ROYAL PRINCE ALFRED HOSPITAL

Physical Activity Coaching for Adults with Mobility Limitations: A Pragmatic Randomised Controlled Trial

INFORMATION FOR PARTICIPANTS

Invitation
You are invited to participate in a research study, looking at the benefits of two physical activity intervention programs aimed at improving physical activity levels among adults with self-reported difficulty walking.

The principal investigators for the study are:
Professor Catherine Sherrington - University of Sydney
Professor Rana Hinman - University of Melbourne
Professor Maria Crotty - The Flinders University of South Australia
Professor Tammy Hoffmann - Bond University Limited
Professor Lisa Harvey – University of Sydney
Professor Nicholas Taylor - La Trobe University
Doctor Leanne Hassett - University of Sydney
Associate Professor Anne Tiedemann - University of Sydney
Dr Bethan Richards – Head of Department of Rheumatology (RPAH) SLHD

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.

What is the purpose of this study?
This study is a randomised controlled trial. The purpose of this study is to investigate the impact of two physical activity intervention packages on the physical activity levels of adults who report that they have walking difficulties compared to no intervention. The information in this sheet can help you decide if you would like to take part in this study and describes what you can expect.

Study procedures and what is involved
The study will be conducted over 12 months. If you agree to participate in this study, you will be required to sign the Participant Consent Form prior to the commencement of any study procedures.

Once it is confirmed that you are eligible to take part in the study, you will be asked to complete a series of questionnaires about your general health, medical, fall history and current physical activity habits. These questionnaires will also be repeated at 3, 6 and 12 months after study commencement. The questionnaires will take about 20 minutes to complete each time.

In addition to the questionnaires, the amount of physical activity you do will be measured at the start of the study and again at 6 and 12 months months after study commencement over a 7-day period using a *StepWatch* activity monitor. This small device is worn around your ankle during the day and is able to accurately estimate how physically active a person has been throughout the day. The *StepWatch* will be posted to you with clear instructions for use and telephone support

will be available. You will also be provided with pre-paid envelopes to return the device and questionnaires to the research centre.

Group Allocation

To determine the benefits of the two intervention programs there will be three groups. The first group of people (Coaching to ComeBACK) will receive the intervention program for 6 months which involves an in-person physical activity assessment, telephone health coaching, , choice to use technology to monitor your activity levels and access to online resources. The second group of people (Texting to ComeBACK) will take part in an intervention program for 6 months, which involves a telephone-based physical activity assessment, text messaging and access to online resources. The third group of people (Texting to ComeBACK later) will not have any intervention for the first 6 months but will then receive the same intervention as the second group (Texting to ComeBACK). If you decide to participate in this research study, you will be randomly allocated to one of the three groups. All groups will receive any usual care provided by your health service providers.

Group 1 Coaching to ComeBACK ***Group***

If you are allocated to the Coaching to ComeBACK group you will receive

i) *a single face-to-face one-hour assessment* of mobility and physical activities undertaken at a home visit from a physiotherapist from which a tailored plan to improve physical activity through participation in suitable activities will be developed in negotiation with you. The choice of physical activity will be guided by personal preference, logistics, physical abilities and evidence of effectiveness.

ii) *6 month phone-based coaching* will be delivered by trained physiotherapists through a centralised service and will support you in getting started and then to keep on going with your physical activity plan. You will be encouraged to access the service approximately once a fortnight for 6 months during the study. Phone coaching appointments vary according to your needs but you could expect that they generally last around 20-30 minutes/session. Access to this service will stop at the conclusion of the study intervention period.

iii) in addition you will be offered technology to use where appropriate to help you being active e.g. (the Fitbit) or a simple pedometer that does not connect to the internet.

iv) have access to online resources to help you be more physically active.

The overall time commitment for the Coaching to ComeBACK group following the initial 1-hour face-to-face assessment is 60 minutes per month of phone based coaching during the 6-month intervention period. The recommendation made to incorporate physical activity into your daily routine will be negotiated with you and this will be different for each person based on current activity levels and abilities.

Group 2 Texting to ComeBACK ***Group***

If you are allocated to Texting to ComeBACK group you will receive

i) *a single phone* session of tailored advice from a physiotherapist to develop a plan to improve physical activity through participation in suitable activities which will be developed in negotiation with you. The choice of physical activity will be guided by personal preference, logistics, physical abilities and evidence of effectiveness. The length of this phone session does vary according to your needs but you could expect that it will generally last around 30 -45 minutes.

ii) *text message follow up* for 6 months intervention duration of the study. You will be able to opt out of receiving these messages at any time.

iii) have access to online resources.

The overall time commitment for the Texting to ComeBACK group following the initial 45-minute phone based session is 5 minutes per month of reading phone text messages. The recommendation made to incorporate physical activity into your daily routine will be negotiated with you and this will be different for each person based on current activity levels and abilities.

Group 3 Texting to ComeBACK ***later group***

If you are allocated to the Texting to ComeBACK later group you will receive the usual care provided by your health service providers for the first 6 months of the study. You will have no contact with the study staff apart from the baseline, 3 and 6-month questionnaires. Following the 6-month reassessment you will receive the same intervention as Group 2 (Texting to ComeBACK) as described above. This includes the single phone session of tailored advice from a physiotherapist to improve physical activity (generally 30-45 minutes) as well as text message follow up for 6 months and access to online resources to support you to be more active.

