Development of a pre-operative education and prehabilitation digital intervention for patients awaiting total knee replacement: a Virtual Knee School

Anna Mary Anderson

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Intellectual property and publication statements

The candidate confirms that the work submitted is her own, except where work which has formed part of jointly authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

Chapter 4 includes work from the following paper, which has been submitted to a peer-reviewed journal but is not yet published:

> **Anderson AM**, Drew BT, Antcliff D, Redmond AC, Comer C, Smith TO, McHugh GA. Content and delivery of pre-operative interventions for patients undergoing total knee replacement: a rapid review

Chapter 5 includes work from the following published paper:

> **Anderson AM**, Comer C, Smith TO, Drew BT, Pandit H, Antcliff D, Redmond AC, McHugh GA. Consensus on pre-operative total knee replacement education and prehabilitation recommendations: a UK-based modified Delphi study. BMC Musculoskelet Disord. 2021;22(1):352. https://doi.org/10.1186/s12891-021-04160-5

The chapters in this thesis are interlinked due to the project's mixed methods design; therefore, brief details from the above papers are also included in other chapters of this thesis.

The researcher is the first and corresponding author on both the above papers. The researcher led all aspects of the work reported in the papers, including the study conception, study design, data acquisition, data analysis, data interpretation, drafting the papers and responding to reviewers' comments on the papers.

The researcher's supervisors/advisors contributed to revising the papers and read and approved the final versions. They also contributed to specific aspects of the papers as described below.

Rapid review paper (Chapter 4)

BTD: study design and data interpretation.

DA: study design and data interpretation.

ACR: study conception and study design.

CC: study conception, study design and data interpretation.

TOS: study design.

GAM: study conception, study design and data interpretation.

Modified Delphi study paper (Chapter 5)

CC: study conception, study design and data analysis.

TOS: study design.

BTD: study conception and study design.

HP: data interpretation.

DA: study design.

ACR: study conception and study design.

GAM: study design and data analysis.

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Abstract

Background: Total knee replacement (TKR) is a common operation usually performed to relieve the symptoms of end-stage knee osteoarthritis. Patients often face a long wait for TKR whilst experiencing severe pain. Even after TKR, ~20% of patients continue to experience long-term pain. Providing pre-operative TKR education and prehabilitation (pre-operative health/wellbeing optimisation) support could improve pre- and post-operative outcomes. However, current pre-operative TKR services are variable, inefficient and often inadequate. A rigorously developed digital intervention could help address these problems.

Aim: To develop a pre-operative TKR education and prehabilitation digital intervention, the *'Virtual Knee School'* (VKS).

Methods and findings: The VKS was developed using an evidence-, theory- and person-based approach and complex mixed methods design. A rapid review (n=52 studies) demonstrated that definitive evidence on the optimal content/delivery of pre-operative TKR interventions is lacking. A modified Delphi study (n=30 patients; n=30 professionals) enabled the development of recommendations on pre-operative TKR interventions, which support digital delivery formats. A qualitative descriptive study (n=14 patients) highlighted the VKS should account for individual differences and be tailored to the pre-operative context. Three theoretical modelling approaches helped guide the design, description and evaluation of the VKS. A VKS prototype was developed based on the preceding studies' findings and iteratively refined through think-aloud interviews (n=9 patients). The interviews evaluated the prototype's usability and explored patients' perspectives of it. The findings suggest the VKS would be a valuable resource for many patients pre- and post-TKR, but the digital delivery format is unlikely to meet all patients' individual needs.

Conclusions: This project rigorously developed a novel pre-operative TKR digital intervention, which warrants further evaluation. Key implications include:

- comprehensive pre-operative TKR education and prehabilitation support should be rapidly accessible in digital and non-digital formats;
- pre-operative TKR digital interventions should employ computer- and self-tailoring to account for patients' individual needs/preferences.

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Abbreviations

ATOCP	Association of Trauma and Orthopaedic Chartered Physiotherapists
BCTTv1	Behaviour Change Technique Taxonomy (v1)
BCW	Behaviour Change Wheel
BCT	Behaviour change technique
BMI	Body mass index
BRC	Biomedical Research Centre
BSI	British Standards Institution
CBT	Cognitive behavioural therapy
CGP-number	Common guiding principle – number of principle
COM-B	Capability, Opportunity, Motivation, Behaviour (model of behaviour)
COREQ	Consolidated Criteria for Reporting Qualitative Research
CREDES	Conducting and REporting of DElphi Studies
DVD	Digital video disc
ELSA	English Longitudinal Study of Ageing
ERPP	Enhanced Recovery Partnership Programme
ESCAPE-pain	Enabling Self-management and Coping with Arthritic Pain through Exercise
HEE	Health Education England
HTA	Health Technology Assessment
IDEAS	Integrate, Design, Assess, and Share
INDEX	IdentifyiNg and assessing different approaches to Developing compleX interventions
IRQ	Interquartile range
JBI	Joanna Briggs Institute
LOS	Length of hospital stay
MMAT	Mixed Methods Appraisal Tool
MoSCoW	Must have, Should have, Could have, Would like (prioritisation model)
MRC	Medical Research Council

NGT	Nominal group technique
NHS	National Health Service (in the United Kingdom)
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NJR	National Joint Registry (for England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey)
NMES	Neuromuscular electrical stimulation
NPT	Normalisation Process Theory
OA	Osteoarthritis
PAG	Project Advisory Group
PAS	Publicly Available Specification
PBA	Person-based approach
PDF	Portable Document Format
PI	Principal investigator
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROM	Patient-reported outcome measure
PROSPERO	International Prospective Register of Systematic Reviews
QI	Quality indicator
QOL	Quality of life
RAND	Research and development (Corporation)
RCT	Randomised controlled trial
RoB	Cochrane risk-of-bias tool
SDT	Self-Determination Theory
SMART	Specific, Measurable, Achievable, Realistic, Timed (goal setting)
TDF	Theoretical Domains Framework
THR	Total hip replacement
TIDieR	Template for Intervention Description and Replication
TKR	Total knee replacement

UCLA	University of California-Los Angeles
UK	United Kingdom
UKR	Unicompartmental knee replacement
VGP-number	Virtual Knee School guiding principle – number of principle
VKS	Virtual Knee School
WCAG	Web Content Accessibility Guidelines
WYAAT	West Yorkshire Association of Acute Trusts

Chapter 1 Thesis introduction

1.1 Introduction

This thesis reports a doctoral research project focused on developing a novel pre-operative education and prehabilitation digital intervention for patients awaiting total knee replacement (TKR)[1]. This chapter briefly summarises the background to the project and outlines its aim and objectives. It then provides an overview of the subsequent chapters.

1.2 Background

TKR is a common orthopaedic operation, with ~97,000 TKR procedures typically undertaken annually in the United Kingdom (UK) alone (1). TKR is usually performed to relieve the symptoms of end-stage knee osteoarthritis (OA) (2). Most patients who undergo TKR are older adults who are overweight or obese (3, 4). Even before the COVID-19 pandemic, many patients faced a long wait for TKR (5). Widespread service disruptions due to the COVID-19 pandemic have compounded this issue (6). Patients awaiting TKR often experience high and deteriorating levels of pain and functional limitations and poor health-related quality of life (QOL) (7, 8). Whilst most patients' symptoms improve significantly post-TKR (9, 10), ~20% of patients continue to experience long-term pain (11). Correspondingly, literature suggests that up to 20% of patients who undergo TKR are not satisfied with their clinical outcome (12, 13). Even those who are satisfied often experience residual symptoms such as stiffness and difficulty kneeling (14, 15).

Various modifiable pre-operative predictors of poor TKR outcomes have been identified. These include pre-operative pain, function, mental wellbeing and lifestyle factors, such as obesity and smoking (16-18). Additionally, lack of expectation fulfilment is an important predictor of dissatisfaction post-TKR (19, 20). Pre-operative TKR interventions that target modifiable predictors of poor TKR outcomes could help improve patient outcomes pre- and post-operatively (21). Key types of pre-operative TKR intervention include pre-operative education and prehabilitation programmes. Pre-operative TKR education typically involves providing information on multiple topics to increase patients' knowledge base (22, 23). This offers many potential benefits such as

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[1] *'TKR'* is used in this thesis when referring to total knee replacement. *'Knee replacement'* is used when the primary source did not specify the type of knee replacement.

providing reassurance and informing patients' expectations (24). Prehabilitation aims to optimise patients' pre-operative health and wellbeing so that they are better able to withstand the stresses of surgery (25, 26). This is proposed to help patients recover quicker post-operatively (25, 26). TKR prehabilitation programmes have traditionally focused on exercise (27). Recent literature advocates multimodal prehabilitation with programmes incorporating elements such as weight optimisation and psychological support (25, 26).

Systematic reviews have suggested that pre-operative TKR education and prehabilitation may reduce length of hospital stay (LOS) (28, 29). However, the pre-operative TKR intervention evidence base has substantial limitations (28). Identifying the most effective pre- and post-operative education support was ranked in the top 10 priorities in a James Lind Alliance Priority Setting Partnership on hip and knee replacement (30). Similarly, the National Institute for Health and Care Excellence (NICE) primary joint replacement guideline highlights that further research investigating pre-operative TKR interventions is needed (31). This guideline also states that patients undergoing joint replacement should be given procedure-specific information and advice on pre-operative rehabilitation (31). Despite this, UK National Health Service (NHS) provision of pre-operative TKR interventions is variable, inefficient and often inadequate (31, 32). Many NHS Trusts traditionally provided pre-operative TKR support via one-off face-to-face group classes (31), often called *'knee schools'* (33: p.118). The COVID-19 pandemic has necessitated the redesign of TKR pathways to minimise face-to-face care (34). Correspondingly, developing remote alternatives to knee schools is a priority (34).

Providing pre-operative TKR education and prehabilitation via a digital intervention could help overcome the above issues and aligns with the NHS Long-Term Plan (35). Digital interventions offer a wide range of potential benefits, such as being able to provide personalised care to large numbers of patients at relatively low cost (36). They also present potential problems, such as the risk of increasing health inequities if people who need the most support are unable to engage with them effectively (37). Rigorous development of digital interventions is vital to address these problems (38). Incorporating evidence, theory and stakeholders' perspectives is particularly important when developing digital interventions designed to support health behaviour changes (38). Despite this, existing reports of randomised controlled trials (RCTs) investigating pre-operative TKR digital interventions provide minimal, if any, details about how the interventions were developed (39-46). In addition, to the researcher's knowledge, all RCTs in this area have been conducted outside the UK or over 13 years ago (39-46).

The findings of two recent observational studies suggest that integrating a digital intervention within NHS TKR pathways may help reduce LOS and improve patient outcomes (47, 48). The digital intervention investigated in these two studies was a commercial online platform (47, 48). Relying on such platforms is likely to be costly for the NHS and risks increasing disparities in service provision.

Prior to commencing this project, the researcher's experiences as a clinical physiotherapist and discussions with her supervisors/advisors had highlighted that TKR care and outcomes are suboptimal. The researcher's experiences had also demonstrated that digital interventions can be valuable if they address patients' priorities. The researcher explored these areas through two Patient and Public Involvement (PPI) consultations. During these consultations, PPI representatives reported being frustrated by the paucity and variability in pre-operative TKR care provision. Although they felt that online resources can be helpful, they were concerned about their reliability and capacity to meet patients' individual needs. PPI representatives felt that a novel UK-based digital intervention, developed specifically for and with patients awaiting TKR, would be valuable. Based on her experiences, the literature and discussions with PPI representatives and her supervisors/advisors, the researcher developed the project aim and objectives detailed below.

