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## Acceptability and feasibility of a cognitive-behavioural intervention for pain management before total knee arthroplasty: a pilot trial

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### ABSTRACT

**Background:** Although psychological factors predict the development of persistent pain after total knee arthroplasty (TKA), psychological interventions to prevent persistent pain are under-explored. This pilot trial evaluated the acceptability and feasibility of a cognitive-behavioural intervention targeting risk factors for post-surgical pain among patients scheduled for TKA (UTN: U1111-1243-1067/ACTRN12621001095853).

**Methods:** Patients with elevated expectations of post-surgical pain and anxiety were recruited from TKA waiting lists. Treatment was remotely delivered by a psychologist over 3 sessions, supported by online and written resources. Eligibility, recruitment and completion rates, and perceptions of treatment were collected. Pain, disability, pain- and treatment-expectations, self-efficacy and catastrophizing were measured pre- and post- intervention.

**Results:** Of 241 people pre-screened, 144 were invited to complete screening, 51 declined, 58 did not meet inclusion criteria, 35 enrolled, and 30 completed the trial. Satisfaction ratings were high, and participants found the content understandable, useful and relevant. Pre to post treatment scores for pain intensity and pain catastrophizing improved with small effect sizes.

**Conclusions:** A psychological intervention is acceptable to patients awaiting TKA and may lead to small improvements in pain-relevant outcomes. An RCT aimed at reducing persistent post-surgical pain by combining cognitive behavioural therapy with physical therapy and medical optimisation is planned.


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## Introduction

Total knee arthroplasty (TKA) is an effective treatment for knee osteoarthritis and leads to improvements in physical function and pain for most patients (Lau et al., 2012; Riddle et al., 2019). However, between 8 and 34% of patients report continued pain more than three months after TKA (Alattas et al., 2017; Beswick et al., 2012; das Nair et al., 2018; Kim et al., 2018; Rice et al., 2018). Persistent post-surgical pain is defined as pain lasting three or more months after surgery despite a successful procedure. Once established, persistent pain is difficult to treat and has a severe impact on quality of life (Kim et al., 2018), healthcare expenditure, and productivity (Gaskin & Richard, 2012).

The strongest predictors of persistent pain after TKA are pre-operative pain intensity and psychological factors such as pain catastrophising or mood (Hinrichs-Rocker et al., 2009; Lewis et al., 2015; Lluch et al., 2018; Rice et al., 2018). A recent predictor study from our group found that pre-operative pain intensity, anxiety and expected pain were better predictors of persistent pain after TKA than other psychological, neuro-physiological, genetic, clinical and surgical predictors (Rice et al., 2018). Therefore, theoretically, targeting psychological risk factors in the peri-operative phase may reduce the incidence of persistent post-surgical pain.

Although psychological factors are established predictors of persistent post-surgical pain, the feasibility and acceptability of delivering CBT interventions prior to TKA remains unclear. There are relatively few published evidence-based outcome studies, and they have produced mixed results (Birch et al., 2020; Cai et al., 2018; Culliton et al., 2018; das Nair et al., 2018; Lluch et al., 2018; Louw et al., 2019; Riddle et al., 2019). Importantly, integrated multi-disciplinary interventions to prevent persistent pain after TKA are lacking. Given that this population may be focussed on a curative procedure for their pain, the extent to which they will engage in an effortful psychological intervention is unknown. To inform the psychological component of a proposed RCT we aimed to undertake a non-randomised pilot trial of the psychological component of this intervention, developed in accordance with the CONSORT guideline extension to pilot and feasibility studies (Eldridge et al., 2016; Lancaster & Thabane, 2019).

This non-randomised pilot trial aimed to test whether it would be feasible to remotely deliver a brief CBT intervention to people awaiting TKA, and whether this would be acceptable for patients. The criteria for feasibility (items 1–2) and acceptability (items 3–4) set by the research team were as follows;

1. Approximately 20% of people waitlisted for surgery should meet inclusion criteria and be willing to take part.
2. At least 80% of people that enrol, complete the intervention (80% retention).
3. Session rating scales for treatment relevance and treatment satisfaction must be >7 on Likert scales ranging from 0–10.
4. Open response items must indicate that participants find the treatment beneficial and believe that it is an acceptable and appropriate intervention prior to TKA.

