1. Title

The effects of hypnosis on bleeding

2. Investigators & Qualifications

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Dr Cyna is a Senior Consultant Anaesthetist at the Women's and Children's Hospital in Adelaide. He is a senior lecturer at the University of Adelaide. He has published widely on topics related to paediatric anaesthesia, analgesia and hypnosis. He has been a lead researcher of numerous observational studies and randomised clinical trials.

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Dr Endlich is a senior registrar at the Women's and Children's Hospital currently doing her last year of training to become a specialist in anaesthesia.

3. Study purpose

The aim of this study it to assess whether hypnosis can affect the control of bleeding.

4. Background

Hypnosis appears to be an altered state of conscious awareness in which the hypnotized person becomes more responsive to suggestions. Suggestions are verbal or non verbal communications leading to subconscious changes to perception, mood and/or behaviour.

Hypnosis has been used as an adjunct to medical practice for over a century and has more recently become an area of scientific inquiry and clinical practice. Hypnosis is grounded largely on empirical studies although there are notable exceptions (RCTs) showing efficacy in a variety of clinical settings (1), especially in the treatment of pain and anxiety during invasive medical procedures (2-3).

Hypnosis as an intervention has been shown to be cost effective when used as an adjunct to clinical practice (4-5). Hypnotic suggestions to induce relaxation and to control fear have been reported to successfully reduce haemorrhage in haemophiliac patients half a century ago (6-7) In

addition, hypnotised patients have been shown to be able to control their own blood flow and possibly minimise blood loss (8-10). However, to date these studies have been of poor design and there have been no volunteer studies to confirm these findings.

The control of bleeding would be advantageous for patients having surgery under local or general anaesthesia where blood loss may be an important contributor to increased perioperative mortality and morbidity.d

Previous research therefore appears to suggest that hypnosis could play a role in the control of bleeding if this effect was confirmed in a well designed experimental study.

We therefore aimed to investigate whether hypnotised volunteers were able to stop and control the amount and location of their bleeding in response to suggestion.

5. Preliminary Study

The planned study is a pilot study performed in order to obtain baseline data for a larger randomised study in which we plan to compare bleeding time, amount of bleeding, local temperature and blood flow over the puncture sites between a hypnotised and non hypnotised arm of the same volunteer.

7. Participants

Healthy volunteers will be recruited within our workplace and circle of acquaintances.

Inclusion criteria:
- age: >18
- healthy adults

Exclusion criteria:
- age: <18
- coagulopathic
- mental disease
- drug or alcohol dependence
- chronic pain that has not been investigated and diagnosed by a qualified doctor

8. Study design

Following ethics approval and written informed participant consent, study participants will be asked to sit comfortably in a vacant clinical room such as DOSA. Here subjects will have a standardised hypnotic induction by an experienced hypnotist (AMC) using an eye fixation technique and progressive muscle relaxation for deepening the trance state. After suggestions for the development of arm anaesthesia using anaesthetic glove imagery, small areas of skin over the anatomical snuff box of each hand will be cleaned by the hypnotherapist / anaesthetist with antiseptic wipes.

After obtaining permission from the volunteer while in hypnosis (either with a finger signal or nod of the head) a 23 gauge needle will be inserted through a skin fold overlying the anatomical snuff box in each hand. Following randomisation of which arm will stay in hypnosis (the participant's left or right) suggestions will be given for the allocated arm to stay in hypnosis when the needle is removed and that bleeding will be controlled so that the skin stays dry. Similarly in the contralateral arm allocated to bleed normally when the needle is removed, it will be suggested that when the needle is removed the arm will come out of hypnosis and the blood vessels return to their normal

caliber so that bleeding occurs normally. A second researcher will then be asked to enter the room to measure our key outcomes. Both needles will then be removed simultaneously and bleeding from each puncture site measured by this researcher using filter blotting paper to absorb any blood and a stopwatch to time when bleeding starts and ceases in each hand following needle removal.

The Randomisation will be obtained by a computer generated random number sequence and allocation concealment assured by using consecutively numbered opaque envelopes containing the randomisation sequence. The envelopes will be opened after needle insertions but before the outcome assessor enters the room. Following the hypnosis intervention a blinded observer will measure bleeding using absorbant standardised blotting paper on removal of the needles and the outcome assessor will measure the spread of blood absorbed by the paper in mms and he/she will be asked which arm they believe to be hypnotized.

Dependent on equipment availability we also plan to use thermo-imaging of the puncture site as a measure of temperature change and local blood flow as a secondary outcome. Videotaping of the whole process is also planned.

We plan to recruit 20 subjects in the first instance to assess the feasibility and sample size of a future study investigating this phenomenon.

Following completion of all measurements, participants will have their hypnosis terminated in a standardised fashion (11) and all prior hypnotic suggestions removed as subjects return to normal conscious awareness.

Data collection will be via a data-sheet for each patient. Study data will then be transcribed on an excel spreadsheet for further analyses. Descriptive statistics will be reported, Chi squared between arms for dichotomous outcomes and students t test for continuous data such as blood blotting paper measurements will be used as appropriate. Differences in the measurements of bleeding outcomes between the two allocated hypnosis and non hypnosis hands will be analysed and a P values < 0.05 will be considered significant.

9. Safety, ethical and ecological considerations

Hypnosis can have some unwanted side effects such as:
- dizziness
- headaches
- temporary disorientation
- temporary amnesia

To minimize the potential of such effects an experienced hypnotist will conduct the study and guide each participant back to his previous self after completion of the measurements. All participants will also be given our telephone number to call if they notice anything out of the ordinary or if they have concerns or questions after taking part. They can also come to this health facility at anytime to see Dr Allan Cyna or Dr Yasmin Endlich in person.

Risks of the needle prick are:
- infection
- bleeding
- damage to structures
- pain, discomfort

These risks are minimised by using very small needles (23-gage) and antiseptic. Additionally, there are no structures at risk when using the proposed skin fold.

10. Consent form

An informed consent will be obtained. See attachment.

11. Confidentiality
All study data will be stored in a password protected computer disk and / or locked filing cabinet for 15 years after publication of the trial report.

12. Other relevant information
none

13. Other ethics committees to which the protocol has been submitted.
none

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