Plain Language Statement

CENTRE FOR HEALTH, EXERCISE AND SPORTS MEDICINE
DEPARTMENT OF PHYSIOTHERAPY

THE UNIVERSITY OF MELBOURNE

Title: Better Knee, Better Me Study™: Effectiveness of two scalable health care interventions supporting self-management for knee osteoarthritis – a randomised controlled trial.

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Co-researchers: Prof Rana Hinman, Dr Catherine Keating, Dr Thorlene Egerton, Prof Joseph Proietto, Dr Priya Sumithran, Dr Jessica Kasza, Prof Anthony Harris, Prof Andrew Briggs, Ms Carolyn Page, Prof Frank Keefe, Prof Christine Rini, Dr Jonathan Quicke, Prof Peter Choong, A/Prof Michelle Dowsey, Ms Belinda Lawford

Introduction

Thank you for your interest in this research study. The following few pages will provide you with further information about the study, so that you can decide if you would like to take part.

Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about.

Your participation is voluntary. If you don't wish to take part, you don't have to. If you begin participating, you can also stop at any time with the option of withdrawing data that you have already provided to the researchers.

What is this research about?

Knee osteoarthritis (OA) is a common chronic joint condition. It often causes joint pain and stiffness and reduces quality of life. It is important to find the best ways to help people manage their OA. Having better access to good-quality information and accurate advice may be one way to help. This may include advice about management options such as exercise and weight loss, and help with treatment decision-making and planning. Research is needed to better understand the most appropriate combination of support for managing OA.

This study will compare the effects of three different approaches to providing information, help and support for people who have a painful knee. We will evaluate how people respond to these different approaches by monitoring their pain, ability to do daily tasks, quality of life and satisfaction with the help they receive over one year. We will also monitor whether they have surgery for their knee pain over the next 2-5 years.

Who can participate?

You can participate in the study if you are a Medibank Private member with a level of cover that includes arthroplasty surgery and aged over 44 and under 81 years; have had pain in your knee joint for the last 3 months or more; are overweight with a Body Mass Index (BMI) of 28-40; have access to a telephone and the internet; have access to the same set of scales to weigh yourself; be

willing to follow advice for self- management, which may include exercise, physical activity and/or a weight loss program if it forms part of your study treatment program; and can commit to participating in the study for 12 months.

There are several reasons that the study may not be suitable for you. These will be discussed during screening and include:

- have already had knee joint replacements on both knees
- are booked in for knee joint replacement or arthroscopic (key hole) surgery
- have a diagnosis of rheumatoid arthritis or other inflammatory arthritis
- have Type 1 diabetes or take insulin for Type 2 diabetes
- have had a stroke or cardiac event in the last 6 months
- have participated in a meal replacement weight loss program or a strength training program for your leg muscles in the last 6 months

What will I be asked to do?

If you participate in this study, you will be allocated to one of the three groups. All participants will receive information and advice to help them manage their knee pain. The way the help is given and the specific programs offered will differ depending on the group you are in. You cannot choose which group you are in. This type of study is known as a 'randomised trial'.

A randomised trial allows us to compare different treatment approaches and work out which achieves the most benefit for participants. To do this, study participants are put into groups and managed differently. All participants will complete questionnaires at the beginning and then 6 months and 12 months later. The results are compared to see whether one treatment is better than another at the 6-month and 12-month time points. To ensure the groups are similar to start with, a computer allocates each study participant into a group randomly, like flipping a coin. Neither the researchers nor the study participants can decide which group the participant is in and participants cannot change groups during the study.

If you participate in this study, your GP (local doctor) will be notified about any treatment programs you participate in and we may refer you to see your GP if we have concerns about your health along the way. Therefore, you will need to provide us with your GP's contact details.

The three treatment groups are:

i) Website (Information group). A new website has been developed by experts and based on the most recent research findings. It has information and advice on things you can do to help reduce the pain you experience and make it easier for you to do the things you want to do. The website will include some ideas for exercises and losing weight and information to help you compare the different treatment options that are available for people with knee OA. You may access the website at your convenience over the entire 12-month period.

ii) Website + physiotherapist consultations. In addition to the website, the people allocated to this group will have 6 consultations over the internet with a physiotherapist who has specialist knowledge about managing knee OA. The consultations will take approximately 20-45 minutes and will be spread over the first 6 months. The physiotherapist will provide education about OA and treatment options, advice and support to help you manage your knee OA. The physiotherapist will work with you to develop personalised goals and a tailored management plan with your verbal consent. Plans may include a strengthening exercise program that can be performed at home, a physical activity plan, and help with other self-management strategies. You will be encouraged to keep going with your plan after your physiotherapy consultations finish.

iii) Website + physiotherapist and dietitian consultations with weight loss program. This program aims to provide active weight loss support in addition to the services provided by the *website + physiotherapist consultations* program. It includes 6 consultations over the internet with a physiotherapist and 6 consultations over the internet with a dietitian who has specialist knowledge of knee OA and the Very Low Calorie/ketogenic diet. All consultations will take approximately 20-45 minutes and will be spread over the first 6 months. The weight loss program is a Very Low Calorie, low-fat and low-carbohydrate diet that requires you to initially replace two meals per day with meal replacement products (shake, bar or soup) and prepare a low-carbohydrate, low-fat meal for the third meal of the day. Participants are encouraged to aim to lose at least 10% of their body weight within 6 months. The program is delivered with support from the dietitians and overseen by medical specialists. The length of time that you replace your meals will depend upon your weight loss goals and your rate of weight loss. Long term weight maintenance strategies and tips for coping with the triggers for unhealthy food choices will be addressed during the program to help people to maintain their weight loss after their dietitian support finishes.