We also measured change scores for a range of pain-relevant outcomes to identify potential process variables that might be the most amenable to change with the present CBT intervention.

## Methods

### *Trial design*

A non-randomised pilot trial was conducted to test the acceptability and feasibility of a psychological component of a planned multidisciplinary RCT. Outcomes related to potential process variables were assessed before and after three treatment modules. A sample size of  $N=30$  was recruited based on sample size recommendations for pilot studies (Lancaster & Thabane, 2019).

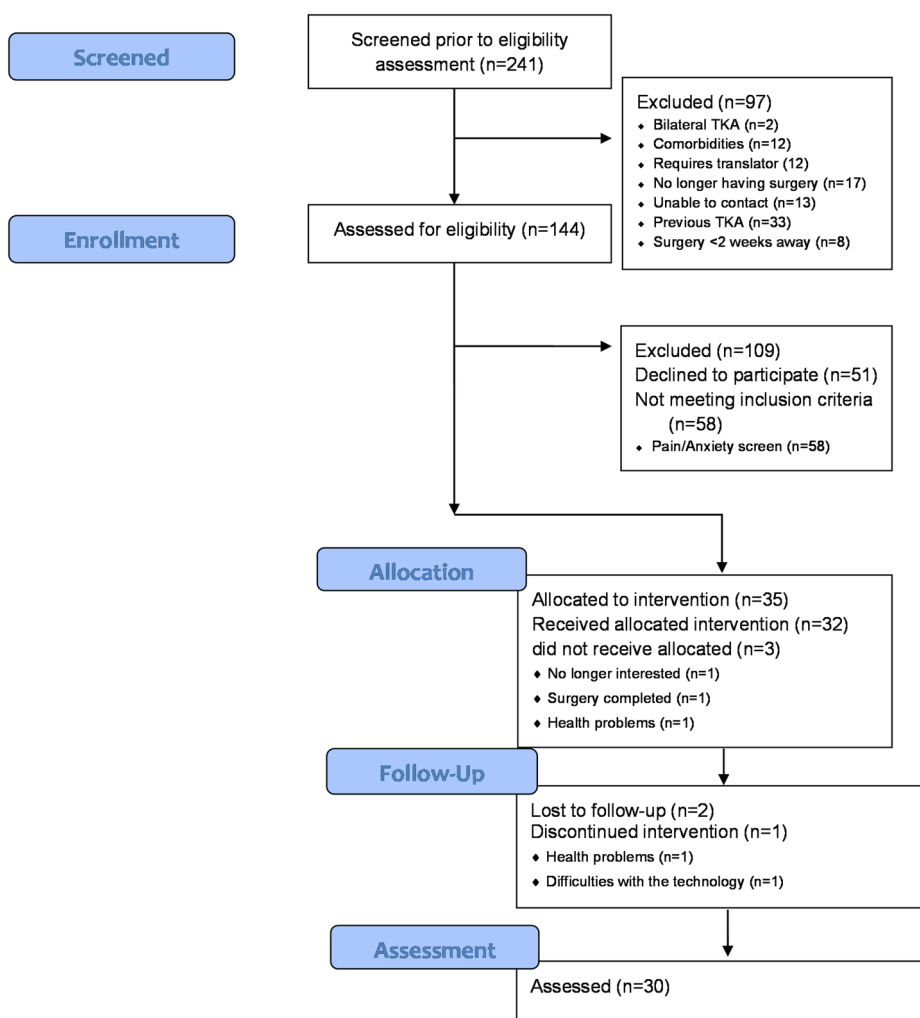
### *Ethical approval and trial registration*

Ethical approval was granted by the Health and Disability Ethics Committee (New Zealand Ministry of Health; HDEC ref 19/NTB/208/AM01), and locality approval was granted by the Waitematā District Health Board (RM14565). Each participant gave written informed consent to participate. This trial was registered with the Australian New Zealand Clinical Trials Registry on 18.08.21 (ACTRN12621001095853) universal trial number, U1111-1243-1067.

