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Protocol

Effectiveness of hypnosis with the Dave Elman technique in third molar extraction: Study protocol for a randomized controlled trial (HypMol)

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ABSTRACT

Introduction: Extraction of a third molar is painful for patients, and this clinical condition can be used to evaluate the analgesic effects of pain treatments. For reduction of pain during third molar extraction, hypnosis can be beneficial. Under hypnosis and during follow up, patients receiving hypnosis showed less pain than patients not receiving hypnosis, and postoperative analgesic use was lower in patients with additional hypnosis during third molar extraction. The aim of this monocentric randomized controlled study is to test the effectiveness of hypnosis in patients with third molar extraction, taking into account patients' expectations, treatment preferences and hypnotic depth.

Methods: A total of 33 patients with molar extractions on both sides will receive two types of pain-reducing interventions (randomized crossover trial) in order to investigate the effects of hypnosis. During one extraction, the patient will first receive hypnosis as an add-on intervention (the Dave Elman technique) and reduced medication during the third molar extraction. In the other molar extractions, patients will receive regular medication without hypnosis. The order of interventions and side of the third molar will be randomized. The primary outcome of the intervention is the area under the curve of pain intensity after the extraction (measured after extraction, 3 h after extraction, in the evening, and at the first and second day after extraction). Secondary outcomes are pain medication and the preferred treatment after two appointments.

Discussion: We expect that the results of this study will improve knowledge about the effectiveness of hypnosis in a dental setting with a sound methodology. We can also explore working mechanisms such as treatment expectations and preferences about treatment outcomes.

1. Introduction

The extraction of a third molar is painful for patients, and this clinical condition can be used to evaluate the analgesic effects of pain treatments. Postoperative pain normally begins 1 to 3 h after extraction and ranges from moderate to severe intensity with a substantial burden for patients [1,2]. Patients receive infiltrative and/or conductive anesthesia with local anesthesia on a regular basis to reduce pain severity during extraction [3]. After extraction, patients can take analgesic drugs if needed and nonpharmacological treatments such as cooling the extraction area with a cooling pack are also recommended for pain relief and reduction of postoperative swelling [4].

In addition to these medical treatments for pain relief, treatment under hypnosis was also found to be beneficial to reduce pain during and after third molar extraction. Hypnosis can be considered to be a beneficial treatment in surgery in general with moderate effects on mental distress and pain [5]. Similar effects were found in the dental setting in a recent meta-analysis [6]. During tooth extraction and during follow up, patients who received hypnosis showed less pain than patients who did not receive hypnosis [7]. Studies also showed a reduction of postoperative analgesic use when patients received hypnosis during third molar extraction [7–10].

A major limitation of the already conducted trials in the field of third molar extraction is the rather low sample size in most studies (five of the available eight studies used a sample size of 30 or fewer participants per group) and the problem that pain ratings have a considerably large variation between patients. Therefore, a within-subject crossover design might be better suited to account for the different pain