1.3 Project aim and objectives

The overall aim of this project was to develop a pre-operative TKR education and prehabilitation digital intervention, the *'Virtual Knee School'* (VKS). To achieve this, the following project objectives were identified.

- 1a. To identify and synthesise recent literature on the content and delivery of pre-operative TKR interventions.
- 1b. To develop evidence- and consensus-based recommendations on the content and delivery of pre-operative TKR interventions.
- 2. To explore patients' perspectives of potential barriers and facilitators to engagement with the VKS.
- 3. To use theoretical modelling to guide the design, description and evaluation of the VKS.
- 4. To develop a prototype version of the VKS and iteratively refine it by evaluating how patients use it and exploring their perspectives of it.

1.4 Thesis structure

Chapter 2: Literature review

This chapter reports a narrative literature review that expands the brief background provided above. The review focuses on three areas: TKR key considerations (e.g. patient characteristics), pre-operative TKR interventions and digital interventions. The chapter concludes by summarising the project rationale.

Chapter 3: Methodology

This chapter provides an overview of intervention development approaches and mixed methods research. The selection of an evidence-, theory- and person-based approach and complex mixed methods design is justified. The chapter also outlines key ethical and governance considerations and highlights the central role of PPI in this project.

Chapter 4: Rapid review of the content and delivery of pre-operative TKR interventions (Phase 1a)

This chapter reports a rapid review that addressed project objective 1a. A convergent segregated mixed methods design was employed. Two types of studies were identified, appraised and narratively synthesised – randomised trials of pre-operative TKR interventions (*'outcomes studies'*) and primary studies exploring patients' and/or health professionals' experiences/perspectives of pre-operative TKR interventions (*'views studies'*).

Chapter 5: Modified Delphi study to develop recommendations on pre-operative TKR interventions (Phase 1b)

This chapter describes a UK-based, three-round, online modified Delphi study that addressed project objective 1b. Round 1 consisted of an initial set of recommendations developed from the Phase 1a findings. An expert panel of patients and professionals suggested additional items and rated the importance of each item. Free-text and quantitative data were analysed using directed content analysis and descriptive statistics respectively. Panellists' Round 3 importance ratings were used to develop a final set of recommendations.

Chapter 6: Qualitative exploration of potential barriers and facilitators to engagement with the Virtual Knee School (Phase 2)

This chapter reports a qualitative descriptive study that addressed project objective 2. Online focus groups were conducted with patients who were awaiting/had undergone

TKR. Participants' perspectives of barriers and facilitators to engagement with the behaviours targeted by the VKS and digital features that could address the barriers/facilitators were explored. To assist this, participants were shown digital trigger materials (example digital features) developed from the Phase 1 findings. Data were analysed using reflexive thematic analysis.

Chapter 7: Theoretical modelling to guide the Virtual Knee School design, description and evaluation (Phase 3)

This chapter details how three theoretical modelling approaches were integrated to address project objective 3. All three approaches were informed by the Phase 1–2 findings and PPI consultations. Guiding principles were developed to concisely summarise the key design objectives and features of the VKS. A behavioural analysis was conducted to systematically analyse the behaviours targeted by the VKS, identify potential VKS features and characterise the features using standardised terminology. The guiding principles and behavioural analysis findings were integrated in a logic model to provide a diagrammatic representation of the VKS.

Chapter 8: Virtual Knee School prototype development and iterative refinement using the think-aloud method (Phase 4)

This chapter reports the systematic intervention development and user testing process employed to address project objective 4. A prototype version of the VKS was developed by integrating the Phase 1–3 findings, conducting multiple PPI consultations/coproduction activities and drawing on relevant guidelines. The prototype was then iteratively refined based on the findings of in-person and online think-aloud interviews with patients who were awaiting/had undergone TKR. The interviews focused on evaluating how patients used the VKS prototype and exploring their perspectives of it. A bespoke approach for efficiently analysing qualitative data during person-based intervention development studies was employed.

Chapter 9: Discussion and conclusion

This chapter discusses key findings of the overall project. All the project phases are summarised and meta-inferences generated by integrating their findings are presented. Strengths and limitations, assessment of the project success and implications for practice and future research are discussed. Lastly, the conclusion of the overall project is provided.

Chapter 2 Narrative literature review

2.1 Introduction

This chapter provides background to the overall project by reporting a narrative review of literature published up to 14th February 2022. The chapter firstly discusses key considerations related to TKR, such as patient characteristics and post-operative outcomes. It then provides an overview of pre-operative TKR interventions, followed by digital interventions. Finally, the project rationale is summarised. The broad nature of this review complements the rapid review reported in Chapter 4, which provides detailed information about the content and delivery of pre-operative TKR interventions to address project objective 1a.

2.2 Total knee replacement key considerations

2.2.1 Definition

TKR is a common orthopaedic procedure typically undertaken to relieve the symptoms of end-stage knee OA (2). During TKR surgery, the articular surfaces of both tibiofemoral joint compartments are replaced (3, 49). The patella may also be resurfaced (50). The main alternative to TKR is conservative management (51, 52). The NICE OA guideline states patients should only be referred for consideration of joint surgery if they have been offered the core conservative treatments of education, exercise and weight loss interventions if overweight/obese (51). When arthritic changes are limited to one joint compartment, unicompartmental knee replacement (UKR) may also be an alternative to TKR (53). UKR surgery involves replacing the affected joint compartment only (3). Results from the largest multicentre RCT of UKR and TKR, involving 27 UK sites, suggest that UKR offers similar clinical benefits to TKR and is more cost-effective at five-year follow-up (53). However, data from other RCTs, national joint registries/databases and cohort studies indicate the risk of revision is higher for UKR than TKR (54). Currently, only ~10% of knee replacement procedures recorded on the National Joint Registry (NJR)[2] are UKRs (1).

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[2] Records data from National Health Service (NHS) and private sector hospitals in England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey.

2.2.2 Patient characteristics

According to NJR data, ~98% of TKRs are performed due to OA (55) – a chronic disease in which the destructive and reparative processes of joint tissues are imbalanced, leading to structural alterations throughout the joint (56). A key risk factor for OA is increasing age (57). Correspondingly, NJR data indicate the average age of patients undergoing TKR is ~70 years old (58). Relatively few TKRs are performed in patients below 40 or over 90 years old (58), in line with the increased risk of revision and mortality in younger and older patients respectively (59). Additional important risk factors for knee OA include female gender and being overweight or obese (57). These also align with NJR data, which indicate ~57% of patients undergoing TKR are females, ~34% are overweight and ~56% are obese (4, 58). Correspondingly, a prospective cohort study of 105,189 patients with knee OA found that being overweight or obese increased the risk of knee replacement by at least 40% and 100% respectively (60).

2.2.3 Demand and service provision

TKR is one of the most common musculoskeletal operations (2). The demand for TKR has increased dramatically over the past two decades both in the UK and abroad (3, 61, 62). Multiple factors are likely to have contributed to this, including the ageing population, rising obesity levels and increased sports-related knee injuries (61, 63, 64). Predictions accounting for changing population demographics published in 2015 suggest ~119,000 TKRs will be performed in the UK in 2035 (63). A key limitation of these predictions is that they do not account for *'supply-side constraints'* such as the availability of hospitals and health professionals (63: p.597). The number of TKRs recorded on the NJR plateaued at ~97,000 per year between 2016 and 2019 (1). In 2020, this figure fell to ~45,000 due to widespread service disruptions arising from the COVID-19 pandemic (6). Even if the demand for TKR surgery remained constant and service provision was increased by 5% above the 2019 level, it would take ~10 years to address the accumulated deficit in TKR surgery (6).

2.2.4 Waiting times and burden

The NHS Constitution for England affords patients the right to start consultant-led treatment for non-urgent conditions within 18 weeks of referral (65). Even before the COVID-19 pandemic, this target was frequently breached for TKR. For example, in 2018–2019, over 31,000 knee replacement procedures were undertaken in patients who had waited at least 18 weeks, whilst 1,700 were undertaken in patients who had waited a year or more (5). The backlog of patients awaiting TKR accumulated during the COVID-19 pandemic has compounded this problem (6). Unless service provision is increased above pre-pandemic levels, TKR waiting times will continue to be at least six months longer than before the pandemic (6). The burden of longer waiting times is not equitable. An analysis of elective referral waiting lists undertaken in July 2021 revealed that patients living in the most deprived areas in England were 1.8 times more likely to have been waiting over a year for treatment compared to those living in the least deprived areas (66).

Increased TKR waiting times can have a profound impact on patients, potentially increasing their risk of problems such as muscle wasting, reliance on opioids and poor mental wellbeing (67). A cross-sectional study conducted in 10 UK orthopaedic departments in 2020 found 23% of patients awaiting TKR were in a health state *'worse than death'* (8: p.673). This was almost double the percentage of a pre-pandemic control group (8, 68). Furthermore, patients appeared to experience a clinically significant decline in health-related QOL for each additional six months they spent on the waiting list (8). Research conducted before the COVID-19 pandemic has also demonstrated that patients awaiting TKR often experience high and deteriorating levels of pain and functional limitations and poor health-related QOL (7, 69).

2.2.5 Post-operative outcomes

The success of TKR has traditionally been evaluated based on implant survival (70). From that perspective, TKR outcomes are *'excellent'* (71: p.1972). Pooled registry data suggest ~93% of TKRs last at least 15 years and ~82% last at least 25 years (49). From the patient perspective, outcomes such as persistent pain appear to be more important indicators of TKR failure than early revision surgery (72). As the emphasis on patient-centred TKR care has grown, patient-reported outcome measures (PROMs) have become recognised as key to evaluating TKR success (73). A multi-stakeholder-endorsed Outcome Measures in Rheumatology (OMERACT) core domain set recommends measuring pain, function and patient satisfaction in all TKR trials (74, 75).

Systematic reviews and meta-analyses suggest patient-reported pain, function and health-related QOL improve significantly between pre- and post-TKR time points (9, 10). Correspondingly, TKR is widely accepted as a cost-effective intervention for end-stage knee OA (2, 76). However, selecting a comparator to evaluate TKR outcomes is challenging and there is a dearth of RCTs investigating the effectiveness of TKR (2). To help address this, Skou et al. (77) conducted an RCT in Denmark in which 100 patients received a 12-week non-surgical treatment programme alone or TKR followed by the same 12-week programme. At two years follow-up, both groups showed clinically relevant improvements in pain and function, but the improvements in the TKR group were approximately double those observed in the non-surgical group (78). A cost-utility analysis involving covariate adjustment and imputation of missing values at two years indicated TKR followed by the non-surgical programme was not cost-effective compared to the non-surgical programme delivered alone and subsequently followed by TKR if required (79). However, a cost-utility analysis without adjustment did not support this finding (79). The results of Skou et al. (77) are not directly applicable to UK contexts. For example, the non-surgical treatment programme was considerably more intense than conservative treatment options and post-TKR rehabilitation offered by the NHS.