### *Participants*

Participants were recruited from the TKA waitlist at North Shore Hospital, Te Whatu Ora, Waitematā, New Zealand. Between February 2021 and January 2022, 241 consecutive patients waiting for a single knee replacement were assessed for eligibility. Those who met inclusion criteria (below) were sent a link to an online information sheet and consent form. Participants who indicated consent were directed to an online questionnaire. The completion of both the consent form and the questionnaire enrolled participants into the trial. See the Results section and [Figure 1](#) for recruitment details.

Inclusion criteria were >18 years, waitlisted for a single primary unilateral TKA, able to communicate in English, and identified as having elevated anxiety or expected pain post-surgery according to screening questionnaires. The screening questions were as follows: elevated anxiety was considered a score of  $\geq 10$  on items 22, 27, 29, 34, 36 and 40 from the trait anxiety scale of the state-trait anxiety inventory; elevated pain expectations were considered a score of 1 or greater on a single item "Please indicate the level of pain you think you will experience in your operated knee six months after your surgery (0–10)" (See [Supplementary File 1](#)). The cutoff for the expected pain item appears low (1/10) but this was the median score from a previous cohort (Rice et al., 2018), suggesting that pain expectations after TKA may potentially be considered dichotomous. The specific screening items were selected because trait anxiety and expected pain were predictors of post-surgical pain in previous research by our group (Rice et al., 2018). However screening questions needed to be



**Figure 1.** Consort diagram illustrating recruitment and retention in the study.

administered on the telephone so a limited number of STAI items were included to reduce burden, and because scores for the selected items closely represented scores for the longer scale. Participants were excluded if they had a medical condition that prevented participation, if they were uncertain about whether they would proceed with their TKA, if they planned to have their TKA in a different medical setting, or if their TKA was scheduled within the upcoming 2 wk.

### Procedures

The intervention was designed following a strengths-based, person-and-whānau (family or close others) centred approach. To ensure responsiveness to indigenous persons, modules were developed in consultation with a Māori cultural advisor (EM) and were structured to prioritize relationship building (whanaungatanga). Whānau (family) were invited to attend treatment sessions.

The intervention comprised three treatment sessions, one targeting negative pain expectations, one targeting anxiety, and one follow up appointment (see Table 1). Each session was delivered *via* videoconferencing (Zoom) or telephone appointment according to participant preferences. Participants were provided with hard copy workbooks and online materials (or CD and DVD recordings if preferred) to use over the course of the intervention. Before and after the three appointments, participants completed online questionnaires using secure REDCap software (Harris et al., 2009) and were sent a gift voucher to thank them for their participation. Participants also completed a final set of questionnaires six months after their surgery.