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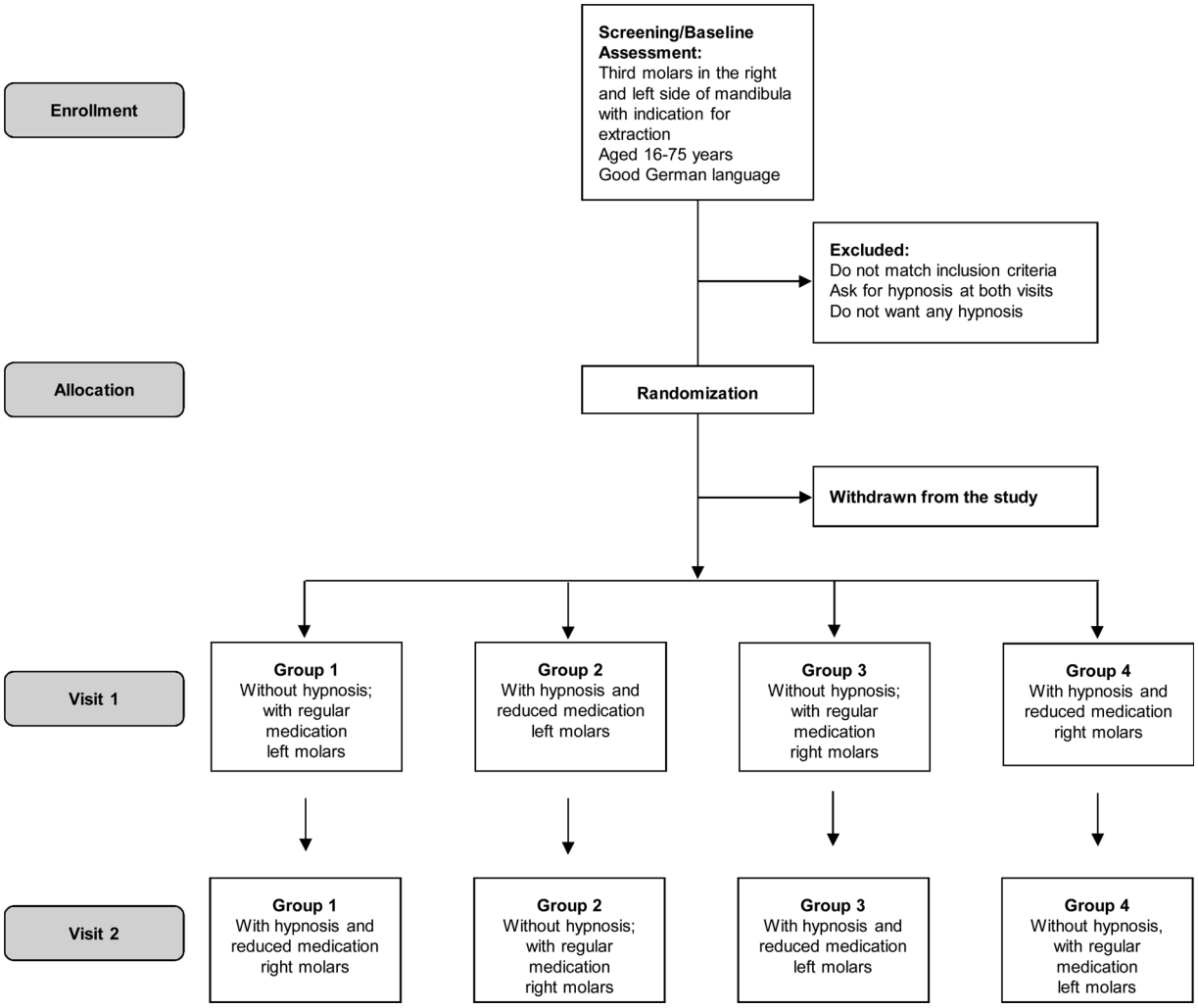

Fig. 1. Flow chart of the molar extraction with additional hypnosis and reduced medication or without hypnosis and regular medication. Each patient will receive both type of treatments, but the order and side of extraction will be randomly allocated.

sensitivity of patients. Such a crossover design was used earlier by two groups in Iran [7,11], but only 16 or 24 patients were included, and reporting standards such as CONSORT [12] were neglected.

For the application of hypnosis in the clinical routine, the question of a specific patient's hypnotizability comes up from a theoretical perspective and is discussed as a prerequisite for hypnosis. However, two problems with this theoretical assumption have to be considered. First, a general problem is that hypnotizability is difficult to assess. Long interviews are often not feasible, and reliability between interviewers is questionable [13]. Second, in randomized controlled trials (RCTs), patients have been allocated either to a control or hypnotic group without checking an individual's hypnotizability. Nevertheless, many randomized controlled trials have shown that patients can benefit from hypnosis regardless of any pre-assessment of their hypnotizability [8–10]. Consequently, each patient who consents to be hypnotized might be hypnotizable with a proper technique [14]. It is disputable if standardized suggestions in hypnosis are equally effective as personalized suggestions since, in regular hypnotherapy, the use of individually adjusted suggestions is recommended [15]. However, in a situation where hypnosis is delivered as part of a medical treatment such as a surgery, some standardization is necessary for feasibility reasons. In addition, the results can be more easily implemented into clinical routine and taught in courses. Therefore, our study will use a standardized protocol for the hypnosis with enough flexibility to adapt it in timing to patients' needs.

