon of variation in the time interval between heartbeats and enables continuous and flexible adaptation of the frequency of the heartbeat to actual requirements. Heart rate

Table 1
Participant timeline providing an overview over the procedures and assessment instruments involved at each stage of the trial.

Stage	Pre-visit	Screening/baseline	Intervention period						Follow-up
Visit	Week 1	Week 2	Week 4		Week 6		Week 8		Week 10
	0	1	2 pre	2 post	3 pre	3 post	4 pre	4 post	5
Pre-assessment for eligibility	●								
Participant information	●	●							
In-/exclusion assessments									
Interview									
Demographics, pain history and characteristics, previous treatments		●							
Physical examination									
Sensory testing, SLR, muscular strength, SIJ, PAIVM, Waddell Signs		●							
In-/exclusion		●							
Informed consent		●							
Randomization, allocation		●							
Outcome assessments									
Primary outcome									
VAS		●	●	●	●	●	●	●	●
Secondary outcomes									
HRV, MCD, MDMQ, PPT, Spinal range of motion		●	●	●	●	●	●	●	●
5D–ASC				●		●		●	
CEQ		●	●		●		●		
(Changes in) therapies and medication, FESV, FMI-14, FreBaQ, iDI, LADL-Q, TSK-GV		●	●		●		●		●
Treatment satisfaction, voluntary remarks				●		●		●	●
Tertiary outcomes									
DSF, ECR-R, mindfulness experience, NEO-FFI, relationship to warm water		●							

Abbreviations (in alphabetical order): 5D-ASC 5-Dimensional Altered States of Consciousness Rating Scale; CEQ Credibility Expectancy Questionnaire; DSF Deutscher Schmerzfragebogen [German Pain Questionnaire]; ECR-R Experiences in Close Relationships – Revised; FESV Fragebogen zur Erfassung der Schmerzverarbeitung [German Pain Coping Questionnaire]; FMI Freiburg Mindfulness Inventory; FreBaQ Fremantle Back Awareness Questionnaire; HRV Heart Rate Variability; iDI Internet-suitable Disability Index; LADL-Q Limitations in Activity of Daily Living – Questionnaire; MCD Movement Control Dysfunction; MDMQ Multidimensional Mood Questionnaire; NEO-FFI NEO-Five Factor Inventory; PAIVM Passive Accessory Intervertebral Movements; pre, before the intervention; post, after the intervention; PPT Pressure Pain Threshold; SIJ provocation tests on Sacroiliac Joint; SLR Straight Leg Raise-Test; TSK-GV Tampa Scale of Kinesiophobia (German version); VAS Visual Analog Scale.

variability therefore can be considered as a measurement for the adaptability of an organism to internal and external stimuli and is frequently used to describe psychological strain, particularly via RMSSD (root-mean square of successive differences), LF (low-frequency power, 0.04–0.15 Hz), HF (high-frequency power, 0.15–0.40 Hz), respectively LFnu (low-frequency normalized unit) and HFnu (high-frequency normalized unit), and LF/HF (low-frequency/high-frequency-ratio) [54]. It was tentatively investigated with respect to WATSU [55]. A 10 min autonomic baseline status in supine position and the monitoring of the entire duration of each intervention will be conducted with the use of Polar RS800CX (Kempele, Finnland) [56,57]. This device was successfully employed in aquatic conditions [56]. It showed excellent criterion validity and reliability compared to electro cardiogram measurements in standing and trotting dogs [58] and moderate reliable 2-week test-retest reliability in healthy subjects [59]. Data will subsequently be transferred to the Kubios HRV standard version program (Kuopio, Finland) for analyses of the above mentioned parameters.

- Movement Control Dysfunction (MCD)

Central pain is reckoned to cause or influence maladaptive movement strategies [10,60] that will be assessed by MCD. This battery of six standardized tests showed acceptable reliability of detecting movement/motor control problems of the lower back [61]. The entire battery will be tested at baseline and follow-up assessment. Those out of the six tests that are positive to dysfunction will additionally be retaken before and after each intervention.

