Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

Title	Good Life with osteoArthritis: Denmark (GLA:D)
Short Title	GLA:D
Protocol Number	GLA:D protocol 2021V4Cleanversion, dated 23 September 2021
Coordinating Lead Researcher	Dr Christian Barton
Project Sponsor	La Trobe University

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1. What is the study about?

You are invited to take part in this research project. The research project is collecting information about an evidenced-based treatment program for hip/knee osteoarthritis. The treatment program is called GLA:D® Australia (Good Life with osteoArthritis from Denmark). The research project also aims to collect information about the impact of the GLA:D® Australia program on private health insurance expenditure.

The GLA:D® Australia Program is a 6-week program, consisting of 12 x 60minute exercise sessions and 2 x 60-90minute education sessions delivered by a GLA:D® trained clinician. La Trobe University oversee the GLA:D® Australia Program.

This Participant Information Sheet tells you about the research project. It explains what is involved. Knowing what is involved will help you decide if you want to allow us to collect information about your participation in the GLA:D® Australia program. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend, your clinician or your local doctor.

After you have read the information, and had your questions answered, you can decide if you do or do not want to participate. If you decide not to participate, this won't affect your relationship with La Trobe University or your private health insurer.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

The study has two aims: 1) to collect information about the GLA:D® Australia Program for improving osteoarthritis related hip/knee pain and/or disability 2) to collect information about the impact of the GLA:D® Australia program on private health insurance expenditure.

If you consent to taking part in this research, this means that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the use of your personal and health information as described
- Consent to the use of data collected during this research project in future research projects that are related to the current project topic. You also understand that you may or may not be informed of the use of data in future research projects

This study is needed as current treatment approaches, including arthroscopic surgery, braces, medication, injections, etc. are costly, can have dangerous side effects and may not be the best first option for treating osteoarthritis related hip/knee pain and/or disability. The information we collect about the GLA:D® Australia program will allow us to continue to refine and improve the program for Australians with osteoarthritis.

The results of this study will strengthen the body of evidence supporting the GLA:D® Program for osteoarthritis related hip/knee pain and/or disability documented overseas. GLA:D® is effective at reducing symptoms, improving function, decreasing use of painkillers and reducing sick leave in Denmark. Findings of this study may also assist with future application for funding/subsidies governments or reimbursements from private health insurers to make the treatment more accessible and affordable.

2. Do I have to participate?

Being part of this study is voluntary. If you want to be part of the study we ask that you read the information below carefully and ask us any questions.

You can read the information below and decide at the end if you do not want to participate. If you decide not to participate this won't affect your relationship with La Trobe University, your clinician or your private health insurer. Participation in the GLA:D® Australia program is separate to the research, and you can still do the program even inf you choose not to participate in the research study.

3. Who is being asked to participate?

You have been asked to participate because you meet the following criteria:

- You have been diagnosed with hip and/or knee OA by your treating clinician
- Aged 45 years or over
- Movement related joint pain
- Either no morning stiffness/morning stiffness lasting no longer than 30 minutes

4. What will I be asked to do?

If you want to take part in this study, we will ask you to answer some questions about yourself and your hip or knee problem online, when you start the GLA:D® Australia program. You will be sent an email to answer the same questions 3 months and 12 months after starting the GLA:D®

Australia program. Participation in the GLA:D® Australia program is separate to the research, and you can still do the program even if you choose not to participate in the research by providing your information.

The information we will ask you will include your age, your address, your email address, how much pain you have, whether you have had surgery, whether you have any other health conditions and how much your arthritis affects your lifestyle. It will take you 20-30 minutes to complete the online questions at each time point (baseline, 3 months, 12 months). Your clinician will ask you to stand up and sit down as many times as possible in 30 seconds, and will time how quickly you can walk 40 metres (at the start of the program and 3 months after starting the program). This information will also be recorded and entered online.

5. What are the benefits?

There will be no clear benefit to you from your participation in this research, however providing us with information about your condition online will enable us to continue to refine and improve the GLA:D® Australia program. The expected benefits to society in general are that it will enable the researchers to develop a very rich source of information about the benefits of the GLA:D® Australia program, and continue to refine and improve the program based on this information. Evaluating the impact of the GLA:D® program on private health insurance expenditure may enable us to improve funding for the GLA:D® program in Australia. Osteoarthritis is a major cause of reduced participation in work, reduced physical activity, and increased risk of cardiovascular disease, diabetes, overweight and obesity in developed nations including Australia. The GLA:D® Australia program will reduce pain, improve function and improve participation in work and physical activity in affected individuals. This is likely to have large benefits to society.

6. What are the risks?

With any study there are (1) risks we know about, (2) risks we don't know about and (3) risks we don't expect. If you experience something that you aren't sure about, please contact us immediately so we can discuss the best way to manage your concerns.

Name/Organisation	Position	Telephone	Email
GLA:D® Australia	Program Staff	(03) 94795380	GLAD.Australia@latrobe.edu.au
Dr Christian Barton	Co-investigator	(03) 94791428	c.barton@latrobe.edu.au
Dr Joanne Kemp	Co-investigator	(03) 94791428	j.kemp@latrobe.edu.au

We have listed the risks we know about below. This will help you decide if you want to be part of the study.