The prediction of responders to hypnosis is an often-discussed topic, and expectations about hypnosis as well as the hypnotic depth are considered to be the main drivers of treatment effects. High expectations have been shown to go along with better hypnotizability [16,17]. Positive expectations of patients were empirically shown to increase the probability of responding to hypnosis [18], and such expectations might also contribute to treatment effects of hypnosis in molar extraction. We therefore will assess patients' expectations about the effectiveness of hypnosis before receiving hypnosis before the surgical procedure. The depth of the hypnosis after the treatment can also be considered an important predictor of treatment success [19]. For this purpose, the Inventory Scale of Hypnotic Depth [20] was developed, and our study will use this individual perception as a mediator of treatment outcomes. However, the evaluation of the hypnotic depth is a post hoc evaluation of patients and, unlike expectations, is therefore not a proper predictor.

2. Methods/design

2.1. Study registration

This study protocol has been registered on the German Clinical Trials Register, DRKS Nr. 00011848 on 11 April 2017. http://apps.who.int/trialsearch/Trial2.aspx?TrialID=DRKS00011848

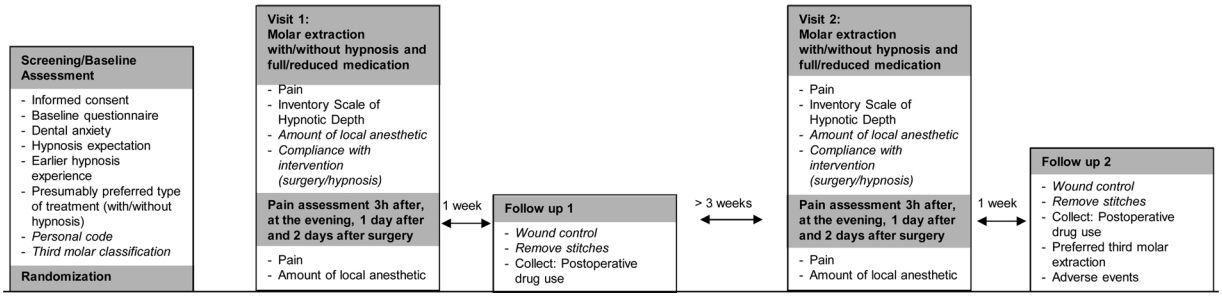

Fig. 2. Procedures and interventions during the HypMol Trial.

2.2. Objectives

The aim of this study is to investigate the effectiveness of hypnosis with reduced medication in patients undergoing third molar extraction on both sides in regard to pain and pain medication compared to the regular treatment for this condition (regular medication). As a primary outcome, we will assess the level of postoperative pain. Secondary outcomes will be postoperative analgesic use within 2 days after the third molar extraction. Patient's expectations about hypnosis and hypnotic depth will be used as a predictors for hypnosis treatment response, and at the end of treatment, we will also assess if the patients preferred the third molar extraction with or without the additional hypnosis.

2.3. Study design

The manuscript is based on the study protocol version 3.0 of 10 April 2017. We will perform a within-subject crossover randomized controlled study that compares modified usual care (reduced medication with Rudocain 0.85 ml) and hypnosis with usual care (regular medication with Rudocain 1.70 ml) in patients with third molar extraction on both sides (see Fig. 1). The kind of treatment and the side of the surgical intervention will be allocated randomly to the first and second visit. We will perform a randomized four-armed trial with two independent factors (sequence of side of third molar extraction [left / right] and sequence of hypnosis intervention [modified usual care with hypnosis vs. usual care without hypnosis]). Patients will be randomized in a 1:1:1:1 ratio.

Group 1: Extraction left, no hypnosis with regular medication (visit 1). Extraction right, hypnosis with reduced medication (visit 2).

Group 2: Extraction left, hypnosis with reduced medication (visit 1). Extraction right, no hypnosis with regular medication (visit 2).

Group 3: Extraction right, no hypnosis with regular medication (visit 1). Extraction left, hypnosis with reduced medication (visit 2).

