PARTICIPANT INFORMATION SHEET AND CONSENT FORM

CLINICAL TRIAL / INTERVENTIONAL STUDY

A Pilot Randomised Controlled Trial of SMS Support for Patients Tapering Opioids for Chronic Pain.

Invitation
You are invited to participate in a research study that will investigate how individuals experience the first 4-weeks of opioid medication tapering and whether receiving SMS text messaging offers additional support to patients with chronic pain during opioid tapering.

The study is being conducted by:

- Professor Paul Glare, Chair in Pain Medicine, Sydney Medical School, The University of Sydney; Director of the Pain Management Research Institute, Royal North Shore Hospital
- Associate Professor Claire Ashton-James, PhD, Pain Management, Northern Clinical School, The University of Sydney
- Dr. Ali Gholamrezaei, MD, PhD, Research Fellow, Northern Clinical School, The University of Sydney
- Michael Magee, PhD candidate, Pain Management Research Institute, Royal North Shore Hospital
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Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. ‘What is the purpose of this study?’
The purpose is to investigate how individuals experience the first 4-weeks of opioid medication tapering, what factors influence their confidence in their ability to taper and whether delivering education and advice about chronic pain and opioid dose reduction via text messages can provide additional support to patients with chronic pain during opioid tapering. It is hoped that this study will help improve our understanding of this early tapering experience (for example, the challenges and needs during this time) and to find effective interventions to improve health outcomes by providing information in the form of text messages.

2. ‘Why have I been invited to participate in this study?’
You are eligible to participate in this study because you are currently prescribed opioids for chronic pain, and it has been recommended that you reduce your dose.
3. ‘What if I don’t want to take part in this study, or if I want to withdraw later?’

Participation in this study is voluntary. It is completely up to you whether you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with your treating clinicians or the staff caring for you.

If you wish to withdraw from the study, you can do so at any time without having to give a reason. You can withdraw from receiving the text messages by replying “STOP” to the text messages at any time.

If you choose to withdraw, you can complete and sign the ‘Participant Withdrawal of Consent Form’ at the end of this document and return it to the address supplied or send an SMS or email to the investigators requesting an online copy of the withdrawal form.

If you withdraw from the study, all of your data and information will be deleted from study records and will not be used in any future research, unless you agree to your de-identified (anonymised) information and data being published and used in future research.

Note: The principal investigator of the study may remove a research participant from the study at any time in the event the participant’s safety may be compromised such as the following:

- any unanticipated health problems;
- the participant is non-compliant with the study protocol / procedures;
- principal investigator determines that it is in the best interest of the participant to be removed from the study.

4. ‘What does this study involve?’

Your involvement in the study will last for 4 weeks and it starts from the day your treating clinician recommends you reduce your opioid dose using a dose reduction plan.

If you decide you would like to participate in this study,

1. You will provide your contact information to your Pain Specialist who will ask a member of the research team to contact you by phone to confirm your interest and eligibility to participate in the study and to answer any questions you may have.

2. Once you agree to participate in the study, the online consent form and baseline survey will be emailed to you to collect your information relevant to your tapering experience, such as information relating to your pain, mental health and health status.

3. This is a randomised clinical trial. Sometimes researchers don’t know whether an intervention can help management of patients with a particular condition, so comparison is needed to be made between different treatments. To do this, study participants are put into groups that receive different interventions, and the outcomes of each group are compared. To ensure the groups are similar to start with, a computer allocates each study participant into a group randomly, like the flip of a coin. Neither the doctor, researchers, nor the study participant can decide which
treatment the participant receives. Once you have consented to participate in the study and completed the baseline survey, you will be randomised into one of the two study groups.

4. Regardless of which group you are allocated to, you will continue your treatment as usual under supervision of your doctor.

5. You will complete some short questionnaires on a weekly basis and some once at the beginning and after 4 weeks. These questionnaires will help the researchers to understand your experiences before, during and after the initial period you start tapering.