Although most patients experience favourable outcomes post-TKR, a substantial proportion do not. A systematic review by Beswick et al. (11) estimated the proportion of patients with an unfavourable pain outcome post-TKR was at least 10–34% based on all relevant studies and ~20% based on the highest quality study. Their comparative estimates for patients undergoing total hip replacement (THR) were lower, at 7–23% (all relevant studies) and 9–13% (two highest quality studies) (11). Similarly, a prospective observational study in 11 European countries found the incidence of moderate to severe chronic post-operative pain was 27% for TKR, compared to 12% for all surgical procedures combined (80). Estimating the true prevalence of chronic pain post-TKR is difficult for various reasons (81). For example, patients may be reluctant to report negative outcomes (82) and have problems completing pain questionnaires due to factors such as fluctuating pain levels and the impact of comorbidities (83).

Persistent post-operative pain is one of the most frequently reported factors associated with overall patient dissatisfaction following TKR (13, 71). Numerous studies have reported up to ~20% of patients are not satisfied with the clinical outcome of their TKR (12, 13, 84). However, reported levels of satisfaction after TKR vary widely between studies (13). This may be at least partly due to the widespread use of non-validated outcome measures (13). Even patients who are satisfied with their TKR commonly report residual symptoms such as stiffness, swelling and difficulties with daily activities (14, 15). Furthermore, a study of 422 adults undergoing TKR by Hodges et al. (85) found 53% and 45% of the cohort reported inadequate physical activity and excessive sedentary behaviour respectively at one year post-operatively. This is concerning given the key role regular physical activity plays in maintaining older people’s health and wellbeing (86).

2.2.6 Modifiable predictors of poor outcomes

Various modifiable and non-modifiable predictors of poor TKR outcomes have been identified (16, 87). Key modifiable predictors are discussed below because they could be targeted by pre-operative TKR interventions to help improve post-operative outcomes (21). A systematic review and meta-analysis by Lewis et al. (87) identified higher levels of pre-operative pain and pain catastrophising as the strongest predictors of persistent pain post-TKR. Other modifiable predictors identified included other pain sites, poorer pre-operative function, depression and anxiety (87). Correspondingly, a UK-based cohort study of 2,080 patients found worse pre-operative pain, function and mental wellbeing were significant predictors of worse patient-reported pain and function scores at up to 10 years post-TKR (16). However, caution is needed when focusing on post-operative outcome scores rather than the change in scores, as patients with worse pre-operative function gain greater functional improvements from baseline compared to those with better pre-operative function (16, 88). A systematic review by Devasenapathy et al. (21) identified predictors of performance-based rather than participant-reported TKR outcomes. Worse pre-operative function and lower ipsilateral quadriceps strength were associated with poorer objective functional outcomes at six months post-operatively. The level of evidence was low, primarily due to methodological limitations of the included studies.

In addition to being predictors of post-operative pain and functional outcomes (16, 87), worse pre-operative pain and poorer mental health are associated with dissatisfaction post-TKR (13, 20). Another key predictor of dissatisfaction is lack of expectation fulfilment (19, 20). Despite this, a systematic review and best evidence synthesis by Hafkamp et al. (19) reported evidence on the association between pre-operative expectations and post-operative satisfaction is conflicting. This may be because identifying an optimal level of pre-operative expectations is challenging. High expectations may motivate patients to engage with rehabilitation and achieve their desired outcomes (19, 89). However, patients’ expectations are often too optimistic (90). Ensuring patients’ expectations are realistic is essential to minimise the risk of them being unfulfilled (19). Patients with low health literacy may have lower expectations than those with adequate health literacy (91). Correspondingly, a cross-sectional study of 453 patients found low musculoskeletal health literacy was associated with worse participant-reported knee symptoms and lower satisfaction post-

TKR (92). An important limitation of this study was that satisfaction was assessed by asking patients whether they would choose to undergo the same operation again, rather than via a validated satisfaction questionnaire (92).

Lifestyle-related factors are also predictors of poor TKR outcomes. Obesity, smoking and alcohol misuse are associated with a higher risk of complications post-TKR (17, 18, 93, 94). A systematic review and meta-analysis by Pozzobon et al. (17) found obese patients also have worse short- and long-term pain and long-term disability outcomes post-TKR/UKR compared to non-obese patients. Pozzobon et al. (17) were unable to identify sufficient evidence to establish whether regular pre-operative physical activity is a predictor of TKR outcomes. The more recent cohort study by Hodges et al. (85) demonstrated that patients who undertook inadequate physical activity before their TKR were at increased risk of being inadequately physically active at one year post-TKR. Similarly, excessive sedentary behaviour pre-TKR was found to predict excessive sedentary behaviour post-TKR (85). A systematic review and meta-analysis by Konings et al. (95) identified patients who stopped engaging in sports in the year before their TKR were unlikely to recommence sports post-operatively. Conversely, patients who continued engaging in sports in the year leading up to their TKR were likely to engage in at least as many low/medium impact sports post-TKR as they did before they started experiencing restricting knee symptoms (95). Notably, most studies included by Konings et al. (95) were retrospective. This makes their findings susceptible to recall bias, which can occur when participants are unable to accurately remember past experiences (96).

2.3 Pre-operative total knee replacement interventions

2.3.1 Importance of pre-operative interventions

Pre-operative TKR interventions encompass all types of interventions delivered in the pre-operative phase of the TKR care pathway – the period between when a patient is listed for TKR and the day they are admitted to hospital to undergo surgery (97). As highlighted above, patients listed for TKR typically experience a high symptom burden (7, 8). There is consensus internationally that interventions such as education, exercise and weight management programmes are key to managing OA symptoms (98). These interventions could also address many of the modifiable predictors of poor TKR outcomes highlighted above (17, 20, 87). Pre-operative TKR interventions therefore have the potential to improve patient outcomes both pre- and post-operatively. Furthermore, the support patients receive in the pre-operative phase can influence their overall experiences of TKR (99).

The importance of pre-operative interventions is highlighted in the NICE guideline on primary joint replacement (31). This states that patients should be given procedure-specific information and advice on pre-operative rehabilitation (31). Furthermore, the UK charity Versus Arthritis advocates local health systems should provide patients awaiting joint replacement with a six-part support package (100). The proposed support package, developed in consultation with patients, includes elements such as personalised self-management support, mental health support and physical activity programmes (100).

Pre-operative interventions are key components of enhanced recovery programmes (101). These programmes aim to reduce length of hospital stay (LOS) and improve patient outcomes by optimising care in the pre-, peri- and post-operative phases (102). A consensus statement from the Enhanced Recovery After Surgery (ERAS ®) Society recommends TKR enhanced recovery programmes should include pre-operative education, smoking cessation and alcohol cessation programmes (101). The UK Department of Health delivered an Enhanced Recovery Partnership Programme (ERPP) between 2009 and 2011 (103). This aimed to achieve implementation of TKR enhanced recovery pathways in all NHS hospitals (102). A natural experiment study by Judge et al. (102) found the ERPP maintained pre-existing trends of gradually improving patient-reported outcomes and rapidly decreasing LOS. Over the study period of April 2008 to December 2016, the mean LOS reduced from 5.7 to 3.6 days (102). Judge et al. (102) suggested the pre-existing trend of reducing LOS might have been related to some trusts introducing enhanced recovery programme elements prior to the ERPP roll out. The ongoing reductions in LOS are likely to have been related to multiple enhance recovery programme elements, such as improved pre-operative patient education, increased use of regional analgesia and early post-operative mobilisation.

The emphasis on reducing LOS has continued, with day-case TKR now being possible (104, 105). Short hospital stays increase the post-operative responsibilities placed on patients, who may face problems such as social isolation and difficulties with daily activities (106). Pre-operative TKR interventions are therefore particularly important to enable patients to prepare for their discharge in advance (106).

2.3.2 Pre-operative education

Pre-operative education includes interventions delivered prior to surgery that aim to improve patients’ health behaviours and/or outcomes by increasing their knowledge base (22). For patients awaiting TKR, pre-operative education typically comprises information on multiple topics such as mobility, hospital procedures and pain management (23, 29). The information may be delivered in various formats, including verbal discussions, written materials and digital resources (23, 107). Adequate pre-operative TKR education is vital to ensure patients can make an informed decision about proceeding with their planned operation and take an active role in their care (31). Pre-operative TKR education has been proposed as an approach for addressing several predictors of poor TKR outcomes such as pain catastrophising, anxiety and low musculoskeletal health literacy (87, 92, 108). Furthermore, pre-operative education could support patients to make practical preparations for the post-discharge phase, such as purchasing frozen food (106).

Buus et al. (24) undertook a systematic review and narrative synthesis to explore how patients undergoing knee replacement experience the pre- and post-operative information they receive from health professionals. Their findings highlighted numerous benefits of pre-operative education, such as providing reassurance and informing patients' expectations. They also demonstrated the potential negative consequences of inadequate information provision. For example, patients reported stopping their rehabilitation exercises due to fear of harming their prosthesis. Qualitative research undertaken with health professionals supports these findings (107, 109). For example, orthopaedic nurses have reported that patients who attend pre-operative TKR education classes have more realistic expectations and are more invested in their post-operative rehabilitation than those who do not (109).

The results of a Cochrane review by McDonald et al. (29) suggest pre-operative TKR education may reduce LOS compared to usual care. No significant benefits on post-operative pain, function, health-related QOL or complication risk were identified. These results need to be interpreted cautiously as only five TKR studies were included, all of which present significant limitations. Furthermore, McDonald et al. (29) did not distinguish between purely educational and multicomponent interventions. The interventions of both studies reporting LOS included components such as an exercise programme and optional social work input (110, 111). The beneficial intervention effects cannot therefore be attributed to pre-operative education alone. In addition, the average LOS in the control groups of both these studies was over 7 days (110, 111), which is substantially longer than in current care pathways. McDonald et al. (29) only included studies published up to May 2013. A more recent systematic review by Dennis et al. (112) included RCTs published up to December 2018. RCTs of all types of pre-operative TKR interventions were eligible, but only if they assessed pain at least six months post-operatively. Their results suggest pre-operative education alone, or combined with exercise, does not prevent chronic pain post-TKR, but this was based on low to moderate quality evidence from two RCTs only.

A high quality RCT published by Tolk et al. (113) in 2021 investigated standard education versus standard education plus an additional module on realistic expectations for long-term TKR recovery. After attending the education sessions, expectation total scores remained unchanged in the control group but decreased significantly in the intervention group. At one year post-operatively, the primary intention-to-treat analysis indicated the proportion of patients who were very satisfied with the result of their knee operation did not differ significantly between groups. Tolk et al. (113) also performed a predefined per protocol analysis, which only included patients who attended the pre-operative education sessions. The per protocol analysis indicated that a significantly higher proportion of patients in the intervention group were very satisfied with their operation result compared to the control group. Tolk et al. (113) therefore concluded that the additional educational module was effective at improving post-operative satisfaction, but acknowledged that their conclusion cannot be extrapolated to patients who did not attend the education sessions.