**Table 1.** Intervention design, content, and materials.

Module 1: What to expect from knee replacement	
Focus	Building positive expectations for surgery.
Duration	Approximately 45 min
Content	<ul style="list-style-type: none"> <li>• Rapport building</li> <li>• Education about surgery aimed at enhancing expectations of the efficacy of TKA for improving knee function.</li> <li>• Neuroscience education based on the booklet by Adrian Louw (2015).</li> <li>• Optimistic goal setting for activities</li> <li>• Social modelling videos depicting people who had successfully recovered from TKA.</li> <li>• Information about how to access help should they have concerns following TKA.</li> </ul>
Resources:	Chapter 1 of the trial workbook/website entitled "Understanding Pain & Optimising Recovery" Section 1 of the My Knee Surgery Plan booklet. This included brief activities to consolidate new information such as a checklist of things that might influence their pain (i.e. 'having pain for a long time' and 'difficulty relaxing') as well as a section to identify behavioral goals. Powerpoint slideshow for use during video call
Module 2: Managing anxiety and pain	
Focus	Understanding and managing anxiety and pain
Duration	45 min
Content	<ul style="list-style-type: none"> <li>• Review of previous session,</li> <li>• Discussion of activities from the My Knee Surgery Plan workbook</li> <li>• Discussion of goals identified.</li> <li>• Education about anxiety, the fight or flight response, and the relationship between pain and anxiety.</li> <li>• Introduction to the cognitive-behavioral model to explain the relationship between anxiety and pain.</li> <li>• Explanation of how relaxation strategies can be used to manage pain and anxiety, both pre- and post-operatively.</li> </ul>
Resources	Relaxation recordings (website or CD) with relaxation diary Chapter 2 of the trial workbook/website entitled "Preparing for Surgery: Stress & Relaxation" Section 2 of the <i>My Knee Surgery Plan</i> booklet. Powerpoint slideshow for use during video call
Follow-up	
Focus:	Consolidation and application of intervention materials
Duration:	Approximately 20 min.
Content:	<ul style="list-style-type: none"> <li>• Review of the previous session</li> <li>• Discussion of activities completed in the <i>My Knee Surgery Plan</i> workbook</li> <li>• Discussion of experience practicing relaxation techniques and addressing barriers to practicing relaxation at home</li> <li>• Discussion of questions or concerns about their upcoming surgery and the content of the treatment sessions</li> </ul>
Resources	Chapters 1–4 of the trial workbook/website Sections 1 & 2 of the <i>My Knee Surgery Plan</i> booklet Powerpoint slideshow for use during video call

## Measures

### Acceptability measures

Acceptability and perceptions of the intervention: Participants indicated on 10-point Likert scales how easy was it to understand the modules, how likely they were to use the skills and information learned, treatment satisfaction, treatment relevance, how much of the workbook they read, and how much of the [online material](#) they accessed. Participants also answered 5 open-ended questions to gather information about their perspectives of the appointments and the intervention materials, and any suggested improvements they had regarding the intervention. See [Supplementary File 2](#).

### Process measures

Pain Intensity and Disability: The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (Bellamy et al., 1988) comprises five items measuring pain intensity, two items measuring stiffness, and 17 items measuring physical function. Participants also completed the 11-point Pain Numeric Rating Scale (NRS) (Farrar et al., 2001) which measures pain intensity over the previous two days on a scale from 0 (no pain) to 10 (extreme pain).

Pain Expectations: Anticipated post-surgical pain was measured with a single item (Rice et al., 2018): "Please indicate the level of pain you think you will experience in your operated knee six months after your surgery". Participants responded on an 11-point Likert scale ranging from 0 (no pain) to 10 (extreme pain).

Treatment Expectations: Treatment expectations were measured with the five-item Expectation for Treatment Scale (ETS) (Barth et al., 2019). This measures patients' expectations of their coping ability, vitality, physical health, and reduction of complaints following treatment.

Anxiety: The State-Trait Anxiety Inventory (STAI) (Ramanaiah et al., 1983) is a 40-item scale measuring current (state) anxiety and stable (trait) anxiety.

Pain Self-Efficacy: The Pain Self-Efficacy Questionnaire (PSEQ) (Nicholas, 2007) is a 10-item scale measuring confidence to engage in various aspects of life despite pain.

Pain Catastrophizing: The Pain Catastrophizing Scale (PCS) (Sullivan et al., 1995) is a 13-item measure of the extent to which an individual's response to pain is characterized by rumination, magnification and helplessness.

## Data analysis

Data were collected using REDCap 13.1.28 and analyzed using SPSS Statistics v27. Data were screened for normality and outliers. Recruitment and completion rates were recorded. One-way analysis of variance (ANOVA) was used to test for differences between participants who completed the trial, and those who were excluded, declined, or withdrew. All outcomes met homogeneity of variance assumptions. Welch tests and Hochberg's GT2 post-hoc tests were used to account for differing sample sizes. Treatment acceptability ratings were not normally distributed so are reported as the median (mdn) and inter-quartile range (IQR). Open ended questions were coded according to themes and described. Effect sizes (ESs) and confidence intervals (CIs) for changes in potential process variables from pre- to post- intervention were calculated and repeated measures *t*-tests were used to test for significant differences.

