Statistical Analysis Plan (Short)

Comparing effects of knee osteoarthritis educational information, with and without pathoanatomical content, on consumer osteoarthritis management beliefs: An online randomised controlled trial.

Version: 1

Author/s of SAP: Ms Fiona McManus and Dr Karen Lamb (Biostatisticians, Centre for Epidemiology and Biostatistics), University of Melbourne
Dr Belinda Lawford, CHESM, University of Melbourne

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Author/s of template: Ms Sabine Braat (Deputy Head MISCH Biostatistics), University of Melbourne (Template adapted from www.pfizer.com)

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1 Introduction

Objectives	1 Primary Objective To compare the effects of knee OA educational information, with and without pathoanatomical content, on i) beliefs about the necessity to have an x-ray to confirm an OA diagnosis, and ii) beliefs about the necessity of joint replacement surgery in adults who have not had a knee joint replacement. 2 Secondary Objectives To compare the effects of knee OA educational information, with and without pathoanatomical content, on management beliefs (about exercise and physical activity, the safety of exercise, medications, x-rays to determine treatment), level of concern, and OA knowledge in adults who have not had a knee joint replacement. To explore whether a history of knee pain in the last 3 months moderates the effect of knee OA educational information without pathoanatomical content on the two primary outcomes, i) beliefs about the necessity to have an x-ray to confirm an OA diagnosis, and ii) beliefs about the necessity of joint replacement surgery in adults who have not had a knee joint replacement.
Study Design	Two-arm, parallel groups superiority randomised controlled trial.
Planned Sample Size	556 participants.
Study Procedures	The entire trial will be administered in one single online survey. Participants will initially complete screening questions within the survey to determine eligibility. Eligible participants will then complete baseline outcome measures before being randomly allocated to one of two groups, both of whom will then be asked to immediately read a digital information pamphlet about knee OA on screen: i) Control group: the pamphlet will contain information about OA including biological pathoanatomical information and language about OA ii) Experimental group: the same pamphlet as the Control group, but with all pathoanatomical information and language relating to the structure of an OA joint removed.

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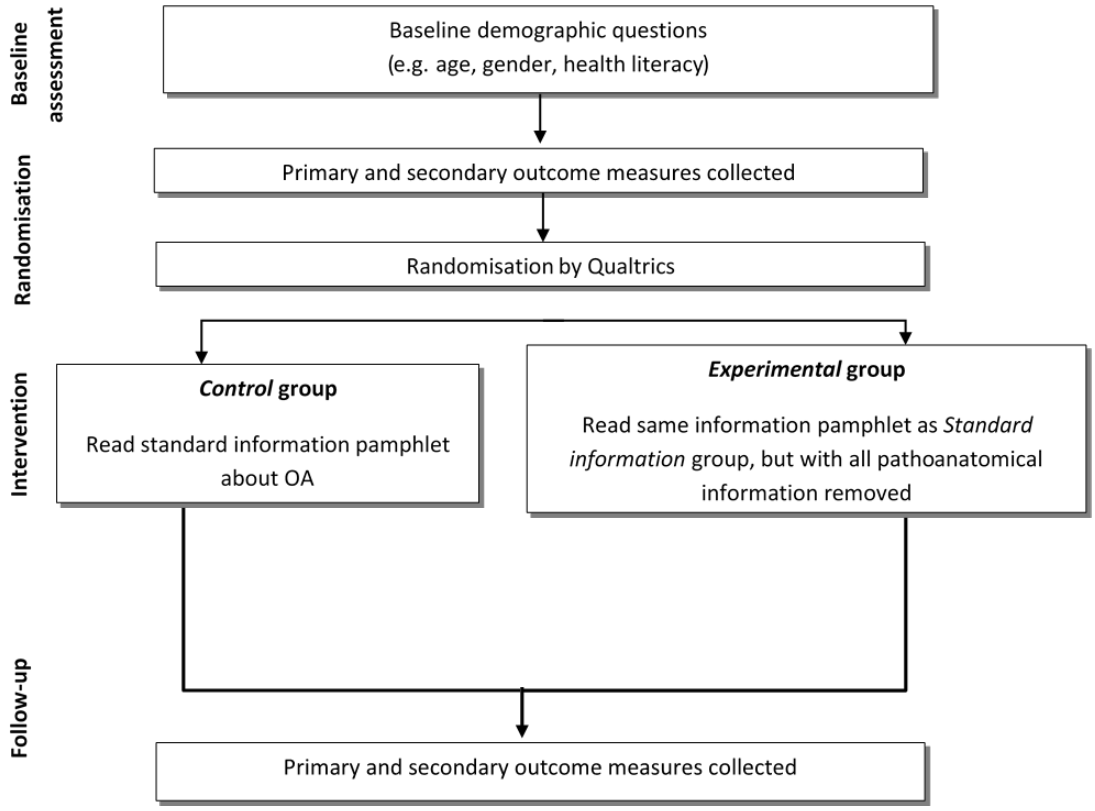
	All participants will complete outcome measures again, immediately after reading their allocated digital information pamphlet.
Duration of the study	Anticipated participant recruitment start: June 2022 Anticipated data collection end: June 2022 Based on our previous similar study [1], which recruited 735 participants in four days through a similar mechanism, we anticipate recruitment for this RCT will take approximately 6 days.