6. You will be asked to complete the questionnaires online. We need your email address to send you a link to the questionnaires. If you anticipate difficulty accessing internet or completing questionnaires online any time during the study, you may complete these questionnaires over the phone. You may receive text message or phone call reminders from a member of the research team to complete the questionnaires.

7. If you are allocated to the intervention group, in addition to your treatment as usual, you will be requested to watch an explanatory video at the beginning of the study that explains the study and then you will receive text messages via phone. The messages may be delivered during the day (usually 9am-5pm) and on 4 to 7 days of the week for the length of the intervention (4 weeks). All the messages are designed to be 'one-way' meaning you are not required to reply.

It is not necessary to reply to the messages. But, if you do decide to reply to any message you receive, all return messages will be saved and may be analysed later to help understand the usefulness and acceptability of the messages.

**Please note that if you experience a flare up of pain or any other pain-related problem, you should contact your treating doctor or clinician as part of the usual care.**

8. In order to understand your experience of tapering and evaluate whether the intervention is making any difference, you will be asked to complete a number of surveys and questionnaires. You will be asked to complete some questionnaires that evaluate your pain, mood, quality of life, other symptoms and use of opioid medications.

9. If you are in the intervention group, you also will be asked to complete a survey at the end of the intervention to give us feedback about the acceptability and usefulness of the SMS intervention.

10. This study is a single-blinded trial, it means that the study participants do know which treatment group they are in but their treating clinician and the researchers who assess the information do not know which treatment the participant is receiving (although, if the treating clinician needs to find out for safety reasons, they can do so).

In this particular study, an independent researcher keeps the codes of the groups until the study is finished and all data are gathered. You will be asked to not inform your treating clinician or the researchers you are in contact with about the group you
are in, unless directly requested by your clinician or one of the research team members or you decide to do so for safety reasons.

5. ‘How is this study being paid for?’
This study is supported by a grant to the University of Sydney from the Ernest Heine Family Foundation.

6. ‘What are the alternatives to participating in this study?’
If you decide not to participate in this study, and you wish to continue treatment, you will still receive the standard treatment available for your condition.

7. ‘Are there risks to me in taking part in this study?’
We strongly advise you NOT to watch the video and or read any text messages and or response to any phone calls whilst driving or crossing roads to ensure your safety and abidance with State Government laws.
We expect there to be minimal risk involved for you when participating in the study aside from giving up your time. If any unexpected consequences occur during your participation or you feel distressed by this study, please contact the trial coordinator [Michael Magee 02 9463 1528] for advice, your GP or attend your local Hospital Emergency Department.

Regardless of being in the intervention or control group, if you experience a flare up of pain or any other pain related problem, you should contact your treating doctor or clinician as part of the usual care. There are also some telephone support services which you can contact. For mental health support call lifeline: 13 11 14 (24 hours), for withdrawal support contact the Alcohol and Drug Information Service: 1300 340 357 (24 hours), for chronic pain support call the Pain Link Peer Support service: 1300 340 357 (leave a message for call back service).

Your participation in this study will cost you some time and energy. The intervention itself will take only a minute or two to read and digest the text message. The completion of all the surveys will take around 30 minutes. We will invite some people to complete a feedback survey which will take approximately 10 minutes to complete. The surveys will involve questions relating to your function, pain, quality of life, how your symptoms have changed, and your use of medications. It is possible that you may feel inconvenienced by completing the questionnaires. If this happens, you are able to withdraw from the study as explained above in section 3.

8. ‘What happens if I suffer injury or complications as a result of the study?’
If you suffer any injuries or complications as a result of this study, you should contact the trial coordinator as soon as possible, who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the treatment, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.
If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

9. ‘Will I benefit from the study?’
This study aims to understand tapering better and support patients with chronic pain during reduction of opioid medication dose leading to improvements in health outcomes and confidence in self-management of pain. However, we cannot guarantee or promise that you will receive any direct benefits from this research. Allocation to the study groups is randomised by the computer and is not based on doctor, participant, or researcher decision.

