Participant information sheet

StudyU: a new tool to self-manage chronic pain

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Invitation to participate

This research is being carried out by Health Hub Doctors Morayfield and Woorim, The University of Queensland (UQ), Princess Alexandra Hospital, Champion Health Agency and the HassoPlattner Institute, Germany. Please take the time to read this information. You may wish to discuss the study with a relative or friend before deciding about whether to take part.

What is this research about?
Chronic pain is common and hard to treat. In this research study, you will test a non-drug treatment, like exercise or meditation, to see if it helps your pain. You will use a free mobile app (StudyU) to rate your pain once a day, helping you and your doctor to decide what works best for you.

You will choose which non-drug treatment you want to test. Researchers will set-up your Personalised Treatment Trial in StudyU, to test your non-drug treatment. Your experiment will last 8-12-weeks. After you complete your experiment, you will receive a personalised report, which you can also share with your doctor, about whether or not the activity you chose worked for you.

What are Personalised Treatment Trials?
A Personalised Treatment Trial is a new way of working out whether a treatment is working for you. Most research studies test treatments on groups of people and calculate average results. Personalised Treatment Trials are different, because they test whether a treatment works for a particular individual, like you.

Who can participate?
You may be eligible to participate if you:
1) Are 18 years or older,
2) Are experiencing persistent pain that is impacting on the way you function in daily life,
3) Own a mobile phone (ether iPhone or Android) that can connect to the internet.

If you agree to take part in this study, your doctor or nurse will help you pick a non-drug treatment, and a member of the UQ study team will ask you some further questions to check if you can participate in this study.

What will participation involve?
Your Personalised Treatment Trial will take 10-12 weeks. The length of the trial will be a shared choice between you and the UQ study team. A list of potential activities, available at no or low cost to you, may include:

- Mindfulness practice
- Online pain management support
- Online mental health support
- Low impact exercise (e.g. chair yoga, tai chi)
- Walking program (self-managed or group)
- Pool program
- Personalised exercise plan
- Group fitness program
- Other activity – you can discuss other options with your doctor or nurse.

Your total length of time in the study will be around 4 months, including the 10-12-week Personalised Treatment Trial. You will receive a follow-up survey four weeks after your Trial finishes. If you decide to join this study, you will complete the following steps:

1. **Referral from Doctor:** You will be referred to the UQ study team by a participating Health Hub Doctor. A nurse may assist the doctor in completing the referral form. Your doctor will review your medical history including medications, and any disease or condition that might affect your pain or the type of activity you can participate in. If necessary, you may be referred for further assessment (for example, by an exercise physiologist or physiotherapist).

2. **Initial Survey:** Before starting the Personalised Treatment Trial, you will be contacted by the UQ study team to answer questions about your pain, including other health and personal information. This will take 5 minutes. Questions will assess your disability from pain, pain severity, pain self-efficacy (how you feel about managing your pain), depression, anxiety, stress, and quality of life.

3. **Download the StudyU App on your mobile:** The UQ study team will help you download the StudyU mobile app and set up your Personalised Treatment Trial. You can download StudyU yourself using the QR codes or links below or wait for a UQ study team member to contact you.

App store (iPhones)
https://apps.apple.com/us/app/studyu-health/id1571991198?ign-itscg=30200&ign-itsct=apps_box_link

Google Play (Android)
https://play.google.com/store/apps/details?id=health.studyu.app&pli=1

4. **Your Personalised Treatment Trial Starts**: Your Trial will be 10-12 weeks long. There will be a baseline (no treatment) phase where you do not use the new treatment for 2 weeks. Next, is a treatment phase, where you start your new treatment for **6-8 weeks**. After the treatment phase, you will stop the new treatment but continue to rate your pain for another 2 **weeks.** Rating your pain will take less than one minute each day. StudyU team members will check in with you weekly to see if you need any help with your Trial.

5. **Report of your Trial results:** After your Trial is over, the UQ study team will analyse your daily entries into the StudyU mobile app to create a report. This report will be sent to you and your referring doctor. We recommend that you make an appointment with your referring doctor to discuss whether the treatment you tried worked. You and your doctor can also decide whether to continue the treatment at the end of the trial or try a new one. If you have any concerns about your doctor being informed about this study and your results, please let us know.

6. **Follow-up questionnaire and interview:** About four weeks after the Trial finishes, you will be asked to complete a follow-up survey about your Trial experience. You will also be invited to participate in a recorded interview, taking about 45-50 minutes, to tell us more about your experience using the StudyU App.

What are the benefits of taking part?

This Trial will help you decide whether the treatment works in improving your daily function or chronic pain symptoms. You will still be able to use the StudyU mobile app once the research study finishes.