Group 4: Extraction right, hypnosis with reduced medication (visit 1). Extraction left, no hypnosis with regular medication (visit 2).

2.4. Study population

Patients aged 16 or older with third molars on the right and left side of the mandibula with an indication for extraction in an outpatient setting by a dentist will be eligible for the study. The patients will need sufficient German language skills to give reliable answers on questionnaires and a mobile phone for receiving text message notifications to complete the questionnaires in a timely manner. Patients with a diagnosed mental disorder with associated dissociation problems (schizophrenia, borderline personality disorder, posttraumatic stress disorder), current use of illegal drugs or psychotropic drugs or opiate use will be excluded.

2.4.1. Patient information and informed consent

The investigator must explain to each participant the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks and benefits and any discomfort it may entail. Each participant must be informed that participation in the study is voluntary, that he/she may withdraw from the study at any time and that withdrawal of consent will not affect his/her subsequent third molar extractions. All participants for this study will be provided a participant information sheet and a consent form describing this study and providing sufficient information for participants to make an informed decision about their participation in this study. Enough time will be given to the participant within a baseline consultation with the dentist to decide whether to participate. The participant should read and consider the statement before signing and dating the informed consent form and should be given a copy of the signed document. The consent form must also be signed and dated by the investigator (or his designee), and it will be retained as part of the study records. At this first consultation (baseline assessment), the inclusion and exclusion criteria will be checked, and the randomization will take place after informed consent. The participant information sheet and the consent form, together with the protocol, was submitted to the Cantonal Ethics Committee (CEC) for review and approval for the study.

2.5. Procedure

2.5.1. Recruitment and screening

The recruitment of patients is planned to be done between February 2017 and August 2018 for a period of 19 months. All patients with a minimum of two third molars in the mandibula with indications for extraction will be recruited in the outpatient dental clinic Meyenberger in Wil, Switzerland. Potential participants will be screened by the dentist and will be informed about the study purpose. The patients will receive an informed consent form to sign at the initial appointment with the dentist (see Fig. 2). If the patients provide informed consent, they will be asked to complete a baseline questionnaire and dental anxiety scale [21] and a questionnaire about their expectations of the hypnosis intervention [22], their earlier experience with hypnosis and their presumably preferred third molar extraction. All data will be collected in a strictly pseudonymous form. The patients will receive a 50 CHF voucher for the dental clinic at the end of the study. The hypnosis treatment will be offered for free (without any compensation from health insurance).

2.5.2. Molar extraction

The extraction of the third molar will be done lege artis [3]. The extraction of the third molars will occur in two separate dental visits (visit 1 and visit 2). At each visit, the third molars from one side of the mandibula and, if existing, in the maxilla will be extracted. First, the patient will rinse with a mouth wash solution for disinfection. As appropriate, a topical anesthesia can be given followed by an infiltrative and/or conductive anesthesia with local anesthesia by Rudocain injection of 1.7 ml. If the tooth is removed under hypnosis, 0.85 ml of anesthesia will be used. In both treatment conditions, the use of additional anesthesia injections will be possible and will be documented separately. If necessary for removal of the third molar, a mucogingival

flap will be made to cover the bone and the third molar, and the crown will be presented with a rotation instrument under water cooling. If necessary, the tooth can be separated and then removed with the saccus dentalis. For wound healing, a drainage and stitches can be placed. Any deviations from this prespecified procedure will be documented by the dentist on a form. The patient will receive postoperative behavior instructions, for example, cool the extraction area, rinse with a mouth wash solution, and refrain from participating in sports for one week, chewing sticky food for 24 h, mechanical clearing of the wound and smoking. The patient will receive a cooling pack, disinfection rinse solution (0.2% chlorhexidine digluconate 200 ml) and analgesics (mefenamic acid 500 mg) to take home. The patient will be instructed to rinse with Dentohexin twice per day for one minute, beginning the day after third molar extraction. If needed, the patient can take the provided Spiralgin 500 mg as a painkiller, and we will recommend the patient not take more than 3 pills per day.