Figure 1. Study chart



2 Data Source

Participant recruitment will be managed by an external company, Cint Pty Ltd. Data security will be managed according to their data privacy and security protocols.

Data collection will be managed wholly online through Qualtrics, an electronic data capture system. Qualtrics is a secure web application for building and managing research questionnaires and databases. The University of Melbourne holds a licence for staff use of Qualtrics and surveys and associated data will only be accessible via secure login by the study research staff.

Re-identifiable/coded data

Questionnaires will be completed electronically and anonymously, with no identifying information being recorded. Electronic data will be stored in the Qualtrics website, accessible only to the study research staff by password protection. Data from within Qualtrics will eventually be exported to Microsoft Excel and other statistical packages used by the researchers for analyses and stored securely on password-protected servers accessible only to the study research staff.

3 Analysis Objectives

The aim of this study is to compare the effects of knee OA educational information, with and without pathoanatomical content, on consumer OA management beliefs in adults who have not had a knee joint replacement.

3.1 Aim 1

To compare the effects of knee OA educational information, with and without pathoanatomical content, on i) beliefs about the necessity to have an x-ray to confirm an OA diagnosis, and ii) beliefs about the necessity of joint replacement surgery in adults who have not had a knee joint replacement.

We hypothesise that removing pathoanatomical content will lead to lower beliefs that an x-ray is necessary to confirm an OA diagnosis and lower beliefs that joint replacement surgery is necessary, compared to information with pathoanatomical content.

3.2 Aim 2

To compare the effects of knee OA educational information, with and without pathoanatomical content, on management beliefs (about exercise and physical activity, the safety of exercise, medications, x-rays to determine treatment), level of concern, and OA knowledge in adults who have not had a knee joint replacement.

We secondarily hypothesise that removing pathoanatomical content will lead to higher beliefs that exercise and physical activity is necessary and is safe, lower beliefs that medication is necessary, lower beliefs that x-rays are required to determine treatment, lower levels of concern, and higher OA knowledge.

To explore whether a history of knee pain in the last 3 months moderates the effect of knee OA educational information without pathoanatomical content on the two primary outcomes, i) beliefs about the necessity to have an x-ray to confirm an OA diagnosis, and ii) beliefs about the necessity of joint replacement surgery in adults who have not had a knee joint replacement.

4 Analysis sets/Populations/Subgroups

Inclusion Criteria

Participants will be eligible for the study if they meet the following inclusion criteria:

i) Aged 45 years or over;
ii) Have (n=278), or have not (n=278), experienced any activity-related knee joint pain in the past 3 months;
iii) Currently living in Australia.

Exclusion Criteria

Participants will be ineligible for the study if they have:

i) Inability to understand or read English;
ii) Have had a joint replacement in any of their knee joints.

5 Endpoints and Covariates

All variables are listed in Appendix 1 and the coding of the derived variables can be found in Appendix 2. Outcome measures are also provided in the table below.

Primary outcome measures		
Belief about x-ray to diagnose knee OA	***Baseline:*** *If you were told by your doctor that you had knee osteoarthritis, would you think an x-ray is necessary to confirm the diagnosis?* ***Post-intervention:*** *Having read the information sheet, if you were told by your doctor that you had knee osteoarthritis, would you think an x-ray is necessary to confirm the diagnosis?*	11-point Numeric Rating Scale (NRS) ranging from 0=definitely unnecessary to 10=definitely necessary
Belief about joint replacement surgery	***Baseline:*** *If you were told by your doctor that you had knee osteoarthritis, would you think joint replacement surgery (to replace the affected joint with an artificial joint) is necessary for your knee at some stage?* ***Post-intervention:*** *Having read the information sheet, if you were told by your doctor that you had knee osteoarthritis, would you think joint replacement surgery (to replace the affected joint with an artificial joint) is necessary for your knee at some stage?*	11-point NRS ranging from 0=definitely unnecessary to 10=definitely necessary
Secondary outcome measures		
Beliefs about treatment options		
Belief about exercise and physical activity	***Baseline:*** *If you were told by your doctor that you had knee osteoarthritis, would you think exercise and physical activity is helpful to manage it?* ***Post-intervention:***	11-point NRS ranging from 0=definitely not helpful to 10=definitely helpful