Feedback to open ended questions was summarized by coding each comment according to content and grouping codes to identify recurring themes or topics. The two researchers (NT and DB) who completed this process have training and experience in reflexive thematic analysis but given the lack of complexity of the open-ended data, the analysis is a content summary rather than a full qualitative analysis.

## Results

### *Recruitment and retention*

Between February 2021 and January 2022, 241 consecutive patients from the TKA waitlist were pre-screened, and 97 were excluded (due to bilateral TKA, comorbidities, requiring a translator, no longer having TKA, having had a previous TKA, surgery being too soon, and being non-contactable). Of the 144 invited to complete screening, 51 declined, 58 completed screening measures but did not meet the cut off scores for elevated anxiety and expected pain, 35 completed informed consent procedures and enrolled in the trial. Three withdrew before the initial appointment, and two withdrew after one appointment, resulting in a final sample size of 30. See [Figure 1](#).

### *Sample*

Participants were majority women (66.7%) and the mean age was  $70.0 \pm 8.3$  years. There were no gender or age differences between those who completed the intervention and those who declined, were excluded, or withdrew. See [Table 2](#) and [Supplementary File 1](#).

### *Treatment satisfaction*

Scores on Likert scales indicated that participants found the information easy to understand, were likely to use the skills or information learned, were satisfied with the support package, found the content relevant, read most of the workbook, and accessed most of the [online material](#), see [Table 3](#).

### *Participant feedback*

Open responses from 26/30 participants indicated that participants found the treatment beneficial, acceptable, and appropriate prior to TKA. Analysis of open-ended comments generated three findings: 1) the intervention was educational and enhanced confidence, 2) the intervention was easy and convenient, and 3) people valued the therapeutic relationship, described in more detail below.

The first finding was that people found the intervention educational, which enhanced confidence for surgery. Participants appreciated that the content was well-researched, evidence-based, and informative. *"Workbook and video was very informative and relaxation exercises are and will continue to be very useful."* Participants consistently indicated that information helped them to feel more confident about their upcoming surgery, *"I feel I'm going into surgery with a greater understanding of what I need to practice to get through*

**Table 2.** Baseline demographic and screening measure scores for participants who completed the trial (N=30).

Age (m (SD))		70.0 (8.3)
Gender (%F)		66.7 (20)
Expected pain (mdn [IQR])		3.0 [2,5]
Anxiety score (mean, (SD))		14.6 (3.4)
Comorbidities		1.7 (1.4)
Ethnicity % (n)	NZE/European	79.9 (24)
	Māori	16.7 (5)
	Asian	3.3 (1)
Marital status % (n)	Single	13.3 (4)
	Married	50 (15)
	Partnership	10 (3)
	Divorced/separated	10 (3)
	Widowed	13.3 (4)
Education attainment % (n)	None	10 (3)
	High school	46.7 (14)
	Trade cert	16.7 (5)
	Diploma	6.7 (2)
	Bachelors	10 (3)
Employment % (n)	Post Grad	6.7 (2)
	Retired	56.7 (17)
	Full time	16.7 (5)
	Part time	3.3 (1)
	Unemployed seeking	6.7 (2)
	Home	3.3 (1)
	Self employed	3.3 (1)
	Unable to work	10 (3)
OA duration in yrs. Mean, (SD)		12.21 (11.46)

m = mean; SD = standard deviation; mdn = median; IQR = interquartile range.

**Table 3.** Descriptive statistics for treatment satisfaction items indicating intervention acceptability.

	Mdn	IQR	Range
How easy was it to understand the discussion and information we provided?	9	8, 10	4–10
How likely are you to use the skills or information you learned when you have your surgery?	9	8, 10	5–10
How satisfied were you with the information/support package?	9	8, 10	5–10
How relevant was the information/support package for you?	9	8, 10	3–10
How much of the workbook did you read?	10	9, 10	0–10
How much of the <a href="#">online material</a> did you access?	9	5.5, 10	0–10

Mdn = Median; IQR = interquartile range.

*my surgery in the best possible way.*" Overall, this finding indicates that participants valued explanations that improved their understanding of pain and what to expect, which helped them to feel more prepared and confident for surgery.