- Pain Pressure Threshold (PPT)

Sensitivity to pressure (PPT) yields indirect but objective evidence for the experience of pain [62] and will be assessed with a digital pressure algometer (Wagner, Greenwich CT, USA; diameter 1 cm). The algometer will be applied 4 cm alongside the vertebral column, on a level to the process of vertebra L3, above the quadratus lumborum muscle. Pressure will be applied with increasing force at a rate of approximately 1 kg/cm^2 per second until the participants report a painful sensation. The force values will be recorded (kg/cm^2). Participants will be requested to differentiate between tenderness and the feeling of pressure versus real pain. PPT is described as a reliable method, with enhanced reliability when measured by only one examiner [63].

- Spinal range of motion

Range of motion of the back will be assessed by SpinalMouse® (idiag AG, Fehraltdorf, Switzerland), a hand-held, computer-assisted electromechanical device designed to measure the spinal curvature. It contains two rolling wheels that follow the contour of the spine and will be guided slightly paravertebrally from a marked starting point (process of vertebra C7) to a marked ending (the top of the natal cleft). Landmarks will be determined visually and through palpation by an investigator and marked directly on the skin with a cosmetic pen. Distance and angle measurements are transmitted to a base station positioned next to the examination site. The device's software then uses an intelligent, recursive algorithm to calculate the relative positions of the vertebral bodies and the sacrum. For 'global' regions of the spine, the SpinalMouse® appears to consistently deliver reliable values for standing curvatures and ranges of motion [64]. These will be determined by three measurements: at first, participants will be instructed to stand upright in a relaxed position with their feet shoulder width apart, knees straight and arms hanging relaxed. For the second measurement participants will be asked to bend over, keeping their legs straight and trunk flexed as far as comfortably possible while attempting to curl the head towards their knees. Support – if necessary – may be provided by gripping the back of the lower leg. For the third measurement, individuals are instructed to lean backwards as far as comfortable possible, with the face turning upwards/to the ceiling.

The employed self-report questionnaires will be distributed in a paper-pencil version and cover:

- 5-Dimensional Altered States of Consciousness Rating Scale (5D-ASC).

Deviations from normal states of consciousness during the interventions were reported for both, Flotation R.E.S.T [65,66]. and WATSU [24]. The 5D-ASC is a commonly used instrument for retrospective self-report of such experiences [67,68]. Its 94 questions are presented with horizontal VAS of 100 mm length, anchored as "No, not more than usual" on the left and as "Yes, very much more than usual" on the right. Reliability and validity of the questionnaire are reported to be satisfactory [69].

- Credibility/Expectancy Questionnaire (CEQ)

Beliefs and expectancies of participants regarding proposed interventions might influence the outcome of a treatment [70]. It demonstrated high internal consistency within each factor and for the whole scale. Factors were stable across different populations. The expectancy factor predicted outcome on some measures [71]. The CEQ was adapted to the treatments investigated in the planned trial. Its factors will be assessed by VAS (0–100 mm; 0 = "Not at all", 100 = "Very much").

- Changes in therapies and medication

- [Questionnaire for the assessment of pain processing] Fragebogen zur Erfassung der Schmerzverarbeitung (FESV)

This self-administered questionnaire is suited to document cognitive processing and pain coping abilities. It contains 38 items that have proven acceptable reliability and showed construct-, convergent-, discriminant-, and differential-validity [72].

- Freiburg Mindfulness Inventory (FMI-14)

The literature reports on mind-body interventions to address LBP, e.g., mindfulness based stress reduction [73], and also the interventions in question are of introspective nature. The FMI-14 searches to express participant's mindfulness. The 14 items short form of FMI correlates highly with the long (30 item) version [74].

- Fremantle Back Awareness Questionnaire (FreBaQ)

One's body awareness is an important predictor of clinical severity in LBP [75,76]. FreBaQ is a questionnaire that focuses on alterations in the perception of the back rather than disability or pain. It exhibits minimal ceiling and floor effects as well as acceptable internal consistency, is not biased by demographic or clinical variables, and unidimensional with no redundant items [75].

- Internet-suitable Disability Index (iDI)

The actual disabling effect cnLBP has on the participants of this trial will be self-reported by iDI. This instrument comprises eight questions with reported high reliability. It was successfully tested on construct- and divergent-validity and compares very well to the Oswestry Disability Index regarding item quality, reliability, and validity measures in individuals with spinal disorders [60,77].

