**Participant Information Sheet**

**Feasibility of assessing clinical efficacy and cost-effectiveness of the UPLIFT program vs. usual physiotherapy care for people with persistent low back pain: a pilot randomised non-inferiority controlled trial**

Investigators: Mr Jonathan Dearness

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**Introduction**

At Gold Coast Health we are committed to providing optimal care to our patients.We wish to invite you to be a participant in this research so we can test the feasibility of a group program for people challenged by persistent low back pain (LBP), within the Physiotherapy service.

**What is an Information Statement?**

These pages tell you about the research study. It explains to you clearly and openly all the steps and procedures of the project, to help you decide whether or not you would like to take part. Please read this Information Statement carefully.

***It is okay to say no.*** Before you decide if you want to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

**Project background and aims**

The primary aim of this study is to determine the feasibility and acceptability of conducting a full-scale clinical trial exploring the effects of the UPLIFT program (compared to usual care physiotherapy) among people with persistent LBP. The secondary aim is to explore the clinical and cost effectiveness of the program. UPLIFT is a novel program established by GCUH clinicians, consisting of weekly interactive group sessions of psychologically-informed education and exercise.

**What does my participation involve?**

After clinical assessment determines that physiotherapy intervention would be appropriate, participants will be randomly allocated to one of two groups. If allocated to the **intervention group**, you will attend weekly UPLIFT group sessions for a total of 5 weeks. The sessions will take ~90 minutes each, and will involve:

1. A supervised graded exercise program targeting general conditioning and the restoration of safe movement; and
2. Education sessions; each targeting a different theme: 1) pain neuroscience; 2) activity pacing; 3) flare-up management; 4) acceptance; and 5) adopting healthy lifestyle behaviours (including sleep hygiene and movement).

UPLIFT incorporates motivational interviewing techniques, allowing participants to cognitively and experientially process the program content. Volunteer peer mentors who have successfully completed UPLIFT will assist, sharing their own experience with new participants. UPLIFT’s interactive delivery style aims to improve patients’ knowledge, which underpins behaviour change. Patients in the UPLIFT program are considered active partners in their rehabilitation by aiming to reconceptualise their understanding of pain, develop active coping strategies to self-manage LBP, and re-engage in value-based activities. If you miss a week, or want to refresh on any topic, you can attend any of these sessions again (they will repeat every 5 weeks).

Participants allocated to the **control group** will attend individual physiotherapy sessions, which allow a pragmatic approach for selection of treatment modalities and treatment frequency (maximum of six treatment sessions), over a maximum period of ten weeks. Treatment will be delivered by experienced physiotherapists, working currently in these roles as part of the usual care of low back pain patients.

**You will be asked to complete some surveys** at the start and finish of the study, which should take between 10-15 minutes. Survey questions will be about your satisfaction with care/treatment and the effect of your care/treatment. You may also be asked some questions about your experience with participating in this study in a short interview, which will be recorded (interview is voluntary). Six months after the study, you will be contacted by a research assistant who will ask you to answer one rating question.

**Risks and Discomfort**

We anticipate minimal risk associated with participating in this study. Possible risks may include inconvenience, discomfort or emotional distress. If you experience any of these, you can let us know and we will do our best to alleviate it; otherwise, you are able to withdraw from the study at any time without consequence.

**Benefits**

The intervention aims to improve symptoms of LBP and may also result in improved movement, function and/or exercise habits. The evidence and theory underpinning UPLIFT suggests that it is likely to work in a significant number of cases, but not all. The findings of this study will help us understand if the UPLIFT program is feasible, if it works as well as or better than usual care, if it is cost effective, and if it is acceptable to patients. Hence, it is likely to benefit patients and consumers in the future. Personally, you may get satisfaction from participating and you may benefit from learning how to improve your movement, function, sleep, flare up management skills and overall quality of life. Both arms of the study will be made available to participants after study completion. For example, if you were allocated to the control group (individual physiotherapy) but you want to experience UPLIFT, you have the option to attend the UPLIFT program after you finish the study.

**What information will you be collecting from my health records?**

To help us better understand the treatment and management of LBP, we will look at information related to the number of services accessed by participants and the cost associated with these services. To do this, we will collect information related to your health service usage from Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) and link this data with hospital records and other data collected during the study. Data to be collected from hospital admission, outpatient and emergency department presentations, MBS and/or PBS will include:

1. Hospital admissions, outpatient episodes and emergency department presentations including episode date; clinical, demographic and costing information (such as diagnosis, length of stay, cost of encounter, etc.) for the duration of the study and 12 months prior to consenting, from routinely-collected hospital and emergency department administrative data; and
2. MBS claim details, costs and service provider information; and PBS item description, costs and prescribing details, from Services Australia.

You will be asked to sign a consent form authorising the researchers to access your MBS and/or PBS data as outlined in the consent form. Medicare collects information on your doctor visits and the associated costs, while PBS collects information on the prescription medications you have filled at pharmacies and the cost to the government of those medications. The consent form is sent securely to Services Australia who holds MBS and PBS data confidentially.