2.5.3. Hypnosis

The Dave Elman hypnosis technique follows a defined procedure. We will use verbatim induction based on the Dave Elman procedure [23]. The patient has to focus on a spot marked on the right palm and is given the following directions: “With each breath your eyelids are getting heavier and heavier. Imagine that they are two magnets that are starting to pull themselves together. Just so, heavier and heavier. Think of a special place you would like to visit. A place where you feel happy and relaxed. Go there now…”

Rapid induction: “Please just take a good long deep breath and close your eyes. Now relax the muscles around your eyes to the point where those eye muscles won’t work, and when you’re sure they won’t work, test them and make sure they won’t work… [Subject opens their eyes.] No, you’re making sure they will work. Relax them to the point where they will not work, and when you’re sure they won’t work, test them. Test them hard. Get complete relaxation in those muscles around the eyes… [Client now exhibits eyelid catalepsy.] Now let that feeling of relaxation go right down to your toes… In just a moment, we’re going to do this again, and when we do it the second time, you’re going to be able to relax ten times as much as you’re relaxed already. Now open your eyes. Close your eyes. Completely relax; let yourself be covered with a blanket of relaxation. Now the third time we do it, you’ll be able to double the relaxation that you have now. Open your eyes; now relax. With each exhale, your relaxation will go deeper and deeper. As I’m speaking to you, you may notice different sounds around you. You may hear the traffic, sounds in the clinic or even in this room. This sound will help you go even deeper and deeper. With each sound you hear, your relaxation will grow more and more. Just let it happen.

I’m now going to lift your right hand and drop it, and if you’ve followed the directions up to this point, that hand will be just as limp as a dishrag and will just plop into your lap… (Now, let me lift it -don’t you lift it- let it be heavy -that’s good- but let’s open and close the eyes again and double that relaxation and send it right down to your toes. Let that hand be as heavy as lead… You’ll feel it when you’ve got the real relaxation… Now). Yes you’ve got it. You could feel that, couldn’t you? (Patient: Yes.)”

Deepening: “That’s complete physical relaxation, but I want to show you how you can get mental relaxation as well as physical. Mental relaxation means to make space in your mind. The more space you can make, the better you can focus on your special place. You can make space by counting backwards from one hundred. Each time you say a number, you double your relaxation, and by the time you get down to ninety-eight, you’ll be so relaxed there won’t be any more numbers… “

“You’ll leave the numbers far behind your beautiful place so that they will be gone. Gone, to give you more room to focus better on your special place wherever that may be. But you don’t have to count backwards now. I’ll show you a way that you will be able to put not only the numbers behind this place but a lot of other things too. To let go all of the things that may distract you from this beautiful place. Start with the idea of making that happen and watch it happen.”

“I’m now going to lift your left hand and let it drop down. If you followed my directions up to this point, the hand will be just as limp as a dishrag and will just plop into your lap. … Yes. You’ve got it. You could feel that couldn’t you? Let all those things go, go far behind your place. It’s perfectly normal that your thoughts may wander; just let them go and focus again on this lovely place. If they are important thoughts, as soon as we are finished, you can address them.”

“Now bring the physical and the mental relaxation together to a total relaxation. Now let that feeling of relaxation go right down to your toes…”

“The bigger part of you is now focused on your place. Let yourself be immersed even deeper and deeper in it. The smaller part of you that is still here with us and wants to make sure everything goes well is concentrated on your left hand. Now we lift the left hand up so that it stands up at a 90 ° angle. This is the signal if you need to tell us something during our work. As soon as we see that left hand is lifted up, we’ll stop, and you can tell us whatever you need to. If you need to raise your left hand and communicate with us, this will have no influence on your beautiful state of relaxation. On the contrary, it will help you to feel safer, more secure and at ease so you may go even deeper. Now enjoy your wonderful state of relaxation and your special place. Enjoy this little gift that you have given to yourself.”

When a patient receives hypnosis during third molar extraction, at the end, he or she will be released out of hypnosis with the following: “Now you have to count slowly to the number five. When you reach the number five, you can open your eyes and you will feel very good. With every number you count, your consciousness will be stronger. One, you feel the good feelings going through your body; two, the power is coming back; three, you will have a good day today; four, take a deep breath; and five, now you can open your eyes.”