	Having read the information sheet, if you were told by your doctor that you had knee osteoarthritis, would you think exercise and physical activity is helpful to manage it?	
Belief about safety of exercise	***Baseline:*** *If you were told by your doctor that you had knee osteoarthritis, would you think exercise and physical activity would damage your knee?* ***Post-intervention:*** *Having read the information sheet, if you were told by your doctor that you had knee osteoarthritis, would you think exercise and physical activity would damage your knee?*	11-point NRS ranging from 0=definitely would not damage it to 10=definitely would damage it
Belief about medication	***Baseline:*** *If you were told by your doctor that you had knee osteoarthritis, would you think medication is helpful to manage your knee symptoms?* ***Post-intervention:*** *Having read the information sheet, if you were told by your doctor that you had knee osteoarthritis, would you think medication is helpful to manage your knee symptoms?*	11-point NRS ranging from 0=definitely not helpful to 10=definitely helpful
Belief about x-ray to determine treatment	***Baseline:*** *If you were told by your doctor that you had knee osteoarthritis, would you think an x-ray is necessary to determine the best treatment for your knee?* ***Post-intervention:*** *Having read the information sheet, if you were told by your doctor that you had knee osteoarthritis, would you think an x-ray is necessary to determine the best treatment for your knee?*	11-point NRS ranging from 0=definitely unnecessary to 10=definitely necessary
OA Knowledge		
Knee Osteoarthritis Knowledge Scale	An 11-item questionnaire with the following questions: 1. *Your knee joint wears out with everyday use* 2. *Osteoarthritis will only get worse over time* 3. *Increased knee pain always means that you have damaged your knee* 4. *You need an x-ray or scan to know if you have osteoarthritis* 5. *Being active makes osteoarthritis feel better* 6. *Keeping a healthy body weight is a key part of osteoarthritis care* 7. *X-rays or scans show how much your osteoarthritis affects you* 8. *Making your leg muscles stronger improves your ability to do daily tasks* 9. *Pain from osteoarthritis can be managed without surgery*	Each statement rated as False (1), Possibly False (2), Unsure (3), Possibly True (4), or True (5). Each item is scored on a scale from 1 to 5. Items 1,2, 3, 4, 7, and 11 are reverse scored and added to items 5, 6, 8, 9, and 10. Scores range from 11-55 with higher scores indicating greater/more accurate knowledge about osteoarthritis. Measured at baseline and post-intervention.

	10. *Exercises can ease pain as much as most medications* 11. *Most people with knee osteoarthritis will need a joint replacement at some point*	
Level of concern		
Level of concern	***Baseline:*** *If you were told by your doctor that you have knee osteoarthritis, how concerned would you be that your knee problem would get worse in the future?* ***Post-intervention:*** *Having read the information sheet, if you were told by your doctor that you have knee osteoarthritis, how concerned would you be that your knee problem would get worse in the future?*	4-point Likert scale with response options: Not at all concerned A little concerned Quite concerned Very concerned

6 Handling of Missing Values and Other Data Conventions

If missing data are present, an appendix table will provide summaries of baseline characteristics and baseline levels of primary and secondary outcomes where measured between two groups: those participants who provide both primary outcomes post-intervention, and those participants who are missing either or both primary outcomes. If less than 5% of both primary outcomes is missing, analyses will be performed on complete case data. If greater than 5% of either primary outcome is missing, multiple imputation will be applied for the primary analysis. Missing outcomes will be imputed using chained equations with predictive mean matching and five nearest neighbours for continuous outcomes. Imputation models for continuous outcomes post-intervention will include all primary and secondary outcomes at both baseline and post-intervention, along with age, gender, BMI, education level, state, ethnicity, financial situation, exercise/physical activity participation, care-seeking, knee pain, prior knee surgery, regular pain relief for musculoskeletal condition, and health literacy. Data will be imputed for each treatment group separately. The number of imputed data sets created will be based on the percentage of patients in the sample with missing outcome data (e.g., 15 imputed datasets if 15% of participants have missing data). Estimates from the imputed datasets will be combined using Rubin's rules [2].