- Limitations in Activity of Daily Living Questionnaire (LADL-Q)

The participants' self-perceived general musculoskeletal health and daily task performance will be self-reported by LADL-Q. The internal consistency of the back specific subscale of LADL-Q and Correlation coefficients between LADL-Q subscales and Western Ontario and McMaster Universities Osteoarthritis Index, Shoulder Pain Disability Index, and Oswestry Disability Index are acceptable [78].

- Multidimensional Mood Questionnaire (MDMQ)

Psychological comorbidities as depression and fear are common in chronic LBP [79], thus current mood will be self-reported by MDMQ. The validated questionnaire with good internal consistencies assesses short-term changes in self-reported mood. It consists of a list of 12 adjectives addressing current mood, calmness, and alertness (e.g., "happy, " "nervous," or "awake") ranked on a 5-point Likert scale ranging from "Not at all" to "Very much" [80].

- Tampa Scale for Kinesiophobia, German version (TSK-GV)

Fear of movement is considered a contributing factor to the deterioration of chronic pain conditions due to immobilization [81]. The 17 item self-report checklist TSK-GV is suited to measure such fear. Moderate correlation coefficients were reported concerning measures of pain-related fear, pain catastrophizing, and disability, and its construct-validity was supported [82].

- Treatment satisfaction

Treatment satisfaction will be assessed by VAS (0–100 mm; 0 = "Not at all", 100 = "Completely") immediately after each intervention and after two weeks (prior to the next intervention on the next intervention day).

- Voluntary remarks

After each intervention and at follow-up participants are invited to qualitatively comment on their experiences in the trial.

2.3.3. Tertiary outcomes

Demographic characteristics and psychological traits of participants will be assessed during the baseline procedures, covering:

- [German Pain Questionnaire] Deutscher Schmerz-Fragebogen (DSF)

This questionnaire assesses basic demographic and anamnestic questions as well as a catalogue of valid and reliable pain related questionnaires. DSF was designed to be used by professionals to have an overview and a starting collection of progression parameters for the treatment of individuals who suffer chronic pain. Due to its coherency it is considered an efficient tool [83,84].

- Experiences in Close Relationships – Revised (ECR-R)

The literature reports that activation of c-tactile fibers and attachment style modulate pain [85]. Therefore, a self-report questionnaire to measure the attachment dimensions avoidance and anxiety will be employed. Validation of the German version showed excellent reliability for the respective subscales [86].

- Mindfulness experience

Since the authors of FMI describe that "longer meditation experience, more frequent meditation, as well as the increase in mindfulness by a retreat can be demonstrated by the scale" [74], respective prior experience of the participants will be recorded in years (e.g., of meditation).

- NEO-Five Factor Inventory (NEO FFI)

A personality inventory to assess the big five personality traits (extraversion, agreeableness, openness, conscientiousness, and neuroticism). The internal consistencies of the five scales are reported to range between acceptable and good, as did five-years-retest-reliability [87].

- Relationship to warm water

Positive effects of water are reported in the literature – starting with the mere sound of a natural water fountain [88]. However, since fondness for water might be differing and even influence the effectiveness of the interventions, participants will assess how much they appreciate to be immersed in warm water on a VAS (0–100 mm; 0 = "Not at all", 100 = "Very much").

In addition, water (pool) and air temperatures, and humidity as monitored by respective electronic systems of the concerned facility will be recorded. No biological specimens will be collected.

2.4. Sample size

Sample size calculation was performed with G*Power software (Faul et al., 2007) using ANOVA approach (repeated measures, within-between interactions) as statistical model. To this day there is no comparable intervention study to estimate sample size based on available data from pain measurement of the three interventions floating, WATSU, and Spa session.

To be able to achieve results of clinical relevance (as opposed to statistical significance only), an effect size f = 0.4, indicating a large (and therefore clinically relevant) effect according to the classification of Cohen (1988), is assumed to be adequate. The sample size was calculated with following presumptions: $\alpha = 0.05$, Power ($1–\beta$ error probability) = 0.8, number of interventions = 3 (floating, WATSU, Spa session), number of measurements = 2 (pre, post), and non-sphericity correction = 1. While it can be expected that chronic pain is a relatively stable parameter and individuals with high scores will present high scores pre and post intervention, as well as individuals with low scores will present low scores pre and post intervention, correlations among repeated measures were estimated conservatively low with 0.4.