10. ‘Will taking part in this study cost me anything, and will I be paid?’
Participation in this study will not cost you anything other than the time taken to read the text messages and answer the online surveys. You will not receive payment to participate.

11. ‘How will my confidentiality be protected?’
Of the people treating you, only the investigators named above, your Pain Specialist and the study coordinator will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above and The Northern Sydney Local Health District Human Research Ethics Committee, (HREC) for monitoring purposes and regulatory bodies will have access to your details and results that will be held securely at The Pain Management Research Institute.

We will use Message Media service (https://messagemedia.com/au) to send SMS to your phone. This is an automated secure system which is using protocols for encryption and authentication. No one other than specified above will have access to your phone number and to the messages you will send as replies.

12. ‘What happens with the results?’
We hope that the results of this research project will be published in scientific journals and presented at conferences. In any publication or presentation, information will be provided in such a way that you cannot be identified, except with your express permission. Results of the study will be provided to you, if you wish.

13. ‘What happens to my treatment when the study is finished?’
At the end of the study you will no longer receive any text messages or surveys. You are free to keep all messages you have received on your phone for future reference if you wish. Beyond the length of the study intervention, we advise you to continue working with your doctor for managing your pain and opioid medication dose reduction.

14. ‘What should I do if I want to discuss this study further before I decide?’
When you have read this information, the study coordinator Michael Magee will discuss it with you and answer any questions you may have. If you would like to know more at any stage, please do not hesitate to contact him on 02 9463 1528 during office hours or by email: mmag9080@uni.sydney.edu.au

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15. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by the Northern Sydney Local Health District HREC. Any person with concerns or complaints about the conduct of this study should contact the Research Office who is nominated to receive complaints from research participants. You should contact them on 02 9926 4590 and quote HREC reference 2020/ETH03288.

The conduct of this study at the [name of hospital] has been authorised by the [name of Local Health District]. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer [or other officer] on [telephone number] and quote protocol number [insert local protocol number].

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.

This information sheet is for you to keep.
CONSENT FORM

CLINICAL TRIAL / INTERVENTIONAL STUDY

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1. I agree to participate as a subject in the study described in the Participant Information Sheet set out above.

Please provide your full name

2. I acknowledge that I have read the Participant Information Sheet, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

○ YES

○ NO

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

○ YES

○ NO

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the investigators or treating clinicians.

○ YES

○ NO

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

○ YES

○ NO

6. I agree that data gathered in this study may be used in future research by the Pain Management Research Institute.

○ YES

○ NO

7. I understand that if I have any questions relating to my participation in this research, I may contact Michael Magee by phone (02) 9463 1528 or email (mmag9080@uni.sydney.edu.au) who will be happy to answer them.

○ YES

○ NO
8. I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.
   ○ YES
   ○ NO

Complaints may be directed to the Research Office on Level 13, Kolling Building, Royal North Shore Hospital, St Leonards NSW 2065
Phone 02 9926 4590 | email NSLHD-research@health.nsw.gov.au

‘I understand that by submitting this consent form I consent to participate in the study as stated in the participant information statement.’
   ○ YES
   ○ NO
Appendix 15.13 - Patient Information Sheet & Consent Form  

CLINICAL TRIAL / INTERVENTIONAL STUDY

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REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Pain Management Research Institute, the Pain Management & Research Centre, or my medical attendants.

For online form

Please provide your full name

‘I understand that by submitting this withdrawal form I am withdrawing my consent to participate in the study as stated in the information statement.’

- YES
- NO

‘I agree my de-identified (anonymised) information and data to be used in this and/or future research study.’

- YES
- NO

SUBMIT

For paper form

Signature    Date

The section for Revocation of Consent should be forwarded to:

*Insert Site Principal Investigator name/address*