The results of additional recent RCTs investigating pre-operative TKR education interventions have been heterogeneous (44, 46, 114-117). The majority of those reporting significant intervention effects present important methodological limitations and/or identified effects with questionable clinical relevance (44, 46, 114, 115, 117). Multiple factors are likely to contribute to the paucity of RCTs supporting the value of pre-operative TKR education. Education is a fundamental part of obtaining patient consent and delivering patient care, so it would be unethical not to provide it (29). Even when health professionals provide pre-operative TKR education, patients often obtain information from additional sources such as family, friends and the Internet (99). There is uncertainty about the optimal mode, timing, location and providers of pre-operative TKR education (31). Correspondingly, the NICE joint replacement guideline recommends future research is required to identify how to optimise the delivery of information for patients undergoing joint replacement (31). Furthermore, in a James Lind Alliance Priority Setting Partnership on hip and knee replacement, identifying the most effective pre- and post-operative education support was ranked in the top 10 priorities (30).

2.3.3 Prehabilitation

In a surgical context, prehabilitation is the process of optimising a patient's health and wellbeing before their operation (25, 26). By increasing the patient's pre-operative functional capacity, prehabilitation is proposed to help the patient withstand the stresses of surgery and improve their post-operative recovery (25). Furthermore, evaluating changes in a patient's symptoms during prehabilitation can facilitate decision-making about whether they should proceed with TKR (118). Figure 2.1 presents a conceptual model of prehabilitation.

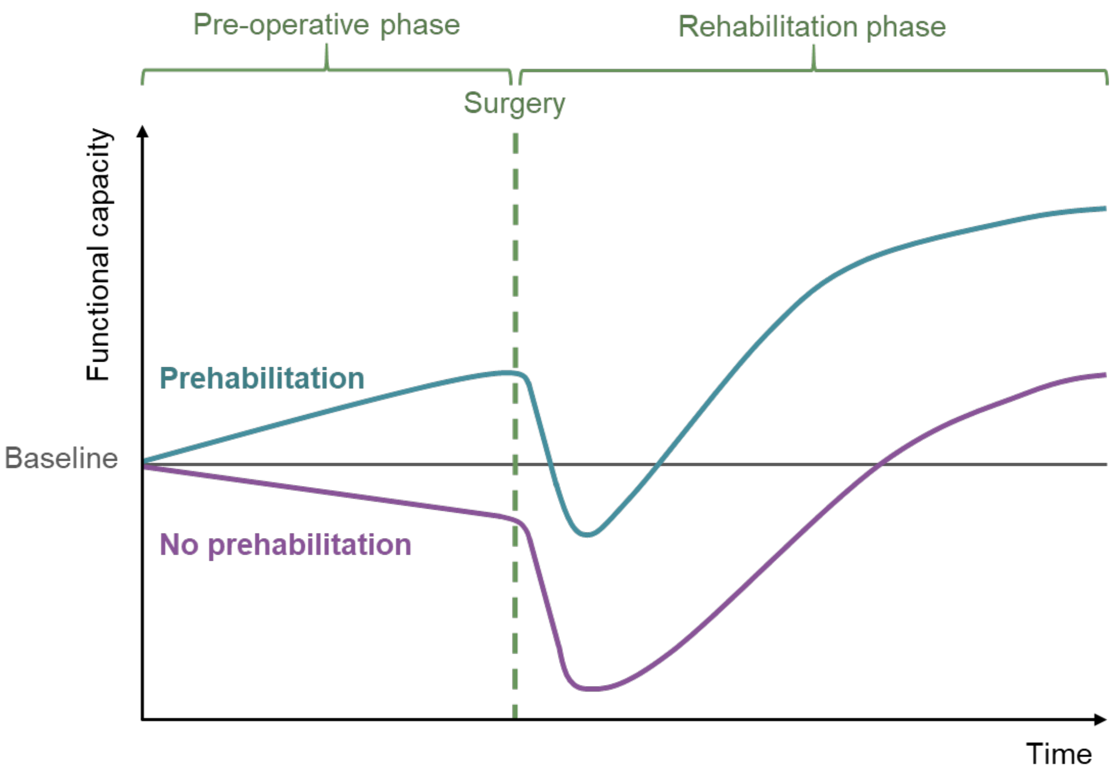


Figure 2.1: Conceptual model of prehabilitation

Based on figures from Banugo and Amoako (25) and Dean et al. (119) and informed by literature on changes in the functional status of patients undergoing TKR (7, 9, 10, 69).

TKR prehabilitation programmes have traditionally involved exercise interventions (27). Such interventions aim to optimise patients' musculoskeletal and cardiovascular systems to mitigate the deleterious effects of post-operative inactivity (27). Recent literature advocates multimodal prehabiliation to address patients' physical and psychological wellbeing (25, 26). Prehabilitation programmes may therefore include multiple intervention types such as exercise, weight optimisation, smoking cessation and psychological support (25, 26). Pre-operative education may be included in prehabilitation programmes to support patients to engage with other intervention components (26). However, pre-operative education primarily aims to increase patients' knowledge base rather than their functional capacity (22). Furthermore, pre-operative education can have a broad range of intended outcomes, such as influencing patients' expectations and encouraging them to make practical preparations (106, 108). Pre-operative education is therefore considered separately to prehabilitation in this thesis.

The main types of prehabilitation intervention are addressed sequentially below as most RCTs investigating pre-operative TKR prehabilitation have focused on a single intervention type. In recognition of the lack of high quality evidence on multimodal TKR prehabilitation, the NICE joint replacement guideline recommends future research should investigate the clinical- and cost-effectiveness of individualised multimodal prehabilitation programmes delivered at least two months pre-operatively (31).

2.3.4 Exercise interventions

An extensive evidence base supports exercise interventions for patients with knee OA (120, 121). For example, a systematic review and meta-analysis of 77 RCTs by Goh et al. (121) found exercise interventions improved pain, function, QOL and performance-based outcomes in patients with knee OA. Goh et al. (121) also investigated potential determinants of the benefits of exercise interventions. Patients with knee OA showed greater improvements in pain compared to those with hip OA. Being listed for TKR/THR did not affect the benefits of exercise interventions on function, QOL or performance-based outcomes. Improvements in pain were smaller for patients who were listed for TKR/THR compared to those who were not but the predefined significance level of $p \leq 0.10$ was only just reached in the multivariate meta-regression. In addition, the effect size for pain in trials with participants listed for TKR/THR was 0.33 (95% confidence interval 0.04-0.63). This is above the threshold for a small effect size (122). This suggests that exercise interventions offer significant benefits for patients with knee OA even when they are listed for TKR. This conclusion needs to be interpreted cautiously as the review by Goh et al. (121) was limited by various factors. These included the high risk of bias in many of the included studies and heterogeneity of the studies' exercise interventions.

In line with the above, a recent systematic review and meta-analysis by Blasco et al. (123) found pre-operative sensorimotor training improved participant-reported pain and function, performance-based functional outcomes and balance prior to TKR. The only post-operative benefit identified was greater performance-based functional outcomes within three months post-operatively (123). Another recent systematic review and meta-analysis by Husted et al. (118) found pre-operative resistance training improved knee extensor strength prior to TKR, but did not identify any other pre- or post-operative benefits. Husted et al. (118) also demonstrated an apparent lack of relationship between the exercise dosage and changes in knee extensor strength. Numerous other systematic reviews have also investigated the effects of pre-operative TKR exercise interventions on post-operative outcomes. An overview of reviews by Almeida et al. (28) included ten systematic reviews of pre-operative TKR exercise interventions published between 2015 and 2020. Their results suggest pre-operative TKR exercise interventions may reduce LOS by one to two days but do not impact pain, function or QOL. Similarly, the aforementioned systematic review by Dennis et al. (112) suggested pre-operative exercise interventions are not effective at preventing chronic pain post-TKR.

The systematic reviews by Blasco et al. (123), Husted et al. (118) and Dennis et al. (112) were all rigorously conducted. For example, they were registered with the International Prospective Register of Systematic Reviews (PROSPERO) and assessed the included studies' risk of bias using the Cochrane risk-of-bias tool (124). The findings of these and other systematic reviews of pre-operative TKR interventions have been limited by aspects of the included trials, including:

- Poor reporting, leading to issues such as difficulty assessing the trials' risk of bias and extracting information about exercise interventions. For example, Husted et al. (118) highlighted most included trials did not provide sufficient details on sequence generation or allocation concealment. Additionally, 10 of the 12 trials included by Husted et al. (118) did not adequately report the exercise intensity in relation to one repetition maximum. The missing information was only obtained for one trial by contacting the trial authors, so Husted et al. (118) had to make various assumptions when calculating the exercise dosage. Furthermore, Husted et al. (118) assessed the prescribed exercise dosage rather than the exercise actually completed due to lack of reporting of exercise adherence.
- Heterogeneity in the exercise interventions, including in the delivery mode, intensity, frequency and duration. This can prevent the trials being meaningfully combined (28).
- Inclusion of an *'undifferentiated general population'* (112: p.13). Dennis et al. (112) suggest this may prevent intervention effects being detected for the minority of patients who experience chronic pain post-TKR. Dennis et al. (112) also propose that the participants in pre-operative TKR trials may be *'highly selected'* because recruiting patients to trials prior to TKR is challenging (p.13).

Subsequent to the above systematic reviews' searches, Skoffer et al. (125) reported the one-year post-TKR data from a high quality RCT investigating pre- and post-operative resistance training versus post-operative resistance training alone. The intervention group showed significantly greater improvements in knee extensor and flexor muscle strength but no other outcomes. Notably, the RCT was underpowered to detect long-term differences in functional status due to 25% of participants being lost to follow-up (125). Another more recently published RCT by An et al. (41) included three arms: a pre-operative tele-rehabilitation group (performed a pre-operative exercise programme with video-based supervision/guidance), a pre-operative education group (performed the same pre-operative exercise programme with telephone support) and a control group (received usual care). Participant reported and performance-based outcomes were assessed at baseline, post-intervention and six weeks post-TKR. An et al. (41) identified significant between-group differences and concluded the tele-rehabilitation programme was beneficial, but their analysis was too limited to draw clear conclusions. The RCT also had multiple other limitations, including a sample consisting entirely of women aged between 65 and 75 years old undergoing bilateral TKR (41).

Two other randomised trials have investigated pre-operative TKR exercise interventions involving digital technologies. Doiron-Cadrin et al. (43) conducted a pilot RCT in which patients undergoing TKR/THR were randomised to an in-person prehabilitation group (performed a pre-operative exercise programme with face-to-face supervision), a tele-prehabilitation group (performed the same pre-operative exercise programme with video-based supervision) or a control group (received usual care). The key finding was that the tele-prehabilitation programme was safe, feasible and perceived as satisfactory by patients. A fully powered RCT is required to determine the programme's effectiveness. An RCT by Rittharomya et al. (40) investigated a combined exercise and diet control intervention, which involved watching a digital video disc (DVD) and remote monitoring through telephone calls or a mobile application. Their results suggested the intervention improved participant-reported and performance-based outcomes over the 12-week intervention period. However, longer-term outcomes were not assessed. Furthermore, the RCT was conducted at a single hospital in Thailand and important details, such as the randomisation approach, were not reported.