The overall time commitment for the initial 6 months of the study period if allocated to the Texting to ComeBACK later group is 0 minutes per month. This will then increase to 5 minutes per month of reading phone text messages for the next 6-month period. The recommendation made for you to incorporate physical activity into your daily routine will be negotiated with you and this will be different for each person based on current activity levels and abilities.

Falls and health utilisation calendars

All study participants will be asked to return monthly calendars (by reply-paid mail) containing questions on any falls and subsequent injuries you may experience along with health utilisation. If calendars are not returned, you will be telephoned to ask if you experienced any falls and physical activity-related injuries during the past month. In order to reduce the risk of bias, the research team member who collects the monthly calendars will not be aware of which group you have been allocated to.

The researchers would like to evaluate the benefits of the study beyond the 6-month intervention period so we ask you to complete the calendars for a 12-month period.

Data Linkage Study

We would like to track hospital and emergency department admissions, ambulance services and any study participant deaths (birth, marriages and death registry records) for up to 2 years after the completion of the study to evaluate if there are any long-term effects from the intervention. Therefore, the researchers would like your permission to link the information you provide within the ComeBACK study, with other sources of information that are routinely collected and managed via the Population Health Research Network (PHRN) for Health data Record Linkage. A strict process will be followed as per Data Linkage policies that ensures the confidentiality of your data.

Data linkage has been used by health systems for many years to bring together information about people, places and events in a way that protects individual privacy and allows researchers and policy makers to gain information and insights about the health and well-being of our community. Data linkage studies have helped to provide valuable information on the causes of and risk factors for disease as well as the evaluation of new approaches to preventing and treating health problems.

If you want to opt out of the linking of your health information, there is an option to indicate this choice on the consent form by ticking the box for opt out.

Qualitative Study
To evaluate the enjoyment and efficiency of the intervention programs a small subset of participants (30-40) will be invited to participate in a semi-structured interview at 3 time points across the study (3 months, 6 months and 12 months). These telephone interviews will be conducted by a researcher who is not involved in delivering the intervention and they will generally last 30 to 40 minutes. We will ask for your consent to audio record each interview prior to the commencement of the interview. Interviews will cover advantages and disadvantages of the intervention, motivation, self-efficacy, confidence, beliefs about physical activity and facilitators and barriers to participation in each component of the intervention.

How is this study being paid for?
The study is funded through a competitive research project grant from the National Health and Medical Research Council. The investigators of this research study declare no duality or conflict of interest.

Are there risks?
While the risks involved with participation in this research are low, there is a slight chance that you may experience muscle soreness at the start of the physical activity program. There is also a chance of more general risk such as falls. This risk is taken into consideration by the researchers involved who are experienced with assessing older people and people with walking difficulties and safety precautions are used and are consistent with current clinical practice.

In addition, your GP will be notified that you are participating in this study and be encouraged to contact us if they think participation will cause you harm. You will be asked to provide contact details for your GP during the Baseline Questionnaire to allow this to occur.

As part of this study you will be asked to answer questions about physical activity, activities of daily living and other aspects of health. If you experience any distress when answering questions, you have the right not to answer the question and leave the response blank.

The interventions may also include health coaching, tailored advice and goal setting approaches. Health coaching employs a motivational interviewing approach that acknowledges the individual's difficulty in becoming more active and explores the confidence they have about engaging in physical activity and develops individualized strategies that can be implemented. If you happen to experience distress during health coaching, the health professional providing the coaching will be able to discuss and explore relevant issues, providing emotional support and advice and refer you back to your GP if required.

Benefits
While we intend that this research study furthers our knowledge and may improve physical activity levels of adults with walking problems in the future, we cannot guarantee that you will receive direct benefits from the study. Access to this intervention service will cease at the conclusion of the study.

Costs
Participation in this study will not cost you anything, nor will you be reimbursed for your time.

Voluntary Participation
Participation in this study is entirely voluntary. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, please be assured that it will not affect

your medical treatment or your relationship with the research staff or institutions who may be caring for you. Sometimes during the course of a study, new information becomes available about the treatment that is being studied. While you are participating in this study, you will be kept informed of any significant new findings, which may affect your willingness to continue in the study.

Confidentiality

Under Australian privacy law all information collected about you must be kept confidential, unless you agree to it being released. Only the researchers in the study, your family doctor and you will know whether you are participating in this study. At the time of entry to the study, you will be assigned a study identification number that will be used on all data collection sheets. Identifiable data (e.g. name, date of birth) will be removed from other data and stored separately in a locked filing cabinet and password protected computer database at The University of Sydney with access only by study staff. All data collected within this study will be stored for 15 years as required by national ethics legislature. You have a right to request access to your data during this time. After this time, paper copies will be securely shredded and electronic copies will be securely deleted. The study results will be published in peer reviewed journals, presented at conferences or other professional forums, but individual participants will not be identifiable in such a presentation.

Future use of data for research purposes

Data such as age, sex and study outcomes may be combined with data from other studies or provided to other researchers to answer new research questions at the completion of this study. At no time will identifiable data be shared or used without your additional consent.

Further Information

When you have read this information, Researchers at the University of Sydney will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact them on 02 8627 6235.

Ethics Approval and Complaints

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol number X18-0234 .

The conduct of this study at the Royal Prince Alfred hospital has been authorised by the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on (02) 9515 7899, email: maree.larkin@health.nsw.gov.au and quote local project reference SSA/18/RPAH/315.

Thank you for taking the time to consider this study.

This information sheet is for you to keep.