2.5.4. Follow-up appointment

Wound control and removal of the stitches will be done about one week after the molar removal.

2.6. Primary and secondary outcomes

Outcomes will be assessed at each of the two visits of the patient for third molar extraction with or without hypnotic intervention. The following outcomes will be assessed.

2.6.1. Primary outcome

We will assess the pain intensity at five time points: immediately after the extraction and 3 h after the extraction, on the evening of the extraction, and one day and two days after the third molar extraction. We will calculate the area under the curve (AUC) to obtain data about pain intensity over this period. For pain intensity we will use a Numeric Rating Scale (NRS) from 0 to 10 [24]. The patients will receive a notification via text message to report on this outcome.

2.6.2. Secondary outcomes

Postoperative drug use will be measured at four time points: 3 h after the third molar extraction, the evening of the molar extraction day, and the following two days. The measured values refer to the time between the third molar extraction and the time point of assessment. The type of medication and the number of pills after the surgical procedure will be counted. Patients will be reminded by text message to complete the drug diary.

In the last questionnaire, after having both kind of treatments (a visit with the dentist one week after the second molar extraction), the patients will be asked for their preferred treatment of third molar extraction (third molar extraction with regular medication or third molar extraction with hypnosis and reduced medication).

2.6.3. Additional measures

At baseline, the patients will fill in the Expectation for Treatment Scale (ETS) [22], which captures the expected impact of hypnosis for pain relief during and after tooth extraction. After hypnosis, the patients will describe the hypnotic depth with the Inventory Scale of Hypnotic Depth [20].

2.7. Randomization

We will use central block-randomization with variable block length in a 1:1:1:1 ratio. The randomization sequence was generated using R (version 3.1.0) by a member of the Institute for Complementary and Integrative Medicine not further involved in the study. For allocation of patients via internet, the software REDCap® (Clinical Trial Center, University Hospital Zurich) was used to assure allocation concealment.

2.8. Statistical analysis

2.8.1. Sample size

Since no earlier data with AUC comparisons are available, we conducted sample size calculation procedures with the mean and standard deviations. According to an earlier study [8] with hypnosis in addition to pharmacological sedation (Propofol) for third molar extraction, the mean pain (NRS) score after surgery was substantially lower in the patients with hypnosis than the patients without hypnosis (2.57 (SD 1.48) vs. 3.97 (SD 1.45)). Based on these results, an expected effect size of hypnosis would be larger than 1. We considered an effect size of less than 1 for a nonpharmacological intervention to be more realistic. Therefore, we reran the power analysis with a mean difference between groups of 1.0 on the NRS between groups, which corresponds to an effect size of 0.68. We assumed five time points for the assessment and made different assumptions about the autocorrelation (rho) of pain assessments ranging from 0.5 to 0.85. Since the real autocorrelation is unknown, the required sample size to detect an effect with 80% power and alpha of 5% varied between 23 (rho = 0.5) and 31 (rho = 0.8) [25]. We used a sample size of N = 33 to account for two dropouts during the study.

2.8.2. Analysis population

We plan to run the analysis for the total sample who had an initial visit for third molar extraction. Since drop outs for visit 2 might be present, we will analyze the dataset in a modified intention to treat approach. Missing information from withdrawn patients at visit 2 will be imputed with established software packages for the primary outcome [26,27]. Patients who never attended any visit for third molar extraction will not be considered since the within-subject design requires at least one data point to estimate missing information.

2.8.3. Statistical hypotheses

For the primary outcome, the course of pain intensity (AUC), we will test the following null hypothesis about the effectiveness of hypnosis (with different doses of medication):

H0: Hypnosis plus reduced medication = the effect of no hypnosis with regular medication on the course of pain intensity (AUC) after third molar extraction. The AUC will be calculated based on the trapezoid formula as described by Pruessner et al. [28].

The secondary outcome will be the amount of pain medication within the two days after molar extraction.

On an exploratory level, we will test whether patients with higher expectations about hypnosis effectiveness will experience more treatment benefits (i.e., less pain) from hypnosis than patients with lower expectations. Similarly, we will test the impact of the following variables on the difference in pain levels between the usual care treatment and the treatment with hypnosis: treatment preference before treatment, hypnotic depth, impression of hypnotic depth from the dentist, and post hoc treatment preference.