To the researcher's knowledge, only one high quality RCT has included a health economic evaluation of a pre-operative TKR exercise intervention (126). This demonstrated that an eight-week supervised pre-operative neuromuscular training programme was cost-effective at conventional willingness to pay thresholds. The results were only reported for patients undergoing TKR and THR combined rather than separately. In addition, costs for implementing the intervention were not included in the analysis because the intervention is *'already on the market in Denmark'* (126: p.8), which would not be the case in the UK.

2.3.5 Healthy lifestyle interventions

Important healthy lifestyle intervention targets in patients undergoing TKR include low physical activity levels/high sedentariness, overweight/obesity, smoking and risky alcohol consumption (18, 127, 128). Patients awaiting TKR may be particularly receptive to interventions addressing these factors because the pre-operative phase presents a *'teachable moment'* – a life transition or health event that can motivate an individual to make positive behaviour changes (129: p.1, 130: p.156). Robinson et al. (129) highlight that deciding to undergo surgery may encourage patients to reflect on their unhealthy lifestyle behaviours, particularly if the behaviours have contributed to their indication for surgery. This is relevant to patients undergoing TKR because being overweight/obese substantially increases the risk of TKR (60). In a UK-based study of 299 surgical patients, participants reported greater motivation for increasing physical activity, achieving/maintaining a healthy weight and reducing alcohol consumption in the four to six weeks before surgery compared to the long-term (131). Participants also reported being significantly less confident than motivated to increase their physical activity, achieve/maintain a healthy weight and stop smoking for both time points (131). This suggests patients are willing to making health behaviour changes pre-operatively but may require support to do so. Providing such support could enable patients to make short-term health behaviour changes and potentially even maintain them long-term (129).

As discussed above (section 2.3.4), numerous studies have investigated pre-operative TKR exercise interventions. Whilst these can be considered physical activity interventions, exercise is a subcategory of physical activity that involves planned, structured, repetitive activities aimed at improving/maintaining physical fitness (132). A prescriptive exercise approach risks reducing patients' overall activity levels if it fails to improve physical activity across the domains of home, recreation/leisure, transport and occupational activities (133). Most RCTs of pre-operative TKR exercise interventions have not included physical activity levels as an outcome. One that did found no significant between-group differences in participant-reported or objectively measured physical activity pre- or post-operatively (134). The first study to investigate a pre-operative sedentary behaviour reduction intervention for patients undergoing knee/hip replacement was a feasibility study published by Aunger et al. (135) in 2019. The study highlighted the intervention is a feasible and potentially valuable approach for reducing patients' sedentary behaviour and a fully powered RCT investigating its effectiveness is warranted.

In 2021, Seward et al. (136) published the first systematic review of pre-operative TKR/THR weight loss interventions for patients with obesity. Only two RCTs and five single-arm case series met the inclusion criteria. Their findings suggest pre-operative weight loss interventions significantly reduce body mass index (BMI) pre-operatively. However, there was insufficient evidence to establish if the interventions led to clinically relevant improvements in post-operative outcomes. Most studies identified by Seward et al. (136) did not investigate combined diet and exercise interventions, despite such interventions being more beneficial than diet-only interventions for patients with knee OA (137). Furthermore, in a mixed methods study by Pellegrini et al. (138), patients who were awaiting/had undergone TKR reported preferring weight loss interventions that combined diet and exercise. As discussed above (section 2.3.4), an RCT by Rittharomya et al. (40) identified pre-operative benefits of a combined exercise and diet control intervention. However, the RCT lacked long-term follow-up and presented various additional limitations, such as not being prospectively registered on a trial registry.

To the researcher's knowledge, the only RCT investigating a pre-operative smoking cessation intervention specifically in patients undergoing knee/hip replacement was conducted by Møller et al. (139, 140). The post-operative complication rate was lower in the intervention group compared to the control group, particularly for wound-related complications. In addition, more patients in the intervention group abstained from smoking at one and 12 months post-operatively. These findings need to be interpreted cautiously as less than a third of the participants underwent knee replacement and the RCT was conducted over 20 years ago in Denmark. This means the findings are not directly applicable to current UK TKR pathways. In addition, whilst the intervention was described as pre-operative, it was delivered six to eight weeks pre-operatively and 10 days post-operatively.

As far as the researcher is aware, no definitive RCTs have investigated a pre-operative TKR alcohol cessation intervention. RCTs investigating alcohol cessation interventions in other surgical populations are also limited. The findings of a Cochrane review published in 2018 suggest perioperative alcohol cessation interventions may increase abstinence and reduce complications in patients with risky alcohol consumption (141).

However, only three studies with small, predominantly/entirely male samples were included. In addition, all three RCTs investigated intensive interventions involving pharmacological therapy. Whilst such interventions may be appropriate for alcohol dependent drinkers, they are arguably not appropriate for the much larger number of *'increased risk'* drinkers, who drink over recommended UK limits but are not alcohol dependent (128: p.2). A recent UK-based feasibility study demonstrated a brief behavioural intervention is a promising approach for reducing alcohol consumption amongst people undergoing knee/hip replacement who meet the criteria for increased risk drinking (128). An RCT is needed to definitively evaluate the intervention's effectiveness.

2.3.6 Psychological interventions

Until recently, the literature investigating psychological interventions for patients undergoing TKR was very limited. Four relatively large RCTs of pre-operative TKR psychological interventions were published in 2021 (39, 42, 142, 143). Two of these investigated digital interventions (39, 42). Anthony et al. (42) investigated mobile phone text messaging-based acceptance and commitment therapy for patients whose TKR/THR was indefinitely postponed due to the COVID-19 pandemic. Buvanendran et al. (39) conducted a two-phase RCT of a pre-operative cognitive-behavioural therapy (CBT) telehealth intervention for patients undergoing TKR with high pain catastrophising scores. Both studies reported beneficial effects of the intervention on at least one pre-operative participant-reported outcome (39, 42). However, Anthony et al. (42) did not follow participants up beyond the two-week intervention period and Buvanendran et al. (39) did not identify any benefits of the intervention on post-operative outcomes. Buvanendran et al. (39) suggested the CBT intervention might not have reduced patients' pain catastrophising scores to the threshold required to have a meaningful impact on other outcomes. In addition, Buvanendran et al. (39) excluded patients with clinically severe anxiety or depression due to the potential effects of those conditions on pain catastrophising and post-TKR outcomes. Targeting the CBT intervention towards patients with clinically severe anxiety or depression may have been more beneficial.

The other two recent RCTs of pre-operative TKR psychological interventions were both conducted by Hanley (142, 143) and involved patients awaiting TKR or THR. In their initial RCT, Hanley et al. (142) compared mindfulness meditation, hypnotic suggestion and cognitive behavioural pain psychoeducation. Immediately post-intervention, the mindfulness meditation and hypnotic suggestion groups reported less pain and anxiety compared to the psychoeducation group. At six weeks post-operatively, participant-reported function was significantly greater in the mindfulness meditation group compared to the other two intervention groups. A follow-up RCT by Hanley et al. (143) compared two different mindfulness styles, mindfulness of breath and mindfulness of pain, with cognitive behavioural psychoeducation. Immediately post-intervention, the mindfulness of breath but not mindfulness of pain group reported less pain than the psychoeducation group. At 28 days post-operatively, the mindfulness of pain but not mindfulness of breath group reported less pain than the psychoeducation group. Hanley et al. (143) proposed the mindfulness of pain intervention may have led to less post-operative pain by influencing cognitive and affective factors such as pain catastrophising. However, they did not assess pain catastrophising or other psychological factors such as anxiety and depression.

2.3.7 Pre-operative intervention provision

Widespread UK variation in pre-operative TKR intervention provision is a substantial and ongoing issue (31, 32, 144). Variability exists in not only the content and delivery of NHS pre-operative TKR education and prehablitation programmes, but also whether they are provided at all (31). A Getting It Right First Time (GIRFT) report published in 2015 identified *'areas of unjustifiable variation'* across all orthopaedic services in England, including in rehabilitation provision (144: p.5). Recommendations to address these issues included:

> 'For TKR patients, pre-operative care should include: education, post operative protocol, identifying patients at risk of a poor functional outcome and organisation of rehabilitation equipment at home.' (144: p.36)

A follow-up report published in 2020 highlighted only 41% of applicable trusts had met the above recommendation (32). Addressing such variation in care provision is a priority to improve both the quality and efficiency of care (32). NHS patients have also highlighted improvements in pre-operative TKR interventions are needed. For example, patients have reported wanting more information about recovering from surgery (102).

When provided, pre-operative TKR education and prehabilition programmes have traditionally comprised a one-off group class (31), often called *'knee schools'* (33: p.118). Group classes may be more efficient than one-to-one appointments but risk failing to address patients' individual needs (109). Some hospitals provide combined classes for patients undergoing TKR and THR, which can be confusing for patients

(99). The timing of group classes can also present problems. When delivered too far in advance of TKR, patients may forget the information by the time of their operation (102, 109). Delivering the classes too close to TKR means patients who receive a rapid referral may be unable to attend (102). Those who do attend may lack time to take any recommended actions (109). Delivering pre-operative classes presents a significant work burden for health professionals (145). Furthermore, the COVID-19 pandemic has resulted in hospital visits needing to be minimised; therefore, developing alternatives to face-to-face classes is a priority (34).

Other approaches used to provide pre-operative TKR information include booklets and more rarely digital resources such as videos (146). These have the benefit of providing information patients can refer back to (102). However, their quality is often poor (146, 147). A review of publicly available NHS TKR information published by Stephens et al. (146) in 2021 found information on key topics was lacking. For example, of the 50 information sheets and nine videos included, only 36% and 31% provided advice on the benefits of exercise/activity and maintaining a healthy weight respectively. A separate review of 20 NHS TKR/THR booklets found many were outdated and did not align with enhanced recovery principles (147). In addition, health professionals have reported being concerned that they will not be able to provide booklets due to funding cuts (148).

2.4 Digital interventions

2.4.1 Rationale for digital interventions

As highlighted above, pre-operative TKR service provision is currently inconsistent, inefficient and often inadequate. Providing pre-operative TKR care via a digital intervention is a promising approach for addressing these issues. Digital interventions encompass all types of interventions delivered via digital technology, such as smartphone apps, interactive websites, text messaging and social media communications (38, 149). Key benefits offered by digital interventions include motivating patients to take an active role in their care; providing timely personalised support; and improving the accessibility, convenience and efficiency of care (36, 150, 151). Once developed, the unit cost of digital interventions can be very low as they can be used repeatedly by large number of patients without requiring costs for staffing, room hire, printing etc. (152, 153). They therefore have the potential to substantially reduce healthcare costs (36, 152). Digital interventions can deliver intervention content with much greater fidelity than human-delivered interventions (153). They can also facilitate the collection of large volumes of ecologically valid data in real time, presenting unique opportunities for research (38).

Digital delivery of pre-operative TKR care aligns with the NHS Long-Term Plan (35). This sets out the ambition of the NHS to offer *'digital first'* and support people to *'manage their own health, guided by digital tools'* (35: p.92). The COVID-19 pandemic has accelerated widespread adoption of digital technologies in the NHS and increased technology uptake amongst patients (154, 155). In an analysis of data collected in June/July 2020 from 3,491 people aged 55–75 years old in the English Longitudinal Study of Ageing (ELSA) COVID-19 sub-study, 45% of participants reported using the Internet more since the start of the pandemic (155). Overall internet usage was high, with 81% of participants using the Internet at least daily. Furthermore, 45% of participants reported using the Internet to find health-related information (155). The greater reliance on digital technologies initiated by the COVID-19 pandemic is anticipated to be sustained long-term (37). In addition, the pandemic is catalysing the redesign of TKR services (34). This presents an opportune time to embed digital interventions into the TKR pathway (34).