In addition to participating in the program to which you are allocated, you will be asked to contribute in several other ways:

Screening and consent: The study involves screening online and by phone (which you may already have done by the time you read this) to check that you can be included in the study. If you are eligible, you will be invited to take part. If you decide to take part, you will be asked to sign a Consent Form and complete a questionnaire. You will then be allocated to one of the three groups.

Questionnaires: You will be asked to fill out a questionnaire at the beginning, and again after 6 and 12 months. The questionnaire can be filled out online. It will take about 45mins to an hour to complete each time. You can contact the University of Melbourne research staff if you need help. In the questionnaire, we will ask you about your pain, difficulties you have with daily tasks, physical activity levels, quality of life, and some background information including your education level, current employment, and duration of symptoms. There are also several questions related to your mood and feelings about having knee pain, such as your confidence in being able to cope with the pain, your attitude to physical activity, weight loss and more. You will also need to provide your current weight using the same set of scales each time you complete the questionnaire. The information provided may also be used in other studies to help us learn more about the management of persistent knee pain.

Completion of the study: At the end of the study, we would also like to find out about your impressions of the program you received. For this you may be asked to rate your satisfaction or be interviewed over the phone.

You are free to try other treatments for your knee pain while you are in the study, but it is important that we know what other treatments you try. You will have the opportunity to tell us about these in the final questionnaires.

Being a research participant means that you will be helping us to find better ways of helping others with knee pain in the future. That means it is important that you aim to complete all the questionnaires in the study and to answer all the questions as honestly as you can regardless of whether or not you participated in your allocated program.

What costs are involved and what is being covered by the study?

There are no charges or enrolment fee payable by you for participating in this research study or with any of the programs provided to participants.

Whilst Medibank is funding this study, to the extent that it is permitted under the Private Health Insurance Act 2007, the cost of the services that you receive will be treated as a claim for benefits under your private health insurance policy. This will not affect the premium you pay for your private health insurance and it will not affect the limits you have for extras cover.

If you consult your GP during the course of the study you will be responsible to pay the GP's fees. If your GP bulk bills to Medicare, then you would not incur a fee. However, if your GP does not bulk bill, you will be responsible to pay the out of pocket expenses.

As this is a voluntary research study, you will not be paid for your participation in the study.

What are the possible risks?

Some of the questionnaires you will be asked to complete require you to consider your pain, how this pain affects your daily tasks, your mood and emotional well-being, as well as your ability to cope with your pain. It is possible that some people could find this difficult emotionally, although we have not found this to be a problem in other similar studies. If you feel uncomfortable about any of the questions, you can discuss this with one of the researchers (see contact details below). If we identify from your answers that you are experiencing high levels of distress or have very low mood, the study coordinator will contact you to recommend you seek guidance from your GP.

Whilst we expect that people following accurate advice, education and information about knee pain would experience improved pain and function, there is a small risk that you may experience a flare up of pain in your knee or in other parts of your body as a result of changing your usual physical activity or behaviour. If this happens, you should discuss this with the research staff. All the research staff have training and experience in looking after people with knee pain.

The Very Low Calorie/ketogenic diet provided to participants in the *website + physiotherapist and dietitian consultations with weight loss program* can make people feel hungry, fatigued, fuzzy-headed, and have headaches, and either diarrhoea or constipation during the first week. This is to be expected and these symptoms are usually manageable and short-lived, but you may need to temporarily avoid activities such as operating heavy machinery or driving if you are affected. If you are taking medications or have high blood pressure, you may need your medications adjusted. The research staff will help you monitor this and will refer you to see your GP if necessary to help with these adjustments.

What are the possible benefits of taking part?

This study aims to further healthcare knowledge and may improve future treatment of people with knee osteoarthritis; however it may not directly benefit you. No matter what treatment group you are allocated to, you will have access to the latest recommendations and advice about living well and managing pain from knee osteoarthritis. Your participation in this study will also help us to find out whether the internet consultations with health professionals and the weight loss program helps further reduce symptoms than the information alone.

Do I have to take part?

No. Participation is completely voluntary. If you do not wish to take part, you are under no obligation to do so. Also, if you decide to take part but later change your mind, you are free to withdraw from the study at any stage. You may also withdraw any unanalysed data previously supplied by you. Your decision about whether to participate or to continue in the study will not affect your future medical care or your relationship with Medibank in any way.