Based on these assumptions a total sample size of N = 24 (full data sets) was estimated. Assuming 10% attrition, at least 26 participants will be recruited. In case of temporary limitations (e.g., urinary tract infection), the washout-period between two interventions may be extended. For missing data, rules of ITT (Intention to Treat) will apply [89].

A flyer describing the trial will be distributed electronically and published on the homepages of the involved institutes and physically (flyer, poster) at the Spa. Depending on the success of recruitment-efforts, social media and newspapers will be considered.

2.5. Assignment of interventions and blinding

Blocked randomization with fixed block sizes will ensure balanced order while considering all six permutations of chronological order of the three interventions (WATSU – Spa session – floating; WATSU – floating – Spa session; floating – WATSU – Spa session, floating – Spa

session – WATSU; Spa session – WATSU – floating; Spa session – floating – WATSU). The randomization of group allocation (allocation ratio = 1:1:1:1:1:1 for each sequence) will be carried out by the sponsor-investigator with the online tool www.randomization.com. A secretary of BUAS (not involved in the trial and blinded to the allocation information) will inserted allocation information in sequentially numbered sealed opaque envelopes that will be kept with the randomization-code in the sponsor-investigator's file in a locked cabinet in a locked room at BUAS [30]. Participants will be enrolled by the investigators at the first visit. After undergoing both, scan for in- and exclusion criteria and baseline-assessment, participants will consecutively receive the sealed envelopes containing allocation information from the investigator.

While Participants, practitioners of WATSU, and staff assisting in the pool area will remain unblinded for logistic reasons, the above-mentioned secretary as well as investigators and statisticians will be blinded to the group allocation (the order, in which the participants receive the interventions). Particularly, investigators will be blinded to the intervention that the participants are undergoing on the day of assessment.

After termination of statistical analyses, also investigators and statistician will be unblinded. Since the risks accompanied with the participation in this trial are considered very low and do not exceed a usual visit of the public facilities involved (e.g., slippery floors), the necessity of unblinding is unlikely. If needed, it however can be initiated at any time by each of the involved individuals.

2.6. Data collection and management

The sponsor-investigator is responsible for proper training of all involved staff, particularly the correct and uniform execution of the assessments, and the standardized documentation of their results.

He is aware of the responsibilities according to Good Clinical Research Practice [90] and adheres to them. All required procedures along with information necessary to report the observations and tests described in this protocol will be recorded online and as hard copy. Data collection forms will be stored in a cabinet at BUAS. Data entered in the CRF (Case Report Form) will be documented in a source document with all the information, on which the entries in the CRF are based, being available in the participant files, e.g., results of inclusion assessment. Participants will be identified in the CRF by their code. The sponsor-investigator must review all pages within the CRF for accuracy and consistency with the protocol, and sign and date the CRF upon completion as designated in the CRF. The participant consent forms are also to be kept in the study documentation. After prior agreement, a check of the consistency of data between the participant files, raw data and CRF as well as with other documents related to the study may be conducted by the responsible authorities and/or by monitors (inspection/audit/monitoring).

All data files electronically recorded during the study period will be stored on a database server (SharePoint) folder. The SharePoint servers of BUAS are kept in a locked, air-conditioned server-room. Only the system- and database administrators have access to these servers and back-up hard drive discs (HDD). A data back-up for the database is run daily. All employees signed a non-disclosure agreement. The back-up HDDs are stored in a safe in a different building.

All study team members have access to the database (the respective SharePoint folder) using a personal password. They are authorized for CRF entries depending on their function based on a role concept (investigator, statistician, monitor, administrator etc.) that regulates permission for each user. A multilevel data validation plan was developed to guarantee the correctness and consistency of the data. Data will be entered only after a check for completeness and plausibility. Furthermore, data are cross-checked for plausibility with previously entered data for each participant.

Data will be extracted from the database into statistical packages to be analyzed. The status of each document on the SharePoint server folder is recorded in special archive tables. Consequently, all changes in all documents are replicable because name, date, time and document version are stored with each change. These tables cannot be altered in future. The study database with all archive tables will be securely stored at BUAS. After termination of the project, data will be stored in a coded form electronically and in paper for 10 years in a locked cabinet in a locked room at BUAS. No conclusions on the participants' identities will be possible by viewing these files.