UK-based studies have highlighted the potential value of embedding digital interventions within TKR pathways (107, 156, 157). In a survey of NHS patients' satisfaction with elective orthopaedic information provision, over half the participants reported wanting more internet resources (156). Correspondingly, patients in a qualitative study by Robinson et al. (157) identified multiple potential benefits of orthopaedic digital interventions, including fostering motivation, providing reassurance and boosting morale. These benefits were attributed to a range of features such as logging/tracking, educational videos and peer/health professional message-based features. Patients in the study by Robinson et al. (157) emphasised the importance of providing digital interventions pre-operatively to facilitate patients' preparations for surgery. A qualitative study by Sharif et al. (107) suggested NHS health professionals would also welcome TKR digital interventions. Sharif et al. (107) specifically explored health professionals' perspectives of virtual healthcare technologies for optimising the pre-operative phase of the hip/knee replacement pathway. Participants identified multiple potential benefits for a range of technologies. These included increasing patient engagement, improving patient information retention and saving time for both patients and health professionals.

2.4.2 Potential problems with digital interventions

As well as offering many benefits, digital interventions present a range of potential problems. These include the risk of causing harm, for example by providing incorrect information (38, 149). The pertinence of this risk to patients undergoing TKR was highlighted in a recent review of 15 freely available TKR/THR smartphone apps (158). Across the four sections of the Mobile App Rating Scale (engagement, functionality, aesthetics and information quality) (159), the lowest (worst) mean score was for information quality (2.75/5) (158). Correspondingly, a review of 55 TKR YouTube videos identified substantial disparities in their reliability, quality and content (160). Digital interventions may also cause harm indirectly if they replace more effective interventions (38). This issue is particularly relevant to digital behaviour change interventions as adherence is often too low to achieve the intended behaviour changes (38, 161).

Another key concern about digital interventions is their potential to increase health inequities (37). Digital health innovations risk creating a *'digital inverse care law'* as those most in need of healthcare are often least likely to access digital technologies (37: 'Abstract'). Furthermore, the digital divide does not only affect those who cannot access digital technologies (162). Three levels of the digital divide are now recognised (Table 2.1).

Table 2.1: Levels of the digital divide

Level of divide	Area of disparity	Disadvantaged group
1	Access to digital technologies	People who cannot access digital technologies
2	Digital literacy	People who lack the knowledge and skills to use digital technologies effectively
3	Outcomes from digital technology use	People who lack the ability to translate their use of digital technologies into beneficial outcomes, such as increased skills or behaviour changes

Table based on Wei et al. (162) and Shaw et al. (163).

Multiple determinants of all three levels of the digital divide exist, including sociodemographic, economic, social, cultural, personal, material and motivational factors (164). Given the older demographic of patients undergoing TKR (58), age is a particularly relevant determinant. An analysis of the ELSA COVID-19 sub-study data by Age UK (165) found 45% of participants aged 75 years old or over do not use the Internet. Correspondingly, the analysis demonstrated the increased internet usage prompted by the COVID-19 pandemic mainly occurred in groups who already used the Internet. Amongst participants aged 52 years old or over who reported wanting to use the Internet more/for more tasks, the most frequently reported barrier was lack of digital skills followed by lack of trust in the Internet (165). Literacy is another important determinant of the digital divide (166). Despite this, an analysis of 15 freely available TKR/THR apps found only one, which was THR-specific, met the criteria for being *‘easy to read’* (167: p.396).

Another potential problem of digital interventions is that they may collect large volumes of personally identifiable and potentially sensitive data (38, 168). This presents substantial information privacy risks (168). These risks are not always adequately managed, even in accredited digital interventions (168). Furthermore, potential users’ concerns about privacy risks can present an important barrier to their engagement with digital interventions (169). Implementing digital interventions in practice can also be problematic due to issues such as a lack of infrastructure and reluctance to adopt new technologies amongst health professionals (107, 151).

2.4.3 Development of digital interventions

To help overcome the potential problems outlined above, rigorous development of digital interventions is vital (38). The development process spans the period from conceiving an intervention idea to investigating the intervention in a feasibility/pilot/evaluation study (170). It therefore includes planning, designing and refining an intervention (171). Investing in the development process maximises the chances that an intervention will prove effective when evaluated and can be successfully implemented in practice (171). This helps to avoid *‘research waste’* (costly evaluations of flawed interventions) (171: p.2, 172). Digital interventions are usually complex, often combining multiple components to achieve various aims (149). Correspondingly, complex intervention and digital-specific guidance are valuable for informing digital intervention development. Table 2.2 summarises three key sets of guidance, which are discussed further below. Chapter 3 (section 3.2) discusses specific intervention development approaches.

Table 2.2: Key guidance for informing digital intervention development

Guidance	Funder	Development process
MRC/NIHR framework for developing and evaluating complex interventions (170)	MRC; NIHR	Update of the previous version of the MRC complex intervention guidance (173) through a gap analysis, international expert workshop, open consultation and expert review.
INDEX guidance on developing complex interventions to improve health and healthcare (174)	MRC; NIHR	Review of published intervention development approaches (171), review of primary intervention development research, international qualitative interviews (175), international consensus exercise (two online Delphi studies and a consensus workshop) (INDEX study) (176).
Recommendations on developing and evaluating digital behaviour change interventions published by Michie et al. (38)	MRC; NIHR; Robert Wood Johnson Foundation	International expert consensus-building workshop.

INDEX, IdentifyiNg and assessing different approaches to DEveloping compleX interventions; MRC, Medical Research Council; NIHR, National Institute for Health and Care Research

All three sets of guidance emphasise the importance of incorporating stakeholder engagement, evidence and theory throughout the development process (38, 170, 174). Stakeholder engagement is key to developing interventions with the potential to have a meaningful impact in real-world settings (170). Stakeholders include anyone who may be affected by an intervention, its evaluation and/or its implementation, such as patients, service providers and policy-makers (170). Various activities can be used to achieve stakeholder engagement (174). For patient-focused digital interventions, PPI activities are essential to ensure that both the intervention development process and the intervention itself meet users' needs (38, 170, 174). Iterative qualitative and mixed methods research is particularly valuable for gaining an in-depth understanding of users' perspectives, experiences and contexts (177, 178). This facilitates the development of digital interventions that are accessible, acceptable and engaging for users (38, 178). Engaging with diverse stakeholders, including those from under-served communities, is an important strategy for promoting health equity by addressing the digital divide (163).

Reviewing existing evidence helps to understand the problem the intervention seeks to address, determine whether similar interventions already exist and identify intervention components and delivery approaches that are likely to be effective (152, 174). It can also reveal key uncertainties in the evidence base (174). These can then be explored through primary research (174, 178). Conducting primary research is also important to ensure that evaluation is embedded in the development process (38). As outlined above, iterative qualitative and mixed methods research is particularly useful for incorporating stakeholders' perspectives. For example, qualitative research can be used to identify what intervention components are likely to be most acceptable to users and obtain feedback on early versions of an intervention (178).

Drawing on existing theories can help inform an intervention's goals, content and delivery (174). This is particularly relevant for digital interventions as systematic reviews suggest digital interventions that are based on theory are more effective at changing users' behaviour than those that are not (179-181). Articulating programme theory is also widely recommended (170, 174). This involves describing how an intervention is expected to achieve its aims within specific contexts (174). Articulating programme theory can facilitate communication with diverse stakeholders (170, 174). It can also help to identify important uncertainties and guide what data to collect during the intervention development and evaluation (170, 174).

2.4.4 Total knee replacement digital intervention evidence base

A systematic review and meta-analysis by Wang et al. (182) demonstrated the potential value of digital interventions for patients undergoing TKR. Seventeen RCTs investigating technology-assisted TKR rehabilitation were included. Nine investigated tele-rehabilitation delivered via telephone (n=5) or video-conferencing (n=4). The remainder investigated game-based therapy (n=5) or web-based therapies (n=3). Wang et al. (182) concluded there is moderate quality evidence that technology-assisted rehabilitation interventions improve pain and low quality evidence that they improve functional mobility compared to usual care at up to three months post-TKR. The effects were not large enough to be clinically relevant. However, the finding that technology-assisted and conventional rehabilitation have similar clinical effectiveness is encouraging as digital interventions offer other potential benefits, such as improving the accessibility and efficiency of care.

Of the 17 RCTs included by Wang et al. (182), only one investigated a digital intervention that spanned the pre-operative phase of the TKR pathway (183). This was a large RCT by Culliton et al. (183), which found an e-learning tool did not influence the proportion of patients whose expectations were met or who were satisfied at one year post-operatively. The e-learning tool consisted of 32 short videos presented by surgeons, therapists or previous patients. Culliton et al. (183) only reported brief details about how the e-learning tool was developed. Inadequacies in the development process, such as insufficient stakeholder engagement, may therefore have contributed to the tool's lack of beneficial effects. Since Wang et al. (182) completed their literature searches, multiple additional RCTs of TKR digital interventions have been published (39-43, 184-193). Most of these investigated interventions delivered post-operatively.

RCTs investigating pre-operative TKR digital interventions are more limited in quantity and particularly quality. As discussed above (section 2.3.3), four RCTs (39-42) and a pilot RCT (43) have investigated TKR prehabilitation interventions involving digital technologies. These included video-conferencing (39, 41, 43), a DVD combined with telephone/mobile application remote monitoring (40) and automated text-messages (42). All four RCTs reported benefits of their interventions but these were limited to pre-operative time points in three RCTs (39, 40, 42). The remaining RCT by An et al. (41) presented significant methodological limitations, so firm conclusions about the effectiveness of its tele-rehabilitation intervention cannot be drawn.

Of three RCTs investigating pre-operative education digital interventions (44-46), only one conducted by Soeters et al. (44) included multiple follow-up time points. Soeters et al. (44) investigated the effects of a single pre-operative physiotherapy session combined with access to a web-based microsite in patients undergoing TKR/THR. The intervention group received fewer inpatient physical therapy visits and met the physical therapy discharge criteria quicker than the control group. Given the intervention included a physical therapy session, these benefits cannot be specifically attributed to the microsite. LOS and participant-reported outcomes at six weeks post-operatively did not differ significantly between groups (44).

Groves et al. (45) investigated the effects of signposting patients awaiting knee/hip replacement to three health-related websites, all of which provided information about anaesthesia. The intervention group showed greater improvements in knowledge of anaesthesia and shifted their preference towards neuraxial anaesthesia compared to the control group. This RCT was limited by its high dropout rate. Of 179 patients enrolled, 61 were excluded due to failing to complete the follow-up questionnaire or because they had been allocated to the control group and reported looking for information about anaesthesia on the Internet. An RCT by Leal-Blanquet et al. (46) found an educational DVD did not influence patients' overall expectations of TKR. This may have been due to participants in both the intervention and control groups receiving verbal education from a specialised nurse.