7 Statistical Methodology

7.1 Statistical Procedures

A biostatistician (Ms Fiona McManus, supervised by Dr Karen Lamb) will analyse de-identified data in Stata version 16.1 (StataCorp LLC, College Station, TX, USA), while blind to group name. Descriptive data will be presented by intervention group as mean (SD), median (IQR) or n (%) as appropriate. Comparative analyses between groups will be performed using intention-to-treat according to the group to which the participant was randomised, irrespective of whether they adhered to the intervention by reading the information. The number included in each analysis will be reported. Standard diagnostic plots will be used to check model assumptions, including assessing linearity and homoscedasticity, where appropriate.

7.1.1 Aim 1

Separate linear regression models for each primary outcome will be used to estimate the between-group mean (95% confidence interval, CI) difference in post-intervention scores, adjusted for the outcome at baseline. Post-intervention time point was 'immediately following reading a digital information pamphlet about knee OA on screen'.

7.1.2 Aim 2

Separate linear regression models for each continuous secondary outcome will be used to estimate the between-group mean (95% CI) difference in post-intervention scores, adjusted for the outcome at baseline. For the ordinal secondary outcome, level of concern, ordinal logistic regression models will be fitted similarly, adjusted for the outcome at baseline. The proportional odds assumption will be assessed using the Brant test. If proportional odds cannot be assumed, multinomial regression models will be fitted. Results will be reported as odds ratios, or relative risk ratios if multinomial regression is used, with corresponding 95% CIs.

The mean (95% CI) effect on each of the primary outcomes, i) beliefs about x-rays and ii) beliefs about joint replacement surgery, of potential moderators, i) a history of knee pain in the past 3 months, ii) highest education level (as a binary variable, no tertiary versus some tertiary) and iii) ever sought care for knee pain from any healthcare provider for each group will be estimated using separate linear regression models for each outcome and each moderator, with an interaction term fitted between group and the potential moderator, adjusting for baseline scores of the relevant primary outcome.

7.2 Measures to Adjust for Multiplicity, Confounders, Heterogeneity

We have two primary outcomes and so have adjusted the alpha for each primary outcome to 0.025 to give an overall alpha of 0.05 across both outcomes. We have several secondary outcomes. All secondary outcomes are exploratory and not powered for. We will therefore not adjust for multiple secondary outcomes but instead report all effect sizes, confidence intervals, and p values in order to let readers use their own judgment about the relative weight of the conclusions. This approach aligns with the usage of p-values favoured by the American Statistical Association [3].

8 Sensitivity Analyses

If multiple imputation is used for the primary outcomes, sensitivity analyses will be conducted on complete case analysis.

9 QC Plans

Data quality will be checked/promoted through a process of identifying extreme values and checking the source of these values in case of a data entry error. A record of any/all manual corrections to data will be maintained. Calculations of scores from multi-item scales will be carried out using Microsoft Excel functions and cross-checked using other statistical packages to reduce errors.

10 Programming Plans

A list of all tables, figures, listings and their templates can be found in Appendix 3.

11 References

1. Lawford, B., et al., *Effect of information content and general practitioner recommendation on treatment beliefs and intentions for knee osteoarthritis: An online multi-arm randomised controlled trial.* ACR Open Rheumatology, 2022. **Submitted June 2022**.
2. Carpenter, J. and M. Kenward, *Multiple imputation and its application*. 2013, West Sussex, UK: John Wiley & Sons, Ltd.
3. Wasserstein, R.L., A.L. Schirm, and N.A. Lazar, *Moving to a world beyond "p< 0.05"*. 2019, Taylor & Francis.
4. Darlow, B., et al., *Knowledge about osteoarthritis: Development of the Hip and Knee Osteoarthritis Knowledge Scales and protocol for testing their measurement properties.* Osteoarthritis and Cartilage Open, 2021. **3**(2): p. 100160.

Appendix 1

VARIABLES IN THE DATA SET

Baseline descriptive measures		
Age	*How many years old are you?*	Years.
Gender	*Are you…*	1, Male 2, Female 3, Transgender male 4, Transgender female 5, Gender variant/non-conforming 6, Prefer not to say
Ethnicity	*With what ethnicity do you most identify?*	1, Australian/New Zealand 2, Aboriginal and Torres Strait Islander 3, European 4, Asian 5, Other Oceania 6, North African & Middle Eastern 7, Sub-Saharan Africa 8, North American 9, South American 10, Other (please specify)
State	*What state do you live in?*	1, ACT 2, NSW 3, NT 4, QLD 5, SA 6, TAS 7, VIC 8, WA
Height	*What is your height?*	Self-reported in metres
Weight	*What is your weight?*	Self-reported in kilograms
Education	*What is the highest level of education you have completed?*	1, Primary school 2, High school 3, Trade or trade certificate 4, University or tertiary institute degree 5, Higher university degree (e.g. Masters, PhD) 6, Don't know/unsure
Financial	*How would you describe your financial situation?*	1, Find it a strain to get by from week to week 2, Have to be careful with money 3, Able to manage without much difficulty 4, Quite comfortably off