The second finding focused on the value of the therapeutic relationship. Participants were grateful to have someone supportive to talk to, and appreciated that the therapists were 'friendly', 'personable', 'informative', and 'empathetic'. One person said, "*They were awesome made me think about and evaluate my situation. It was very helpful to be able to verbalize things and talk them through*" Participants appreciated the way that the therapists explained things, and the personal connection that they developed with the therapists throughout the treatment programme.

The third finding centred around convenience and ease. Participants described the intervention as flexible and easy to accommodate. Participants reported that the written materials were easy to follow and understand, people enjoyed having a hard copy of the workbook and tended to favor this over the website. *"I found it very easy to cope with and comprehensive. Not at all imposing."* This indicates that participants were willing to engage in treatment sessions, and appreciated the convenience and flexibility of online appointments, but valued having hard copy supporting materials.

### Change scores for process variables

There were small effect sizes (ES) showing statistically significant improvements in catastrophising, and WOMAC pain and WOMAC total scores from pre- to post-intervention. Changes in WOMAC stiffness, NRS pain scores, state anxiety, trait anxiety, expected pain, expectations for treatment, and pain self-efficacy were negligible. See Table 4.

Six-month follow-up data: Although follow-up data were collected 6-months after surgery, given substantial surgical delays due to the SARS COV-2 pandemic which

**Table 4.** Mean baseline and post-intervention scores for study outcomes, with effect sizes and confidence intervals.

Scale (possible score range)	Baseline M (SD)	Post-intervention M (SD)	Mean difference	t value	P value (one sided)	Effect size (Hedges)	CI
WOMAC Total (0–96)	62.4 (14.7)	58.5 (13.3)	3.9	1.45	0.08	0.26	–0.10; .61
WOMAC Pain (0–20)	12.5 (3.1)	11.5 (3.0)	1.0	1.84	0.04*	0.33	–0.03; .68
WOMAC Stiffness (0–8)	5.3 (1.6)	5.1 (1.4)	0.2	0.69	0.25	0.12	–0.23; .47
WOMAC Function (0–68)	44.6 (10.7)	41.9 (9.7)	2.7	1.29	0.10	0.23	–0.13; .58
Pain NRS (0–10)	7.10 (1.6)	7.13 (2.0)	–0.03	–0.10	0.46	–0.02	–0.37; .33
PCS-Total (0–52)	18.7 (13.3)	15.6 (14.6)	3.1	1.83	0.04*	0.32	–0.04; .68
PCS-Magnify (0–12)	3.9 (3.0)	3.3 (3.3)	0.6	1.33	0.10	0.24	–0.12; .59
PCS-Helpless (0–16)	8.2 (6.1)	6.8 (6.7)	1.4	1.83	0.04*	0.33	–0.04; .68
PCS-Ruminate (0–24)	6.6 (5.1)	5.5 (5.1)	1.1	1.41	0.08	0.26	–0.10; .61
Expected Pain (0–10)	3.6 (2.6)	3.2 (2.6)	0.4	0.91	0.19	–0.16	–0.19; .51
Expectations for Tx (5–20)	16.0 (2.4)	15.9 (2.4)	0.1	–0.29	0.39	0.05	–0.30; .40
STAI State (20–80)	38.6 (12.7)	37.7 (14.8)	0.9	0.52	0.61	0.09	–0.26; .44
STAI Trait (20–80)	36.7 (11.5)	38.0 (12.6)	–1.2	–1.01	0.16	–0.18	–0.53; .17
PSEQ (0–60)	30.7 (12.9)	32.8 (14.4)	–2.1	–1.14	0.13	–0.20	–0.55; .15

M; Mean, SD; Standard Deviation, CI; Confidence Interval, WOMAC; The Western Ontario and McMaster Universities Osteoarthritis Index, NRS; Numeric Rating Scale, PCS; Pain Catastrophising Scale, Tx; Treatment, STAI; State-Trait Anxiety Inventory, PSEQ; Pain Self Efficacy Questionnaire.

\* $p < 0.05$ .

meant that some participants were still waiting for TKA over two years following the intervention, it was agreed that follow-up data could not be reliably related to the intervention, so these analyses were not undertaken.