The publications of all the above RCTs investigating pre-operative TKR digital interventions provide minimal, if any, details about how the intervention was developed. This is a major concern given the importance of rigorous intervention development discussed above (section 2.4.3). In addition, all the RCTs other than Groves et al. (45) were conducted outside the UK; therefore, the interventions may not necessarily be feasible to implement in NHS settings (107). The RCT by Groves et al. (45) was conducted over 13 years ago, so its relevance to current NHS contexts is limited.

Jayakumar et al. (47) and Higgins et al. (48) more recently explored the integration of a digital intervention within NHS TKR pathways. The digital intervention comprised an online platform for patients and healthcare professionals implemented as part of a patient engagement and pathway management programme. Both studies included a pre-programme cohort analysed retrospectively and a programme cohort analysed prospectively. The programme cohorts had a shorter LOS and greater improvements in at least one PROM compared to the pre-programme cohorts. These findings are limited by the studies' observational designs and delivery of the digital intervention alongside co-interventions. Jayakumar et al. (47) reported that implementation of the programme achieved cost-savings, but acknowledged the savings were specific to their hospital site. The estimated fee for the commercialised programme was £50-60 per patient. This would present a substantial cost to the NHS given the large volume of patients undergoing TKR. The efficiency of the online platform was limited by requiring health professionals' input. Furthermore, it was integrated with the hospital electronic systems, which could limit its applicability to other settings.

2.5 Project rationale

As discussed above, large numbers of patients face long waits for TKR (5, 6). During this time, patients typically experience severe pain and functional limitations (7, 69). This can have a profound impact on their QOL and mental wellbeing (8, 67). These problems may deteriorate further whilst patients wait for surgery (7, 8). A wide range of modifiable pre-operative predictors of TKR outcomes has been identified (17, 20, 87). Pre-operative TKR interventions that address these predictors have the potential to improve patient outcomes both pre- and post-operatively. Despite this, the pre-operative TKR intervention evidence base is limited. The NICE joint replacement guideline highlights future research investigating pre-operative TKR education and prehabilitation interventions is needed (31). At present, NHS TKR services are inconsistent, inefficient and often fail to meet all patients' needs (31, 32, 146). Pre-operative TKR digital interventions offer a promising approach for overcoming these issues. Some NHS Trusts have turned to commercial TKR digital interventions (47, 48), but these are costly and risk widening variations in service provision. RCTs that have investigated pre-operative TKR digital interventions present various limitations. Of particular concern, they have not adequately described the intervention development process, despite rigorous development of digital interventions being vital to their success.

To help address the above issues, this project aimed to rigorously develop a novel pre-operative TKR education and prehabilitation digital intervention, the *'Virtual Knee School'* (VKS). The development process integrated stakeholder engagement, evidence and theory to maximise the chances the VKS will prove successful when evaluated and implemented. Input from PPI representatives was particularly key, as discussed in Chapter 3 (section 3.5). An important objective of the development process was to develop detailed recommendations on pre-operative TKR interventions. These recommendations helped optimise the VKS content and provide an appropriate resource for informing UK pre-operative TKR service provision. The VKS was designed as a fully automated digital intervention to ensure it has the potential to provide a cost-effective resource for patients undergoing TKR throughout the UK. This project is timely given the COVID-19 pandemic has dramatically increased TKR waiting times and accelerated the adoption of digital technologies by the NHS.

Chapter 3 Methodology

3.1 Introduction

This chapter provides an overview of intervention development approaches and mixed methods research. Justification for selecting an evidence-, theory- and person-based approach and complex mixed methods design is provided. The chapter then covers key ethical and governance considerations and explains how PPI was central throughout the project.

3.2 Intervention development approaches

3.2.1 Overview of approaches

As discussed in Chapter 2 (section 2.4.3), rigorous development of digital interventions is key to their success. A diverse array of approaches for guiding the development of digital and other complex interventions is available (171). During the IdentifyiNg and assessing different approaches to DEveloping compleX interventions (INDEX) study (detailed in Chapter 2, Table 2.2) (176), O'Cathain et al. (171) undertook a systematic methods overview of published intervention development approaches. The resulting taxonomy comprises eight categories of approach (Table 3.1).

Table 3.1: Taxonomy of complex intervention development approaches

Category	INDEX team definition	Defined approach
1. Partnership	The people for whom the intervention aims to help are involved in decision-making about the intervention throughout the development process, having at least equal decision-making powers with members of the research team	Co-production, co-creation, co-design, co-operative design
		User-driven
		Experience-based co-design (EBCD) and accelerated EBCD
2. Target population-centred	Interventions are based on the views and actions of the people who will use the intervention	Person-based
		User-centred
		Human-centred design
3. Theory and evidence-based	Interventions are based on combining published research evidence and formal theories (e.g. psychological or organisational theories) or theories specific to the intervention	Medical Research Council Framework for developing and evaluating complex interventions
		Behaviour change wheel (BCW)
		Intervention mapping (IM)
		Matrix Assisting Practitioner's Intervention Planning Tool (MAP-IT)
		Normalisation process theory (NPT)[a]
		Theoretical domains framework (TDF)
4. Implementation-based	Interventions are developed with attention to ensuring the intervention will be used in the real world if effective	Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM)
5. Efficiency based	Components of an intervention are tested using experimental designs to determine active components and make interventions more efficient	Multiphase optimization strategy (MOST)
		Multi-level and fractional factorial experiments
		Micro-randomisation trials
6. Stepped or phased based	Interventions are developed through emphasis on a systematic overview of processes involved in intervention development	Six essential Steps for Quality Intervention Development (6SQUID)
		Five actions model
		Obesity-Related Behavioural Intervention Trials (ORBIT)
7. Intervention-specific	An intervention development approach is constructed for a specific type of intervention	Digital (e.g. Integrate, Design, Assess and Share (IDEAS)
		Patient decision support or aids
		Group interventions
8. Combination	Existing approaches to intervention development are combined	Participatory Action Research based on theories of Behaviour Change and Persuasive Technology (PAR-BCP)

INDEX, IdentifyiNg and assessing different approaches to Developing compleX interventions
[a] O'Cathain et al. (171) state '*Could be considered under implementation based approaches to intervention development because the theory is about implementation*' (p.6).
Table reproduced from Table 1 (columns 1–3) in O'Cathain et al. (171) (https://doi.org/10.1186/s40814-019-0425-6) under the terms of the Creative Commons Attribution 4.0 International License (194) with minor formatting changes only.

O'Cathain et al. (171) synthesised the steps, actions and activities recommended by each approach to produce a list of 18 actions to consider during intervention development. The actions were grouped into seven domains spanning the entire development process from conception to planning for future evaluation. O'Cathain et al. (171) highlight it is not always necessary or feasible to address every action. The optimal approach and actions depend on the intervention being developed.

3.2.2 Considerations for selecting an approach

When selecting an intervention development approach/actions, O'Cathain et al. (171) recommend considering the six questions discussed below.

1. *'What is the intention of the intervention? e.g. changing behaviour'* (171: p.21)

As explained in Chapter 2 (section 2.5), the intention of the VKS is to help address the current UK inconsistencies, inefficiencies and inadequacies in pre-operative TKR care. The VKS aims to achieve this by providing a digital-based pre-operative TKR education and prehabilitation programme that:

- increases patients' health-related knowledge, for example about TKR outcomes;
- supports patients to initiate and maintain health behaviour changes, such as engaging with an exercise programme.

This intention aligns with approaches designed to guide the development of individual-level health interventions with an educational/behaviour change focus. Many of the approaches listed in Table 3.1 meet this requirement. These include the person-based approach (PBA) (178) and Integrate, Design, Assess, and Share (IDEAS) (195), which are summarised below.

2. *'What is the context of the intervention? e.g. public health'* (171: p.23)

Context is a broad concept, which can be defined as:

> 'any feature of the circumstances in which an intervention is conceived, developed, implemented and evaluated' (196: p.1).

This encompasses a wide range of features such as socioeconomic factors, the geographical setting and service/organisational characteristics (196). A key contextual feature of the VKS is that it is designed to be used via a digital device without professional support. This means that the intended users' contexts will vary widely and they will need the motivation and confidence to use the VKS without professional support (178). In addition, the VKS content needs to be pre-specified, whereas face-to-face interventions can be adapted by the professionals delivering them if necessary (38). It is therefore essential to gain an in-depth understanding of potential VKS users' varied contexts and ensure that users' perspectives are prioritised throughout the development process. As discussed in Chapter 2 (section 2.4.2), the development of digital interventions such as the VKS also needs to address other unique challenges, such as the risk of increasing health inequities as certain groups of people may not be able to access digital interventions or engage with them effectively (37).

Four approaches listed in Table 3.1 were developed partly/entirely for digital behaviour change contexts (178, 195, 197, 198). Of these, the PBA (178, 199) and IDEAS (195) are the most relevant to the VKS development because they are not limited to a specific digital intervention type and they are relatively comprehensive in relation to the list of actions developed by O'Cathain et al. (171); therefore, these approaches are discussed below.

- PBA (178, 199): a target population-centred approach that prioritises understanding the psychosocial context and perspectives of intended users. This aims to facilitate the development of interventions that are acceptable, meaningful and engaging for users. The two core elements of the PBA are iterative qualitative/mixed methods research and the creation of *'guiding principles'* (199: 'Abstract'). Guiding principles summarise the intervention's design objectives and key features to help inform decisions throughout the development process, as detailed in Chapter 7 (section 7.3). The PBA has multiple strengths such as being systematic yet flexible and explicitly incorporating PPI (177). Its main disadvantage is that it is relatively resource-intensive (177).
- IDEAS (195): an intervention-specific approach that combines elements from behavioural theory, design thinking and evaluation/dissemination. It provides a framework with 10 phases addressing intervention development, evaluation and dissemination. The phases are grouped into four categories (Integrate, Design, Assess, and Share). Strengths of IDEAS are that it provides specific actions for each phase and is a relatively creative approach due to its emphasis on design thinking strategies such as iterative brainstorming. An important limitation is that

disagreements between intervention development team members may be difficult to manage (195).

3. *'What values inform the intervention development? e.g. working in partnership with the target population'* (171: p.23)

In line with the recommendations for developing digital interventions discussed in Chapter 2 (section 2.4.3), the key values that informed the VKS development were as follows.

A) Ensuring that stakeholders' views remained central throughout the development process.
B) Incorporating evidence and theory into the development process.

Value A aligns closely with approaches in the partnership and target population-centred intervention development categories. As discussed above, the PBA is a particularly relevant target population-centred approach because it applies directly to digital behaviour change contexts (177). The PBA incorporates elements of partnership approaches through PPI, enabling it to combine the strengths of PPI and qualitative research (200). PPI representatives can provide valuable input at all stages of a research project from planning through to dissemination (200). Research participants are not involved in the ongoing research process and hence can offer *'fresh'* perspectives (200: p.4). Purely partnership approaches may encourage PPI representatives to anticipate the needs of other intended users, which is typically challenging (178). The PBA overcomes this issue by directly exploring the perspectives of other intended users through qualitative research (178). In addition, the PBA enables perspectives of a more diverse range of people to be considered (200, 201). For example, not requiring research participants to have a long-term commitment to the project may help with recruiting people who are busy or have relatively low motivation (201).

