**PARTICIPANT CONSENT FORM**

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| **HREC Project Number:** | 202377 |
| **Project Title:** | Education and activity programs to improve health in people with painful knee osteoarthritis. A randomised controlled trial |
| **Division/Unit:** | Division of Health Science, School of Health Sciences |
| **Principal Investigator:** | Dr Tasha Stanton, PhD; Tasha.stanton@unisa.edu.au |

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| Participant Certification |  |  |
| In signing this form, I confirm that:**I have read the Participant Information Sheet and the nature and purpose of the research project has been explained to me. I understand and agree to take part.*** I understand my involvement in this research project and any likely risks or benefits. I also understand that the full extent of my involvement will not be revealed until the completion of my participation in the study when this will be explained.
* I understand that I can withdraw the data gathered as a result of my involvement in the research when a full explanation of the study has been made.
* I understand that I may withdraw from the research project at any stage and that this will not affect my status now or in the future. I also understand that I can request for the information collected prior to my withdrawal not to be used in the study. I understand that in the case of discontinuing this study without notification of withdrawal, some of the information previously collected may be used (without identification). In addition, if I decide to withdraw from the study more than 1 year after commencing, the information previously collected may be used but without identification.
* I understand that while information gained during the study may be published, I will not be identified and my personal results will remain confidential, unless required by law.
* I understand that my responses will be stored in a locked filing cabinet in room C7-31, City East Campus, UniSA (for written questionnaire responses) and/or on a secure UniSA server with a password protected file (for online questionnaire responses). I understand that only the research team will have access to the data.
* I confirm that I am over 18 years of age.
* I understand that I will be audiotaped during the treatment sessions.
* I understand that the recording will be stored in a locked filing cabinet (room C7-31, City East Campus) and/or on a secure UniSA server with a password protected file. I understand that only the research team will have access to the recording.
* I understand that, where I have provided my consent, my Medicare and Pharmaceutical Benefits Scheme (PBS) data from Services Australia will be accessed by the researchers (see back of page for exact information accessed) so that they can understand the costs related to the study treatments. I understand that only the research team will have access to this information.
* I understand that my in-patient hospital admissions data from the Department of Health will be accessed by the researchers (see back of page) so that they can understand the costs related to the study treatments. I understand that only the research team will have access to this information.
* I understand that non-identifiable data from this research project may be used for future research purposes that relate to painful knee-osteoarthritis.
* I understand the statement in the Participant Information Sheet concerning payment to me for the completion of each assessment and treatment session as part of the study
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| *Participant Signature* | *Printed Name* | *Date* |
| Researcher Certification |  |  |
| I have explained the study to subject and consider that he/she understands what is involved. |
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| *Researcher Signature* | *Printed Name* | *Date* |

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| MBS (Medicare Benefits Schedule) |
| [x]  DATE OF SERVICE*Definition: The date on which the provider performed the service*. | Reason: To facilitate the inclusion of relevant items into the cost-effectiveness analysis of the study (e.g. to be able to identify which service item to include in follow up period for the analysis. |
| [x]  MEDICARE ITEM NUMBER ***Definition:*** *A number that identifies the service provided by the provider as per Medicare Benefits Schedule.* | Reason: To allow us to easily identify the type of services participants are receiving that are driving their healthcare resource use. |
| [x]  ITEM DESCRIPTION ***Definition:*** *Describes the service provided by the provider as per Medicare Benefits Schedule* | Reason: To be used with the Medicare Item Number to identify the type of services participants are receiving, to assess which items are used more or less by each group. |
| [x]  PROVIDER CHARGE *Definition: The dollar amount the provider charged for the service.* | **Reason:** To inform our analysis of the cost of the service provided from the provider perspective |
| [x]  SCHEDULE FEE *Definition: Fee listed in the Medicare Benefits Schedule.* | **Reason:** To inform our analysis of the cost of the service as recommended by the government.  |
| [x]  BENEFIT PAID *Definition: This is the Medicare benefit paid to the claimant.* | **Reason:** To inform our analysis of the cost of the service from a government perspective. |
| [x]  PATIENT OUT OF POCKET *Definition: The dollar amount the patient is out of pocket i.e. Provider charge minus benefit paid.* | **Reason:** To inform our analysis of the patient out-of pocket costs in both groups. |
| [x]  BILL TYPE *Definition: The method by which the Medicare benefit was claimed i.e. cash, bulk bill, and cheque to claimant, cheque to provider via claimant, Pce (Easyclaim patient claim), simplified bill and EFT.* | **Reason:** To allow us to identify patients who have been bulk billed for the service, and to assist interpretation of the patient out of pocket cost item.  |
| **[x]  HOSPITAL INDICATOR** ***Definition:*** *Indication of whether or not the service was provided in a public hospital as a private patient, does not include outpatients or emergency department* | **Reason:** To allow us to identify the services provided to patients as a private patient in a public hospital, to allow us to account for the cost implications of this in our analysis. |
| **[x]  ITEM CATEGORY** ***Definition:*** *The Medicare Benefits Schedule (MBS) comprises a hierarchical structure of Categories, Groups, Subgroups and Items numbers, to group similar professional services together.* | **Reason:** To allow us to appropriately aggregate services provided into meaningful groupings, to facilitate understanding of the types of services that are driving resource use in this population, and any differences between intervention and control group participants. |