Will I hear about the results of this study?

Once we have collected the information from all study participants and analysed it, we can send you a summary of the overall study results if you wish. Depending on when you enrol in the study, the results may not be available for several years after you finish your final questionnaires as the study will take approximately three years to complete.

What will happen to information about me?

By signing the Consent Form, you consent to the research staff collecting and using personal information about you for the research study. Any identifiable information obtained during this research study will remain strictly confidential and secure, in line with guidelines set out by the National Health and Medical Research Council and the Privacy Act. Your identity will only be disclosed with your permission, except as required by law. Medibank will be provided with the details of your enrolment (i.e. name and date of birth) and your Medibank membership number to confirm that you are a current member and to enable Medibank to pay for the service you receive. Medibank will also be provided with a copy of your study consent form and any other consent you give in relation to the study (such as consent to a care plan developed for you). Medibank will also be notified of any complaint by you or harm to your health related to your enrolment in the study. They will be informed if you withdraw, but no other information about you will be shared back with Medibank, and your enjoyment of your health insurance will not be impacted in any way as a result of your participation. Medibank will provide the researchers with information about any knee surgery you have in the 5 years after the date of your commencement in the study. The surgery information that Medibank provides will be transferred to the researchers in a secure manner, exclusively for the purposes of this research study.

Conversations you may have with a health care professional over the internet as part of the management provided to you in this study will be audio recorded for quality assurance purposes.

Information that could identify you, such as your name and address, must be obtained to allow research staff to stay in touch with you over the course of the study. The Chief Investigators are responsible for maintaining confidentiality and security of your information. Data will be stored for 15 years.

It is anticipated that the results of this research study will be published and/or presented in several ways including in medical journals and conferences. In any publication or presentation, study participants will not be identifiable.

In accordance with relevant Australian privacy and other laws, you have the right to request access to your information collected and stored by the research team. Please contact the research staff named at the end of this document if you would like to access your information at any time.

How is the research funded?

This study is being funded by Medibank Private and the Medibank Better Health Foundation and in total will cost approximately $950,000. Participants of the study do not incur any charge or enrolment fee for participating.

Participants are responsible to pay the out of pocket component (if any) of any consultation fee with their GP in connection with the study.

Where can I get further information?

If you would like more information about the study, please contact the researchers; Professor Kim Bennell on 03 8344 4135, or Belinda Lawford the Study Co-ordinator on 03 8344 2045. Before deciding whether to take part you may wish to discuss the matter with a relative or friend or with your local doctor. You should feel free to show them this information sheet.

Who can I contact if I have any concerns about the study?

This research study has been approved by the Human Research Ethics Committee of The University of Melbourne. If you have any concerns or complaints about the conduct of this research study, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Office for Research Ethics and Integrity, University of Melbourne, VIC 3010. Email: HumanEthics-complaints@unimelb.edu.au or Tel: +61 3 8344 2073. All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research study.

About the researchers:

Professor Kim Bennell is an experienced physiotherapist and researcher, and is Director of the Centre for Health, Exercise and Sports Medicine in the Department of Physiotherapy at The University of Melbourne.

Professor Rana Hinman is an experienced physiotherapist and researcher in the Centre for Health, Exercise and Sports Medicine in the Department of Physiotherapy at The University of Melbourne.

Dr Thorlene Egerton is an experienced physiotherapist and researcher in the the Centre for Health, Exercise and Sports Medicine in the Department of Physiotherapy at The University of Melbourne.

Dr Catherine Keating is a researcher and Head of Health Economics and Outcomes at Medibank Private.

Professor Joseph Proietto is an endocrinologist and researcher at the Department of Medicine, University of Melbourne.

Dr Priya Sumithran is an endocrinologist and researcher at the Department of Medicine, University of Melbourne.

Dr Jessica Kasza is a biostatistician in the Department of Epidemiology and Preventative Medicine at Monash University.

Professor Anthony Harris is a Director of the Centre for Health Economics at Monash University.

Professor Andrew Briggs is a physiotherapist and researcher at the Faculty of Health Sciences, Curtin University

Dr Carolyn Page is an advanced clinical physiotherapist at St Vincent's Hospital, Melbourne.

Professor Frank Keefe is an experienced clinical psychologist and researcher at Duke University in the United States of America.

Professor Christine Rini is a social/health psychologist and researcher at Hackensack University Medical Centre and Georgetown University School of Medicine.

Dr Jonathan Quicke is an Academic Clinical Lecturer in Physiotherapy and researcher at Keele University in the United Kingdom.

Professor Peter Choong is an Orthopaedic Surgeon and researcher at the University of Melbourne Department of Surgery, St Vincent's Hospital.

Associate Professor Michelle Dowsey is an Epidemiologist and Principal Research Fellow at the University of Melbourne Department of Surgery, St Vincent's Hospital.

Ms Belinda Lawford is a study co-ordinator and researcher in the Centre for Health, Exercise and Sports Medicine in the Department of Physiotherapy at The University of Melbourne.