2.7. Statistical methods

Data will be analyzed using statistical software SPSS (current version). For descriptive analyses means, standard deviations, 95% confidence intervals and median, quartiles, minima, maxima, and for graphical presentation boxplots will be used. To compare the primary outcome between and within the three interventions (floating, WATSU, Spa session) at two time points (pre and post each intervention), ANOVA parametric models for longitudinal data (repeated measures, within-between interactions) will be used if the normality assumption is not violated [91]. Quantitative data will generally be checked for normality using Q-Q-plots and Shapiro-Wilk.

The secondary and tertiary results are analyzed using the same approach and statistical procedures and are used for further exploratory data analyses, which per se do not require a priori power analyses. However, post hoc power analyses will be provided to estimate effect sizes. In addition, Bonferroni correction is used to neutralize alpha error accumulation in multiple comparisons.

All randomized subjects who completed at least one intervention-day will be included in data analyses. In cases of missing data, ITT will be applied. In this case, pre-intervention values of already completed intervention-days will be pooled and carried forward, as will be post-intervention values.

2.8. Oversight, monitoring, and reporting

Because this is a category A (minimal risk) study, routine monitoring of the study will be guaranteed by the project team. For quality assurance, the CEC may visit the research sites to check of the consistency of data between the participant files, raw data and CRF as well as with other documents related to the study. Direct access to the source data and all project related files and original documents (without participant names and personal data) will be granted on such occasions, however, all involved parties must keep participant data strictly confidential.

During data acquisition, weekly monitoring-meetings will take place to assess recruitment process, dropouts, and compliance of the participants. Reports to the CEC will be conducted in time according to the official requirements. There will be no scheduled audits of the trial conduct.

An Annual Safety Report will be submitted to the CEC. The planned interventions and examinations are being applied to individuals regularly, with no known adverse effects. However, on occurrence adverse events will be recorded and reported to the respective authorities (CEC). Their appearance (or absence) will also be documented in future publications concerning this trial. Since there are no risks or inconveniencies anticipated in this Category A study, no insurance beyond the general liability insurance of BUAS will be provided.

Generally, no interim analysis is planned. However, the sponsor-investigator may terminate the study prematurely based on ethical considerations, unexpected serious adverse events, or insufficient recruitment.

Early termination of the study is unlikely, however, on occurrence the responsible CEC would be informed instantaneously. In this case, the sponsor-investigator would decide whether interim analyses will be performed.

The study and its results shall be published adhering to CONSORT guidelines (Consolidated Standards of Reporting Trials) [92] in peer-reviewed international journals, and presented at national (e.g., congress of the Swiss association of physiotherapists) and international congresses (e.g., congress of the World Confederation for Physical Therapy). The full study protocol will be accessible at ClinicalTrials.gov. Publication of the participant-level dataset is not intended.

2.9. Ethical considerations

The investigators will explain to each interested individual written and orally: the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks and benefits, and any discomfort it may entail. Already before the first visit, interested individuals will receive written information on the study's design including informed consent-material to raise realistic expectations and provide sufficient information to make an informed decision about participation in the study within one week (which will be the approximate window from interested persons' first contact to their first visit). During this week, the study team can be contacted via phone or e-mail, and at the first visit interested individuals and investigators answer questions regarding eligibility and participation to determine in- or exclusion.

Potential participants will be informed that the participation in the study is voluntary and that they may withdraw from the study at any time without justification and that withdrawal of consent will not affect their subsequent therapeutic assistance and intervention. They will be informed that their medical records may be examined by authorized individuals, that already collected data will be further processed according to the rules of ITT even when they prematurely withdraw from the study, and that for publication in journals or at congresses, data will not contain identifiable components (as names). Before being submitted to physical baseline assessment, they will read and consider the approved consent form, sign and date the statement of informed consent, as will the investigator. Participants will be given a copy of the signed document; another one will be retained by the investigator as part of the study records.

Deviations from the original study plan will be documented. In case of changes that will systematically occur, the respective authorities (CEC) will be informed and an amendment of the Clinical Study Protocol will be performed. Substantial amendments are only implemented after approval of the CEC. Under emergency circumstances, deviations from the protocol to protect the rights, safety and well-being of participants may proceed without prior approval of the sponsor-investigator and the CEC. Such deviations shall be documented and reported to the sponsor-investigator and the CEC as soon as possible. All Non-substantial amendments are communicated to the CEC within the Annual Safety Report (ASR).