		5, Very comfortably off 6, Prefer not to answer
Exercise_use	*Do you currently participate in regular exercise and/or physical activity (e.g. strengthening program, Pilates, walking, cycling etc)*	1, No 2, Yes, 1 time per week 3, Yes, 2-3 times per week 4, Yes, 4-5 times per week 5, Yes, 6+ times per week
Careseeking	*Have you ever sought formal treatment for knee pain at any time in your life (e.g. treatment from a doctor, physiotherapist, chiropractor, surgeon, or any other healthcare provider)?*	1, Yes 2, No
Knee_pain	*Have you experienced activity-related pain in either of your knee joints in the past three months?*	1, Yes 2, No
Joint	In which knee joint(s) have you experienced pain in the past 3 months? *[only for those who self-report knee pain in past 3 months]*	1, Left knee only 2, Right knee only 3, Both knees
Knee_treatment	*Have you sought formal treatment for your knee pain in the past 3 months (e.g. treatment from a doctor, physiotherapist, chiropractor, surgeon, or any other healthcare provider)?* *[only for those who self-report knee pain in past 3 months]*	1, Yes 2, No
Pain	Select the number which indicates the average amount of pain felt over the PAST WEEK in your most painful knee. *[only for those who self-report knee pain in past 3 months]*	NRS ranging from 0 ('no pain') to 10 ('worst pain possible')
Function	Select the number which indicates how much your most painful knee has interfered with your **physical function** over the PAST WEEK. *[only for those who self-report knee pain in past 3 months]*	NRS ranging from 0 ('no interference') to 10 ('maximal interference with function')
Surgery_use	*Have you ever had knee surgery in the past?*	1, Yes 2, No
Medication_use	*Do you regularly take medication for pain relief for a musculoskeletal condition?*	1, Yes 2, No
Health_literacy	*How easily can you read and understand written health information? I find it…*	5-point Likert scale with response options: 1, Always difficult 2, Difficult 3, Neither easy nor difficult 4, Easy 5, Always easy

Domain	Question	Scale
Primary outcome measures		
X-ray_diag	***Baseline:*** *If you were told by your doctor that you had knee osteoarthritis, would you think an x-ray is necessary to confirm the diagnosis?* ***Post-intervention:*** *Having read the information sheet, if you were told by your doctor that you had knee osteoarthritis, would you think an x-ray is necessary to confirm the diagnosis?*	11-point Numeric Rating Scale (NRS) ranging from 0=definitely unnecessary to 10=definitely necessary
Surgery	***Baseline:*** *If you were told by your doctor that you had knee osteoarthritis, would you think joint replacement surgery (to replace the affected joint with an artificial joint) is necessary for your knee at some stage?* ***Post-intervention:*** *Having read the information sheet, if you were told by your doctor that you had knee osteoarthritis, would you think joint replacement surgery (to replace the affected joint with an artificial joint) is necessary for your knee at some stage?*	11-point NRS ranging from 0=definitely unnecessary to 10=definitely necessary
Secondary outcome measures		
Beliefs about treatment options		
Exercise	***Baseline:*** *If you were told by your doctor that you had knee osteoarthritis, would you think exercise and physical activity is helpful to manage it?* ***Post-intervention:*** *Having read the information sheet, if you were told by your doctor that you had knee osteoarthritis, would you think exercise and physical activity is helpful to manage it?*	11-point NRS ranging from 0=definitely not helpful to 10=definitely helpful
Exercise_damage	***Baseline:*** *If you were told by your doctor that you had knee osteoarthritis, would you think exercise and physical activity would damage your knee?* ***Post-intervention:*** *Having read the information sheet, if you were told by your doctor that you had knee osteoarthritis, would you think exercise and physical activity would damage your knee?*	11-point NRS ranging from 0=definitely would not damage it to 10=definitely would damage it