**Storage, retention and destruction of information**

Participants will be given a unique code (e.g. P01) at the beginning of the study that will be linked to their personal details via an encrypted digital file only accessible to the study team. Data will be stored on Griffith University research data management cloud platform ResearchSpace using a private institutional login accessible only by the researchers. Paper data collection forms, participant surveys and consent forms will be stored in a locked filing cabinet in a code-locked physiotherapy staff room at GCUH. Electronic data files will be password protected, with the password known only to the research team. All confidential information will be securely destroyed after five years from the publication of the projects’ final report.

A summary of the research findings can be made available to you at the completion of this study. If you wish to obtain a copy of these findings, please tick the box on the consent page below.

**Confidentiality**

Your confidentiality will be assured. The information provided by you for this study will be non-identifiable. Only the researchers named above will have access to your details and results, which will be held securely at Gold Coast Health and Griffith University. The research data may be accessed by auditors, ethics committees or regulatory authorities.

* Research data gathered from this study may be published; but identifying information will not be used.
* There is no possibility of re-identification of participant data at any stage, including within publications.
* MBS/PBS data will not be used in any future or unspecified research outside of the approved study. Outcome data generated from this study (i.e. survey data on effects of intervention) may be included in analysis for the larger planned UPLIFT trial, for which this feasibility study is being conducted.
* For care purposes, we will let your physiotherapist know you have been recruited to the study.

**Your participation is voluntary**

Your participation in this study is completely voluntary and there will be no cost to you. If you do not want to take part in this study, you do not have to; you should feel under no obligation to participate. Your decision whether or not to participate will not impact on your medical care in any way or your relationship with Gold Coast Health.

**Withdrawing from the study**

You are under no obligation to continue with the study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons, and you do not need to provide a reason. You can withdraw from the study at any time by completing and signing the ‘Participant Withdrawal of Consent Form’. This form is provided at the end of this document and is to be completed by you and supplied to the research team if you choose to withdraw at a later date. If you withdraw from the study, you will be able to choose whether the study will destroy or retain the information it has collected about you. You should only choose one of these options. Where both boxes are ticked in error or neither box is ticked, the study will destroy all information it has collected about you.

**Privacy Statement:** The information collected is confidential and will not be disclosed to third parties, except to meet government, legal or other regulatory authority requirements.

**Complaints:** This study has been approved by the Gold Coast Hospital and Health Service Queensland Health Human Research Ethics Committee (HREC). If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact the HREC Coordinator by phone: (07) 5687 3879 or by email: GCHEthics@health.qld.gov.au and quote reference: HREC/2021/QGC/75050.

**Contact:** If you have any further queries in relation to any aspects of this study please contact one of the researchers (Jonathan Dearness, contact details on Page 1).

**Thank you for taking the time to consider this study. If you wish to take part, please sign the attached consent form. You will be given a copy to keep.**

**CONSENT TO PARTICIPATE IN RESEARCH**

**Study:** Feasibility of assessing clinical efficacy and cost-effectiveness of the UPLIFT program vs. usual physiotherapy care for people with persistent low back pain: a pilot randomised non-inferiority controlled trial

**Investigators:**  Mr Jonathan Dearness, Dr Shelley Roberts, Professor Michel Coppieters, Dr Joshua Byrnes, Bev Stripp

1. I understand that the researcher will conduct this study in a manner conforming to ethical and scientific principles set out by the National Health and Medical Research Council of Australia and the Good Clinical Research Practice Guidelines of the Therapeutic Goods Administration.
2. I acknowledge that I have read, or have had read to me, the Participant Information relating to this study. I acknowledge that I understand the Participant Information. I acknowledge that the general purposes, methods, demands and possible risks and inconveniences which may occur to me during the study have been explained to me by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and I, being over the age of 18 acknowledge that I understand the general purposes, methods, demands and possible risks and inconveniences which may occur during the study.
3. I acknowledge that I have been given time to consider the information and to seek other advice.
4. I acknowledge that refusal to take part in this study will not affect patient care or my relationship with Gold Coast Health.
5. I acknowledge that I am volunteering to take part in this study, and I may withdraw at any time.
6. I acknowledge that this research has been approved by the Queensland Health Human Research Ethics Committee.
7. I acknowledge that I have received a copy of this form and the Participant Information Sheet, which I have signed.

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| --- | --- | --- | --- |
| Signature of participant  |  | Date: |  |
| Name of participant |  |  |  |
| Signature of witness |  | Date: |  |

🞏 I wish to receive a copy of study findings, to (email): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**RESEARCH PARTICIPANT WITHDRAWL OF CONSENT FORM**

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You can withdraw your participation consent by advising the researcher verbally, via email to jonathon.dearness@health.qld.gov.au or by returning this completed form to:

Jonathan Dearness

Physiotherapy Department

Gold Coast University Hospital

1 Hospital Boulevard

SOUTHPORT QLD 4215

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Gold Coast Hospital and Health Service, Queensland Health, or Griffith University.

* DESTROY all information collected about me to date so it can no longer be used for research
* RETAIN all information collected about me to date so it can continue to be used for research

|  |  |  |  |
| --- | --- | --- | --- |
| Signature of participant |  | Date: |  |
| Name of participant |  |