The investigators affirm and uphold the principle of the participant's right to privacy and that they shall comply with applicable privacy laws. Especially, anonymity of the participants shall be guaranteed when presenting the data at scientific meetings or publishing them in scientific journals. Medical information about participants obtained in this study is considered confidential and disclosure to third parties is prohibited. Direct access to source documents will be permitted for purposes of monitoring, audits, or inspections. Subject confidentiality will be further ensured by utilizing subject identification code numbers to correspond to intervention data in the computer files. For data verification purposes, authorized representatives of the sponsor-investigator or a competent authority, e.g., CEC, may require direct access to parts of the medical records relevant to the study, including participants' medical history.

3. Discussion

Considering the increasingly frequent occurrence of cnLBP and the difficulties to effectively treat this condition, interventions that are claimed to be beneficial while not presenting known negative side-effects warrant thorough investigation [1,2]. Passive immersion appears to meet this description [93].

The environmental setting of the trial (the public Spa, its pool and air temperatures, and humidity) will be the same for all three interventions, as will immersion, thus facilitating comparability of the interventions and allowing emphasis on its differences. In both, WATSU and the Spa session, massages (by the practitioner or by underwater jets, respectively) or stretches (passive or active, respectively) may be applied. In floating, WATSU, and potentially the Spa session, there may be situations of utter silence. All interventions aim at pain relief and physical and mental relaxation.

Taking into account (and assessing) the participants' most likely differing personality-traits and expectations, this study might also be suited to determine whether the participants' experience of the interventions and their effect on pain could depend on such factors. Thus, this study offers a rather unique view on the difference of the experience to be fully independent (Spa session) versus restricted by a setting (floating, WATSU), or with physical contact to another human being (WATSU) versus without it (floating, Spa session). If such relationships between personality traits and treatment preference/effect could be observed in this trial and replicated when prospectively applied in future trials, this information could inform decision making with regard to treatments on land, e.g., when to rather suggest hands-on treatment and when self-reliant training.

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Competing interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Availability of data and materials

The sponsor-investigator will have access to protocols and datasets. The sponsor-investigator and the statistician will have access to the statistical code after completing the study. Only investigators will have access to the statistical code during the study. Public availability of raw data is not intended.

Authors' contributions

It is not intended to mandate professional writers for the publication of the achieved results. The contributions of the authors will presumably be as outlined in Table 2.

Table 2
Authors contributions.

Term	Definition	
Conceptualization	Ideas; formulation or evolution of overarching research goals and aims	AMS; LR, NK
Methodology	Development or design of methodology; creation of models	AMS; AE, LR, NK
Software	Programming, software development; designing computer programs; implementation of the computer code and supporting algorithms; testing of existing code components	n/a
Validation	Verification, whether as a part of the activity or separate, of the overall replication/reproducibility of results/experiments and other research outputs	n/a
Formal analysis	Application of statistical, mathematical, computational, or other formal techniques to analyze or synthesize study data	
Investigation	Conducting a research and investigation process, specifically performing the experiments, or data/evidence collection	AMS, LR
Resources	Provision of study materials, reagents, materials, patients, laboratory samples, animals, instrumentation, computing resources, or other analysis tools	
Data Curation	Management activities to annotate (produce metadata), scrub data and maintain research data (including software code, where it is necessary for interpreting the data itself) for initial use and later reuse	
Writing - Original Draft	Preparation, creation and/or presentation of the published work, specifically writing the initial draft (including substantive translation)	AMS
Writing - Review & Editing	Preparation, creation and/or presentation of the published work by those from the original research group, specifically critical review, commentary or revision – including pre-or postpublication stages	AMS, AE, LR, NK, PF
Visualization	Preparation, creation and/or presentation of the published work, specifically visualization/data presentation	AMS
Supervision	Oversight and leadership responsibility for the research activity planning and execution, including mentorship external to the core team	AE, LR, NK
Project administration	Management and coordination responsibility for the research activity planning and execution	AMS, LR
Funding acquisition	Acquisition of the financial support for the project leading to this publication	n/a

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