Domain	Question	Scale
Medication	***Baseline:*** *If you were told by your doctor that you had knee osteoarthritis, would you think medication is helpful to manage your knee symptoms?* ***Post-intervention:*** *Having read the information sheet, if you were told by your doctor that you had knee osteoarthritis, would you think medication is helpful to manage your knee symptoms?*	11-point NRS ranging from 0=definitely not helpful to 10=definitely helpful
Xray_determine	***Baseline:*** *If you were told by your doctor that you had knee osteoarthritis, would you think an x-ray is necessary to determine the best treatment for your knee?* ***Post-intervention:*** *Having read the information sheet, if you were told by your doctor that you had knee osteoarthritis, would you think an x-ray is necessary to determine the best treatment for your knee?*	11-point NRS ranging from 0=definitely unnecessary to 10=definitely necessary
OA Knowledge		
Knowledge	An 11-item questionnaire with the following questions: 1. *Your knee joint wears out with everyday use* 2. *Osteoarthritis will only get worse over time* 3. *Increased knee pain always means that you have damaged your knee* 4. *You need an x-ray or scan to know if you have osteoarthritis* 5. *Being active makes osteoarthritis feel better* 6. *Keeping a healthy body weight is a key part of osteoarthritis care* 7. *X-rays or scans show how much your osteoarthritis affects you* 8. *Making your leg muscles stronger improves your ability to do daily tasks* 9. *Pain from osteoarthritis can be managed without surgery* 10. *Exercises can ease pain as much as most medications* 11. *Most people with knee osteoarthritis will need a joint replacement at some point*	Each statement rated as False (1), Possibly False (2), Unsure (3), Possibly True (4), or True (5). Each item is scored on a scale from 1 to 5. Items 1,2, 3, 4, 7, and 11 are reverse scored and added to items 5, 6, 8, 9, and 10. Scores range from 11-55 with higher scores indicating greater/more accurate knowledge about osteoarthritis.
Level of concern		
Concern	***Baseline:*** *If you were told by your doctor that you have knee osteoarthritis, how concerned would you be that your knee problem would get worse in the future?*	4-point Likert scale with response options: 1, Not at all concerned 2, A little concerned 3, Quite concerned

Domain	Question	Scale
	Post-intervention: *Having read the information sheet, if you were told by your doctor that you have knee osteoarthritis, how concerned would you be that your knee problem would get worse in the future?*	4, Very concerned
Process measures		
Satisfaction		
Satisfaction_post	*If you were told by your doctor that you had knee osteoarthritis, how satisfied would you be with the information provided to you in the information sheet that you just read?*	1, Very dissatisfied 2, Dissatisfied 3, Neutral 4, Satisfied 5, Very satisfied
Time spent reading information pamphlet		
Qualtrics_timeonpage	Measured by Qualtrics	Minutes
Selfreportedtimeonpage	Self-reported	Minutes (open text box)

Appendix 2

DEFINITIONS OF DERIVED VARIABLES IN THE DATA SET

Variable in data set	Unit	Variable label in spreadsheet	Calculation	Range	Better
Belief about x-ray to diagnose knee OA	11-point NRS	Xray_diag	n/a	0-10	⇩
Belief about joint replacement surgery	11-point NRS	Surgery	n/a	0-10	⇩
Belief about exercise and physical activity	11-point NRS	Exercise	n/a	0-10	↑
Belief about safety of exercise	11-point NRS	Exercise_damage	n/a	0-10	⇩
Belief about medication	11-point NRS	Medication	n/a	0-10	⇩
Belief about x-ray to determine treatment	11-point NRS	Xray_determine	n/a	0-10	⇩

Knee OA knowledge scale	11 item, each scored 1-5 ordinal scale	Knowledge Know_1 Know_2 Know_3 Know_4 Know_5 Know_6 Know_7 Know_8 Know_9 Know_10 Know_11	1=false 2=possibly false 3=unsure 4=possibly true 5=true Items 1,2, 3, 4, 7, and 11 are reverse scored and added to items 5, 6, 8, 9, and 10.	11-55	↑
Level of concern	Single item, 0-4 (ordinal)	Concern	n/a	0-4	⇩

Appendix 3

LIST OF TABLES/FIGURES/LISTINGS

Number	**Title – analysis set**
Table 1	Baseline characteristics of participants by group, reported as mean (standard deviation) unless otherwise stated.
Table 2	Summary measures and between-group mean differences [95% CI] or odds ratios/relative risk ratios [95% CI] for each outcome as appropriate.
Table 3	Moderation of the effect of the removal of pathoanatomical content in knee osteoarthritis educational information on primary outcomes using complete case data.
Table 4	Process measures.
Appendix 1	Baseline characteristics of participants who did and did not complete both primary outcomes, reported as mean (standard deviation) unless otherwise stated.