## Discussion

The present trial indicates that a brief online CBT intervention, delivered prior to TKA is acceptable to patients, and may lead to improvements in some risk factors including pain intensity and pain catastrophising. Feasibility criteria that approximately 20% of those waitlisted for TKA would meet inclusion criteria and be willing to take part were not met, with just 12% of the sample being both interested and eligible. Given our overall recruitment rate of 12%, and attrition rate of approximately 17% (5/35), future trials may benefit from broadening the inclusion criteria, incentivizing participation, and running multicenter trials.

Alongside feasibility, acceptability findings also provide useful information for the delivery of CBT interventions in TKA cohorts. Acceptability criteria were uniformly met, with 85% (>80%) of those enrolled completing the intervention, scores on treatment satisfaction items were universally high (>7/10), and responses to open ended questions were predominantly very positive.

Additionally, effect sizes for potential process variables; pain catastrophising and WOMAC pain were promising. Although psychological factors are reliable predictors of surgical outcomes, this is not widely recognized in the public domain, and people awaiting TKA generally expect that surgery will alleviate pain and disability (Culliton et al., 2018). Findings that a reasonable proportion of people who were eligible to participate were a) willing to enrol (41%), b) completed the intervention (35%), and c) reported benefits, supports continued efforts to develop, implement, and evaluate interventions targeting psychological risk factors during the peri-surgical period. Additionally, although it is sometimes thought that older adults may be less able to engage in digital interventions, findings that this cohort were prepared to take part in a remotely delivered intervention, with web-based education material and video calls, supports the use of digital interventions for older adults, particularly when this overcomes barriers, and facilitates access to care.

Finally, although we designed the intervention to target anxiety and expected pain, results show effects may in fact be specific to pain and pain catastrophising. These are all highly related constructs and it may be that psychological interventions do not target one factor precisely over another related factor. Pain and pain catastrophising may be more amenable to intervention so may be the most suitable intervention targets. However, because the focus of this trial was feasibility and acceptability rather than hypothesis testing, power calculations were not implemented, and findings must be interpreted with caution.

## Limitations

This trial has some limitations. First, because the primary aim was to test the feasibility and acceptability of the psychological component of a larger, definitive RCT, randomization and blinding were not used. Therefore, it is not known whether outcomes

were related to the intervention itself, or are attributable to other, non-specific factors. Second, preventative interventions should target high risk groups, and it is unlikely that our screening identified everyone at risk of adverse outcomes. Third, 51/144 (35%) of patients that may have been eligible, declined to participate. Reasons for declining were not systematically collected, so implications for intervention acceptability cannot be determined. Finally, although the intervention was designed to be delivered in the weeks leading up to surgery, the SARS-Cov-2 pandemic resulted in dramatic increases in surgical wait-times, and most participants did not have a planned surgery date at the time of the intervention. This lack of proximity may have reduced perceived relevance, and engagement with the intervention material. Relatedly, follow-up data were collected 6 months after surgery, with the intention of comparing this to a previous cohort. However, given substantial delays, with some participants still waiting for TKA over two years later, it was agreed that these data could not be meaningfully related to the intervention, so analyses were not undertaken.

### **Conclusions**

The present trial indicates that a brief online CBT intervention, delivered prior to TKA is acceptable to patients, and may lead to improvements in risk factors for poorer outcomes, including pain intensity and pain catastrophising. Participants found the intervention relevant, useful, and helpful, and recruitment and retention rates indicate that with adjustments, a definitive RCT is feasible and warranted. Such adjustments might include broadening eligibility criteria, incentivising participants, or conducting a multi-center study. Although few stand-alone interventions have been found to reliably reduce the incidence of persistent post-surgical pain following TKA, incorporating psychology modules into broader multidisciplinary peri-surgical interventions appears warranted. Findings from this trial will be used to inform the design of a definitive multidisciplinary RCT aimed at reducing the incidence of persistent post-surgical pain following TKA.

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### **Data availability**

Data available from the authors on reasonable request.

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