What are the risks of taking part?
There is some risk that the treatments that you are testing could harm you (for example, exercise may temporarily increase chronic pain). If you have any concerns about medical side effects, you can call Health Hub Doctors Morayfield or Woorim. Morayfield can be reached between 8AM and 8PM daily, including weekends and public holidays on 07 5322 4900. If you have any urgent concerns after 8pm, you can ring 13 SICK and advise you are a patient of Health Hub Doctors Morayfield or Woorim. 13 SICK will address your urgent concerns and send a report to your usual doctor.

Costs
There is reimbursement available for your time to complete the two surveys (at the start and end of your Trial) and an interview (at the end of your Trial). You will be given a $25 gift voucher for each survey, and a $50 gift voucher for participating in the interview. Patients will be offered a $40 gift voucher on study enrolment to compensate them for any costs incurred. Patients who book an appointment with their GP following completion of their self-experiment to discuss their results and future interventions will also be offered a $40 gift voucher to compensate them for any costs incurred.

Do I have to participate?
No. Participation in this research is entirely voluntary (your choice). If you don't wish to join, you don't have to. Your decision to not join the study will not harm you or your relationship with your doctor or the Health Hub Doctors Morayfield/Woorim clinics. If you do consent to participate, you may withdraw at any time, without needing to give anyone a reason why you stopped. If you decide to withdraw or stop your experiment, we will not collect additional information from you. Data collected up to the time you withdraw or stopped will form part of the research project results. If you do not want your information already collected to be included, you must tell this to any UQ study team member, at the time you withdraw or stop.

What will the information collected from me be used for?
All information collected about you will remain private and confidential and securely stored by The University of Queensland (UQ). The StudyU mobile app does not store any personal information identifying you. All non-identifiable data recorded in the StudyU app will be stored in the safe and secure server hosted by HassoPlattner Institute in Germany. This non-identifiable group data will be made publicly available in reports, but no one will be able to identify you. Data collected will form part of an open and free global database to help future research. All personal information linked to the data will remain securely stored at UQ during the study, accessible only to the Chief Investigators, Study Manager and Research assistant, to protect your identity. We will also send a report of your results to your doctor, unless you tell us not to.

After everyone has completed the study, data will be de-identified and archived for 15 years.
Findings from the study may be published in peer-reviewed research publications and presented at conferences. You will not be identifiable from any public reports arising from the project. Non-identifiable data may also be shared with other researchers and contribute to further related research. Future use of the data, if any, will not involve identifiable data. If you would like to receive a summary of the study findings, please tick the box on the Consent Form.

Where can I get more information about the study?
If there is anything you do not understand, or you have any questions or concerns about the research, please contact Associate Professor Jane Nikles, or Ms Shauna Fjaagesund on 07 3381 3043 or 0430 217 732. E: studyU@uq.edu.au.

Ethical approval
This study adheres to the Guidelines of the ethical review process of The University of Queensland and the National Statement on Ethical Conduct in Human Research. Whilst you are free to discuss your participation in this study with UQ study members, if you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Coordinators on 07 3365 3924 / 07 3443 1656 or email humanethics@research.uq.edu.au.

This information is provided for you to keep.

Participant consent form

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Name of Participant: _____

By signing this form, I confirm that I have:

1. Read and understood the participant information sheet.
2. Had any questions or concerns addressed to my satisfaction.
3. Been informed of the possible risks or side effects of the treatments, tests, activities or procedures being carried out
4. Been informed that confidentiality of my information will be maintained and safeguarded. I understand that any information that could be traced back to me will remain confidential and securely stored by The University of Queensland.
5. Been informed that the StudyU mobile app does not store any personal identifying data, it only stores my pain ratings It does not store any information that could link me to my answers.
6. Been informed all non-identifying anonymised data recorded will be stored in a safe and secure way and will form part of a global database and be available for future research.
7. Been informed that all my personal information linked to the data will remain at The University of Queensland, so that no-one outside the study team will be able to know who the information belongs to.
8. Consented for my data to be handled as outlined above.
9. Agreed to participate in the activities of this study.

Signature _____ Date _____

I am happy for my doctor to be given a copy of my study results: Yes ☐ No ☐

I would like to receive a summary of results by email at the conclusion of the study: Yes ☐ No ☐
Email address: _____. Your email address will be securely stored at The University of Queensland and not shared with anyone outside the research team.

I consent for my data to be used in future research that is an extension of or related to this project after receiving human research ethics approval: Yes ☐ No ☐

I consent to be invited to take part in further related research, pending future research funding and human research ethics approval. Yes ☐ No ☐

Leave completed form with Health Hub doctor, nurse or receptionist.