Table 1. Baseline characteristics of participants by group, reported as mean (standard deviation) unless otherwise stated.

Domain	**Group 1 [N = xxx]**	**Group 2 [N = xxx]**
Age (years)		
Gender, n (%)		
Male		
Female		
Transgender male		
Transgender female		
Non-binary		
Other / Prefer not to say		
Ethnicity, n (%)		
Australian/New Zealander		
Aboriginal and Torres Strait Islander		
European		
Asian		
Other Oceania		
North African & Middle Eastern		
Sub-Saharan Africa		
North American		
South American		
State/territory, n (%)		
Australian Capital Territory		
New South Wales		
Northern Territory		
Queensland		
South Australia		
Tasmania		
Victoria		
Western Australia		
Height (m)		
Weight (kg)		
Body mass index (kg/m^2)		
Highest education level, n (%)		
Primary school		
Secondary school		
Trade or trade certificate		
University or tertiary institute		
Higher university degree		
Don’t know/unsure		
Financial situation, n (%)		
Find it a strain to get by from week to week		
Have to be careful with money		
Able to manage without much difficulty		
Quite comfortably off		
Very comfortably off		

Prefer not to answer	
Participation in regular exercise/physical activity, n (%)	
None	
1 time per week	
2-3 times per week	
4-5 times per week	
6+ times per week	
Ever sought care for knee pain from any healthcare provider, n (%)	
Activity-related knee pain in the last 3 months, n (%)	
Joint with knee pain, n (%)	
Left knee only	
Right knee only	
Both knees	
Sought formal treatment for knee pain, n (%)	
Self-reported knee pain (NRS)	
Self-reported physical function (NRS)	
Prior knee surgery, n (%)	
Regular pain relief for musculoskeletal condition, n (%)	
Ability to read and understand written health information#, median (IQR)	

IQR: interquartile range (25th to 75th percentile); NRS: numerical rating scale ranging from 0 ('no pain' or 'no interference') to 10 ('worst pain possible' or 'maximal interference with function').
#Rated using a 5-point scale with terminal descriptors of 1='always difficult' to 5='always easy'.

Table 2. Summary measures and estimated between-group mean differences [95% CI] or odds ratios/relative risk ratios [95% CI] for each outcome as appropriate.

Outcome	**Baseline, mean (SD)**		**Post-intervention ^, mean (SD)**		**Within-group change [a], mean (SD)**		**Between-group difference in post-intervention scores (n=xxx)**	
	Group 1 (n=xxx)	**Group 2 (n=xxx)**	**Group 1 (n=xxx)**	**Group 2 (n=xxx)**	**Group 1 (n=xxx)**	**Group 2 (n=xxx)**	**Mean [b] [95% CI]**	**P-value**
Primary outcomes*								
Belief x-ray is necessary for diagnosis [c]								
Belief joint replacement surgery is necessary at some stage [c]								
Secondary outcomes								
Belief exercise and physical activity is helpful [d,¥]								
Belief exercise would damage knee [c,β]								
Belief medication is helpful [c,¥]								
Belief x-ray is necessary to determine treatment [c,*]								
Osteoarthritis Knowledge [d,§]								
	Baseline, n (%)		**Post-intervention, n (%)**		**Between-group (n=xxx)**			

	Group 1 (n=xxx)	Group 2 (n=xxx)	Group 1 (n=xxx)	Group 2 (n=xxx)	Odds ratio [f] [95% CI]	P-value	Relative risk ratio [g] [95% CI]	P-value
Level of concern [h]					*OR [95% CI]*	*P*	–	–
1 = Not at all concerned					–	–	REFERENCE	–
2 = A little concerned					–	–	*RRR [95% CI]*	*P*
3 = Quite concerned					–	–	*RRR [95% CI]*	*P*
4 = Very concerned					–	–	*RRR [95% CI]*	*P*

SD = standard deviation.
^ Correlation of post-intervention with baseline continuous outcome scores:

- Experimental group.
- Control group.