- You have already chosen to take part in the GLA:D® Australia program. The research project only involves the collection of your information online, and will not affect your participation in the GLA:D® Australia education and exercise program in any way. Data collected will be stored at La Trobe University and is compliant with Australian data protection law. The risks and side effects of taking part in this research are very small, but should be acknowledged. Given the online nature of the data collection, there is a very small risk that your personal (name, address, email address, date of birth) and health-related (medical history, impact of arthritis on your lifestyle) information could become public. The researchers have employed all security measures to minimise the likelihood of this occurring, and only they will have access to the data collected.

- The survey questions have a potential to elicit strong negative emotions or psychological discomfort.

7. What will happen to information about me?

We will **collect** information about you in ways that will reveal who you are.

We will **store** information about you in ways that will reveal who you are.

We will **publish** information about you in ways that will not be identified in any type of publication from this study.

We will **keep** your information indefinitely.

The storage, transfer and destruction of your data will be undertaken in accordance with La Trobe University's Research Data Management Policy https://policies.latrobe.edu.au/document/view.php?id=106/.

The personal information you provide will be handled in accordance with applicable privacy laws, any health information collected will be handled in accordance with the Health Records Act 2001 (Vic) . Subject to any exceptions in relevant laws, you have the right to access and correct your personal information by contacting the research team.

If you are participating in the GLA:D program because of a referral by your health insurance fund and you consent to being involved in this research project, then please be aware that deidentified, aggregated information about the health outcomes (e.g., how much pain you have, whether you have had surgery, how much your arthritis affects your lifestyle) achieved in this program – and collected as part of this research project – may be provided to your health fund. Your health fund will also be told of your participation so that they can pay benefits under your health cover. Your health fund may also provide de-identified aggregated information to the research team about surgical rates for program participants. This does not apply to those who are self-funding GLA:D or funding treatment through their private health insurance extras policy – in these circumstances no health outcomes data will be shared to your health fund.

8. Will I hear about the results of the study?

We will let you know about the results of the study by sending you twice-annually GLA:D® Australia newsletters. This newsletter will contain de-identified information about study results and information about other related research. If you require your own individual results you can contact the study investigators at GLAD.Australia@latrobe.edu.au.

9. What if I change my mind?

You can stop taking part in the research at any time without having to give a reason. You can require information that you have submitted to be withdrawn from the study provided you do this within four weeks following submission of your data. You can do this by:

a. Completing the 'Withdrawal of Consent Form' found https://gladaustralia.com.au/consent-forms-for-participants/ and sending this as an email attachment to GLA:D Australia at GLAD.Australia@latrobe.edu.au;

b. Calling them on (03) 94795380; or
c. Emailing them directly at GLAD.Australia@latrobe.edu.au
d. Your local GLA:D® trained clinician can help you with the withdrawal process if needed.

Your decision to withdraw at any point will **not** affect your relationship with La Trobe University, your clinician or your private health insurer.

When you withdraw we will stop asking you for information. Any identifiable information about you will be withdrawn from the research study. However, once the results have been analysed we can only withdraw information, such as your name and contact details. If results haven't been analysed you can choose if we use those results or not.

10. Who can I contact for questions or want more information?

The person you may need to contact will depend on the nature of your query.
If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact any of the following people:

Name/Organisation	Position	Telephone	Email
GLA:D Australia	Program Staff	(03) 94795380	GLAD.Australia@latrobe.edu.au
Dr Joanne Kemp/LASEM Research Centre	Co-investigator	(03) 94791428	j.kemp@latrobe.edu.au
Dr Christian Barton/LASEM Research Centre	Co-investigator	(03) 94791428	c.barton@latrobe.edu.au

11. What if I have a complaint?

This research is approved by the following Human Research Ethics Committee's (HREC). If you have a complaint about any aspect of the project, please contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	La Trobe University Human Ethics Committee
Ethics Reference Number	HEC21303
HREC Executive Officer	HREC Executive Officer
Telephone	03 9479 1443
Email	humanethics@latrobe.edu.au

GLA:D® AUSTRALIA PROGRAM: Consent Form – Declaration by Participant

I (the participant) have read (or, where appropriate, have had read to me) and understood the participant information statement, and any questions have been answered to my satisfaction. I agree to participate in the study; I know I can withdraw at any time until [four weeks] following the collection of my data. I agree information provided by me or with my permission during the project may be included in a thesis, presentation and published in journals on the condition that I cannot be identified.

I would like my information collected for this research study to be:
☐ Used for future related studies
☐ Shared with my private health insurer

Participant Signature
☐ I have received a signed copy of the Participant Information Statement and Consent Form to keep

Participant's printed name	
Participant's signature	
Date	

Declaration by clinician delivering the GLA:D® program
☐ I have given a verbal explanation of the study, what it involves, and the risks and I believe the participant has understood
☐ I am a person qualified to explain the study, the risks and answer questions

Clinician's printed name	
Clinician's signature	
Date	

***All parties must sign and date their own signature**