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| PBS (Pharmaceutical Benefits Scheme) |
| [x]  DATE OF SUPPLY *Definition: This is the date on which the PBS item was supplied.* | Reason: To facilitate the inclusion of relevant PBS items into the cost-effectiveness analysis of the study (e.g. to be able to identify which PBS item to include in follow up period for the analysis). |
| [x]  DATE OF PRESCRIBING ***Definition:*** *This is the date on which the prescription was written.* | Reason: To facilitate identification of relevant PBS items into cost-effectiveness analysis (e.g. to facilitate identification of on-going long-term medications vs short-term medications) |
| [x]  PBS ITEM CODE***Definition:*** *Number which indicates item prescribed as per Schedule of Pharmaceutical Benefits.* | Reason: To allow us to easily identify the type of pharmaceuticals participants are receiving that are contributing to their healthcare costs. |
| [x]  ITEM DESCRIPTION ***Definition:*** *The description of the item name as it appears in the Schedule of Pharmaceutical Benefits.* | Reason: To be used with the PBS item code to allow us to easily identify the types of pharmaceuticals that participants are receiving that are contributing their healthcare costs. |
| [x]  PATIENT CATEGORY *Definition: The patient category refers to the patient’s concessional status at the time of supply of the benefit of the item* | **Reason:** To allow us to identify the participant concession status at the time of the service, which will assist us with identifying the cost to government of pharmaceuticals in our participants. |
| [x]  PATIENT CONTRIBUTION *Definition: The patient contribution actually paid by the patient.* | **Reason:** To allow us to estimate out-of pocket costs incurred by participants in the study. |
| [x]  NET BENEFIT *Definition: Benefit that Services Australia paid to the Pharmacy.* | **Reason:** To allow us to determine the cost of the PBS item to the health system.  |
| **[x]  ATC CODE** ***Definition:*** *Please note that the ATC Code is as defined by the Commonwealth Department of Health which can be different to the code allocated by the WHO Collaborating Centre for Drug Statistics Methodology (*[*www.whocc.no/atcddd/*](http://www.whocc.no/atcddd/)*)* | **Reason:** To allow us to correctly identify the pharmaceutical provided (independent of differences in nomenclature), to allow us to make comparisons across subgroups in the study regarding increased or decreased use of classes of pharmaceuticals. |
| **[x]  ATC NAME** ***Definition:*** *In the Anatomical Therapeutic Chemical (ATC) classification system, the drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties* | **Reason:** To be used in conjunction with the ATC code, to allow us to correctly identify the pharmaceutical provided (independent of differences in nomenclature), to allow us to make comparisons across subgroups in the study regarding increased or decreased use of classes of pharmaceuticals. |

**Hospital data from the Department of Health:** frequency and duration of admission, with unit costs used from the finance departments.

**Reason:** To allow us to identify any hospital related costs of the participants in both groups.