[a] Within-group change was calculated as post-intervention minus baseline for all outcomes.
[b] Mean (95% CI) difference in post-intervention scores between groups, adjusted for the outcome at baseline, estimated using separate regression models for each outcome.
[c] Negative values favour Group 2.
[d] Positive values favour Group 2.
[f] Ordinal logistic regression model fitted, adjusted for the outcome at baseline where able, as proportional odds could be assumed. Odds ratio > 1 indicate increased odds of Group 2 compared to Group 1.[g] Multinomial regression model fitted, adjusted for the outcome at baseline where able, as proportional odds could not be assumed. Relative risk ratios > 1 indicate increased risk of Group 2 compared to Group 1.
*Measured using the 11-point numerical rating scale ranging from 0='definitely unnecessary' to 10='definitely necessary'.
[¥]Measured using the 11-point numerical rating scale ranging from 0='definitely not helpful' to 10='definitely helpful'.
[β]Measured using the 11-point numerical rating scale ranging from 0='definitely would not damage it' to 10='definitely would damage it'.
[§]Measured using the Knee Osteoarthritis Knowledge Scale [4]. Scores range from 11 to 55, with higher scores indicating greater knowledge about osteoarthritis.
[h] Question asked "if you were told by your doctor that you have knee osteoarthritis, how concerned would you be that your knee problem would get worst in the future?"

Table 3: Moderation of the effect of the removal of pathoanatomical content in knee osteoarthritis educational information on primary outcomes using complete case data.

Outcome	Potential moderators at baseline	Group 1 Mean (SD) [n=xxx]	Group 2 Mean (SD) [n=xxx]	Group 2 – Group 1 Mean (95% CI) [n=xxx]	Interaction p-value
Belief x-ray is necessary for diagnosis *	Knee pain in the last 3 months				
	No				
	Yes				
	Highest education level#				
	No tertiary				
	Some tertiary				
	Ever sought care for knee pain from any healthcare provider				
	No				
	Yes				
Belief joint replacement surgery is necessary at some stage *	Knee pain in the last 3 months				
	No				
	Yes				
	Highest education level#				
	No tertiary				
	Some tertiary				
	Ever sought care for knee pain from any healthcare provider				
	No				
	Yes				

SD=standard deviation; CI=confidence intervals.
*Measured using the 11-point numerical rating scale ranging from 0='definitely unnecessary' to 10='definitely necessary'.
#Highest education level as a binary variable, no tertiary (primary school, secondary school, trade or trade certificate and don't know/unsure) versus some tertiary (university or tertiary institute and higher university degree).

Table 4. Process measures.

Outcome	Group 1	Group 2
Satisfaction with information pamphlet, n (%)		
Very satisfied		
Satisfied		
Neutral		
Dissatisfied		
Very dissatisfied		
Time spent reading information pamphlet, median (IQR)		
Self-reported (mins)		
Measured by Qualtrics (mins)		

SD=standard deviation.

Appendix 1. Baseline characteristics of participants who did and did not complete both primary outcomes, reported as mean (standard deviation) unless otherwise stated.

Domain	**Incomplete one or both primary outcomes [n = xxx]**	**Completed both primary outcomes [n = xxx]**
Group, n (%)		
1		
2		
Age (years)		
Gender, n (%)		
Male		
Female		
Transgender male		
Transgender female		
Non-binary		
Other / Prefer not to say		
Ethnicity, n (%)		
Australian/New Zealander		
Aboriginal and Torres Strait Islander		
European		
Asian		
Other Oceania		
North African & Middle Eastern		
Sub-Saharan Africa		
North American		
South American		
State/territory, n (%)		
Australian Capital Territory		
New South Wales		
Northern Territory		
Queensland		
South Australia		
Tasmania		
Victoria		
Western Australia		
Height (m)		
Weight (kg)		
Body mass index (kg/m^2)		
Highest education level, n (%)		
Primary school		
Secondary school		
Trade or trade certificate		
University or tertiary institute		
Higher university degree		
Don’t know/unsure		

Financial situation, n (%)
- Find it a strain to get by from week to week
- Have to be careful with money
- Able to manage without much difficulty
- Quite comfortably off
- Very comfortably off
- Prefer not to answer

Participation in regular exercise/physical activity, n (%)
- None
- 1 time per week
- 2-3 times per week
- 4-5 times per week
- 6+ times per week

Ever sought care for knee pain from any healthcare provider, n (%)

Activity-related knee pain in the last 3 months, n (%)
- Joint with knee pain, n (%)
  - Left knee only
  - Right knee only
  - Both knees
- Sought formal treatment for knee pain, n (%)
- Self-reported knee pain (NRS)
- Self-reported physical function (NRS)

Prior knee surgery, n (%)

Regular pain relief for musculoskeletal condition, n (%)

Ability to read and understand written health information#, median (IQR)

IQR: interquartile range (25th to 75th percentile); NRS: numerical rating scale ranging from 0 ('no pain' or 'no interference') to 10 ('worst pain possible' or 'maximal interference with function').
#Rated using a 5-point scale with terminal descriptors of 1='always difficult' to 5='always easy'.