2.8.4. Statistical procedures

For the primary outcome, we will compare the AUC with an ANCOVA with sex as the covariate. For a sensitivity analysis of the primary outcome, we will add an interaction term of type of treatment and high / low expectations (median split). We expect that hypnosis will still account for treatment effects, but the interaction term should be able to explain additional variance in the model.

Data on the amount of pain medication (secondary outcome) will be analyzed with a Wilcoxon rank test. For the analysis of predictors of hypnotic response (difference in AUC between hypnosis with reduced medication vs. no hypnosis with regular medication), we will use an ANCOVA model that accounts for expectations of patients, hypnotic depth, and experienced depth of hypnosis according to the dentist impression. A detailed analysis plan including missing data handling procedures will be written after data entry and data cleaning taking the distribution of scores and the performance of scales into account. For data analysis, we will use the software packages SPSS, Stata or R. All analyses will be conducted by a statistician unaware of the allocation of the patients.

2.9. Ethical aspects and data protection

Ethical approval was obtained from the CEC prior to the start of the study (Ethikkommission Ostschweiz, BASEC Nr. 2016-02161, 15. February 2017), and any amendments will be submitted to the CEC. Adverse events will also be reported according to the Swiss legal system to the CEC at minimum in a yearly report. Patient insurance is covered by the institution of the principal investigator (University Hospital Zurich). This trial was registered in the German Registry for Clinical Studies (Nr. DRKS00011848) on 11 April 2017 and is searchable via its Meta-registry (http://apps.who.int/trialsearch/). Data will be entered into REDCap®, which is stored on a secured server of the University Hospital Zurich. Data monitoring and quality control will be conducted according to the established procedures described in the Quality Management Handbook (Version 2.0) of the Institute for Complementary and Integrative Medicine, Zurich, Switzerland. Written and oral informed consent will be obtained from each patient before enrollment and randomization. Subjects' confidentiality will be protected by using pseudonymous data during data collection and data analysis.

3. Discussion

The aim of this study is to investigate the effectiveness of a standardized hypnosis in a routine setting of third molar extraction. The primary outcome of interest is pain within two days after extraction. In addition, we will investigate pain medication as the secondary outcome. Our trial is powered to detect a clinically relevant difference in pain between the different types of interventions.

The treatment with hypnosis requires excellent training and can be learned in available courses. Our approach follows a very structured induction model to increase the reproducibility of the findings. The dentist in our study has substantial experience with hypnosis, and therefore, our findings might overestimate treatment effects. However, the very structured approach of our intervention may help to implement this intervention in other settings with newly trained dentists.

We expect that some patients will not start the treatment after being provided with information and written consent at the first visit with the dentist. For practical reasons, the first surgery must be scheduled within 4 months, and patients might reconsider whether they want to be treated for a variety of reasons (i.e., time, payment, motivation). However, we do not expect any bias, since our analysis of interest is a within subject comparison.

If we are able to show with this trial that hypnosis with less medication during third molar extraction is able to reduce pain intensity, this treatment option might be offered as an additional way to treat

these patients. However, a larger-scale, multicenter trial with a variety of therapists will be required to prove effectiveness on a more general level with higher external validity.

Ethics approval and consent to participate

The study will be carried out in accordance with principles outlined in the current version of the Declaration of Helsinki, the guidelines of Good Clinical Practice (GCP) issued by ICH, and Swiss competent authority's requirements.

Consent for publication

All authors approved this manuscript for publication. After the analysis of this study, the sponsor investigator will make every endeavor to publish the data in a medical journal.

Availability of data and material

Access to all data sets and statistical code will be granted individually upon request.

Conflict of interest & funding

PM provides training in hypnotherapy, but no direct financial gains from this study can be expected. All other authors have no conflicting or competing interests to declare. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Authors' contributions

JB and SM drafted the manuscript. JB, ME and CW developed the study protocol. PM adapted the hypnosis and conduct the hypnosis. PM performs the third molar extractions and PM and ME conduct the control visits. All authors read, revised, and approved the final version of this manuscript.

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