The PBA also addresses value B as it involves synthesising and/or conducting qualitative/mixed methods research, developing bespoke guiding principles and addressing common guiding principles (178). As discussed in Chapter 7 (section 7.3.2), the common guiding principles are based on the constructs of Self-Determination Theory (SDT) (202, 203). Furthermore, the PBA is designed to be used in combination with other theory and evidence-based approaches (178). IDEAS also address values A and B but it provides less flexibility regarding how stakeholders' perspectives, evidence and theory are incorporated compared to the PBA (178).

Approaches in the theory and evidence-based category align closely with value B. A benefit of most approaches in this category is that they are systematic, although Intervention Mapping (204) may be considered too prescriptive (171). When this project was being planned, the updated Medical Research Council (MRC) / National Institute for Health and Care Research (NIHR) framework for developing and evaluating complex interventions (170) had not been published. The previous MRC complex intervention framework (2006 version) (173) recommends that intervention development should include reviewing existing evidence, drawing on/developing relevant theory and modelling the intervention process and outcomes. Benefits of the MRC framework include that it is not prescriptive and has been widely used. However, it offers minimal detail on specific actions to take during the development process (171). Normalisation Process Theory (NPT) (205) has the advantage of explicitly addressing implementation, which is often overlooked during intervention development (171). However, NPT has a relatively narrow focus and does not provide detailed guidance on how to develop interventions (171). Other theory and evidence-based approaches offer more practical guidance but present different limitations (171). For example, the Behaviour Change Wheel (BCW) approach (206) provides an eight-step process for designing behaviour change interventions based on the BCW framework (207), but does not adequately address stakeholder engagement (171).

4. *'What skills and experience does the team bring?'* (171: p.23)

Prior to commencing this project, the researcher had gained skills and experience relevant to developing interventions such as clinical physiotherapy skills, leadership skills and qualitative research experience. However, she did not have direct experience of intervention development. This meant that selecting an approach with detailed guidance was a priority. Examples of such approaches include the PBA (178) and BCW approach (206). IDEAS is less appropriate from this perspective as some of its methods are challenging for relatively inexperienced researchers to conduct effectively (195). To support the project, the researcher assembled a multidisciplinary team of four supervisors and five advisors who brought diverse research- and clinical-related skills and experiences. Notably, one of the researcher's supervisors (LY) led the development of the PBA (178). As described in section 3.4.5, the researcher also assembled a Project Advisory Group (PAG). This included three PPI representatives who brought diverse skills and lived experiences related to TKR and digital interventions.

5. *'Which approaches have resulted in interventions shown to be effective?'* (171: p.23)

Although many approaches have resulted in interventions shown to be effective, the quantity and quality of supporting evidence varies substantially. A particularly large volume of high quality evidence supports the PBA (178). For example, RCTs have demonstrated that interventions developed using the PBA have beneficial effects on QOL amongst people with incompletely controlled asthma (208) and dizziness-related disability amongst older adults with chronic dizziness (209).

6. *'What resources are available for the intervention development?'* (171: p.23)

The VKS was developed during the researcher's three-year Health Education England (HEE) / NIHR Clinical Doctoral Research Fellowship based at the University of Leeds. Correspondingly, the majority of the development work had to be completed by the researcher independently and the project was relatively well resourced in terms of funding for PPI activities, governance support etc. This meant that adopting a comparatively resource-intensive approach, such as the PBA (178), was feasible. However, combining the PBA with another particularly time-consuming approach, such as the Theoretical Domains Framework (TDF) (210), would not have been feasible.

3.2.3 Selection of an evidence-, theory- and person-based approach

Considering the above questions highlights the PBA as particularly appropriate for developing the VKS. To ensure that value B was adequately addressed, the PBA was combined with the MRC framework for developing and evaluating complex interventions (173). The MRC framework was chosen because it is particularly well established and is less prescriptive than other theory and evidence based approaches, such as the BCW approach (206). As described in Chapter 7 (section 7.4), the BCW (207) was used during the theoretical modelling phase of this project. This involved applying the BCW framework (207) during a behavioural analysis, rather than following the eight-step BCW approach (206). In line with relevant literature (211), the overall approach used in this project was described as an evidence-, theory- and person-based approach.

3.3 Mixed methods research

3.3.1 Rationale

As discussed in Chapter 2 (section 2.4.3) and earlier in this chapter (section 3.2.2), mixed methods research is particularly valuable for developing digital interventions and is a core element of the PBA (178). A mixed methods approach was therefore chosen for this project. Mixed methods research combines the strengths of quantitative and qualitative research (212). This offers multiple benefits, such as answering questions that purely quantitative or qualitative approaches could not address (213) and enabling a deeper understanding of a research problem to be gained (214). This makes mixed methods research useful for addressing complex problems (212), such as the one this project seeks to address. A key challenge of mixed methods research is that it typically requires substantial time and resources (213). To help address this, the researcher meticulously planned this project and established a team to oversee it (section 3.4.5).

3.3.2 Definition

Various definitions of mixed methods research have been proposed, including those from methods, methodological, paradigm and practice perspectives (213, 215). To reflect these differing perspectives, Creswell and Plano Clark (213) advocate defining mixed methods based on its core characteristics:

- use of philosophy and theory to frame the study procedures;
- use of specific research designs to guide the study procedures and provide the logic for interpreting the findings;
- rigorous collection and analysis of quantitative (numerical) and qualitative (non-numerical) data to address research questions/hypotheses;
- integration of quantitative and qualitative data and their findings.

Sections 3.3.3 to 3.3.5 consider these characteristics in more detail in relation to this project.

3.3.3 Philosophical and theoretical considerations

Philosophical assumptions provide the foundation for a research project, shaping its overall design and conduct (213). These assumptions are often described as a *‘paradigm’* or *‘worldview’* as they reflect researchers’ underlying beliefs and values (213: p.35). Key elements of paradigms include questions about ontology (nature of reality), epistemology (relationship between the researcher and what they are researching) and methodology (process of conducting research) (213, 216). Table 3.2 summarises these elements for three well-established paradigms.

Table 3.2: Key elements of positivism, constructivism and pragmatism

Paradigm	Ontology	Epistemology	Methodology	Typical approach
Positivism	One objective reality exists	Researcher and what they are researching are independent.	Hypotheses are experimentally tested using deductive approaches.	Quantitative
Constructivism	Multiple subjective realities exist	Researcher and what they are researching are inextricably linked and interact.	Theories/ interpretations are developed inductively by exploring perspectives of individuals.	Qualitative
Pragmatism	Reality depends on the situation	Researcher focuses on addressing a research question in the real world using whatever approaches work best for addressing the research problem.	Qualitative and quantitative data are collected and combined.	Mixed methods

Table based on Cresswell and Plano Clark (213), Guba and Lincoln (216) and Jacobsen (217).

A mixed methods study may be framed using a single overarching paradigm (213). Pragmatism is often chosen for this purpose as it aligns well with mixed methods approaches (Table 3.2) (213, 218). Alternatively, a mixed methods study may involve a *'dialectic stance'*, in which multiple paradigms and perspectives are considered (219: p.124). Creswell and Plano Clark (213) highlight that both options can be useful in different circumstances. Correspondingly, they suggest using a flexible approach, in which one or more paradigms may be used to suit a study's context and design (213). In line with this, the present project was primarily underpinned by pragmatism but differing paradigms and perspectives were considered where appropriate.

Theories may be used in various ways during mixed methods studies, including guiding the research questions, informing the study procedures and interpreting the study findings (213). Most theories used in mixed methods studies are social science theories, such as behaviour change theories, or emancipatory theories, such as feminist theories (213). The use of theory in this study was guided by the PBA (178) and MRC complex intervention framework (173). Correspondingly, three theoretical modelling approaches were chosen (guiding principles, behavioural analysis and logic model), as detailed in Chapter 7.

3.3.4 Mixed methods designs

Multiple typologies of mixed methods designs have been proposed (218). These focus on various design considerations, such as the number of strands, integration of the qualitative/quantitative data and priority of the quantitative/qualitative data (218). Consensus on the optimal typology is lacking (218). The typology proposed by Creswell and Plano Clark (213) was selected for this project because it addresses the intent of mixing quantitative/qualitative data as well as the data collection, analysis and integration procedures. This typology includes three core mixed methods designs (Table 3.3).

Table 3.3: Core mixed methods designs

Design	Main intent	Data collection and analysis[a]	Integration[b]
Convergent	Compare or combine quantitative and qualitative data to provide a greater understanding of the research problem.	Single phase 1. Simultaneous quantitative and qualitative data collection and separate analysis	Single integration point that involves directly comparing the quantitative and qualitative findings and/or transforming one type of data into the other.
Explanatory sequential	Use qualitative data to explain/build on quantitative findings.	Two sequential phases: 1. Quantitative data collection and analysis **then** → 2. Qualitative data collection and analysis	Two integration points: 1. Quantitative findings inform the qualitative data collection 2. Quantitative and qualitative findings are integrated
Exploratory sequential	Use qualitative findings to inform a novel *'quantitative feature'*, such as an intervention or instrument, and evaluate the feature using quantitative methods (213: p.67).	Three sequential phases: 1. Qualitative data collection and analysis **then** → 2. Design of the quantitative feature **then** → 3. Quantitative data collection and analysis	Two integration points: 1. Qualitative findings inform the development of the quantitative feature 2. Qualitative and quantitative findings are integrated

[a] Refers to the separate analysis of quantitative and qualitative data.
[b] In each design, the integrated findings are interpreted to draw overall conclusions.
Table based on Creswell and Plano Clark (213).

The core designs may be used on their own or intersected with other approaches to form a complex design (213). The intersection may be with other research designs, methodologies or theoretical frameworks (213, 220). For example, mixed methods experimental designs involve embedding a core mixed methods design within an experimental design (213). Complex designs typically involve numerous phases spread over several years (213). This can enable multiple objectives to be addressed (213).

The overall aim of this project was to develop a novel intervention, the VKS. During the project design, a small mixed methods process evaluation of the VKS was planned as an additional phase after the intervention development. The process evaluation was not conducted due to a combination of factors. These included delays associated with the COVID-19 pandemic (detailed in the COVID-19 impact statement) and an amendment to the VKS refinement data collection procedures due to the large volume of content included in the VKS (detailed in Chapter 8, section 8.4.3). This meant that the VKS was not evaluated as comprehensively as originally planned. However, evaluation of the VKS was embedded in the development process through user testing of the VKS prototype. This aligns with the international recommendations on developing and evaluating digital behaviour change interventions discussed in Chapter 2 (Table 2.2). These state that evaluation should be included in all stages of the development cycle through activities such as user testing (38).

Developing and evaluating a novel intervention aligns with the intent of an exploratory sequential design (Table 3.3). With this design, qualitative findings inform the novel intervention. This helps to ensure that the intervention is contextually relevant for its intended users (213). Given that incorporating other types of evidence and theory is also key to intervention development (173), an evidence-, theory- and person-based approach was selected for this project, as discussed above (section 3.2.3). Correspondingly, this project had multiple objectives that could not be addressed by qualitative research alone (Chapter 1, section 1.3). This project therefore employed a complex design in which the overarching design was exploratory sequential. Each phase was given equal priority, conducted largely sequentially and informed by the preceding phase(s) (Figure 3.1). Table 3.4 and Chapters 4–8 provide further details of each phase.

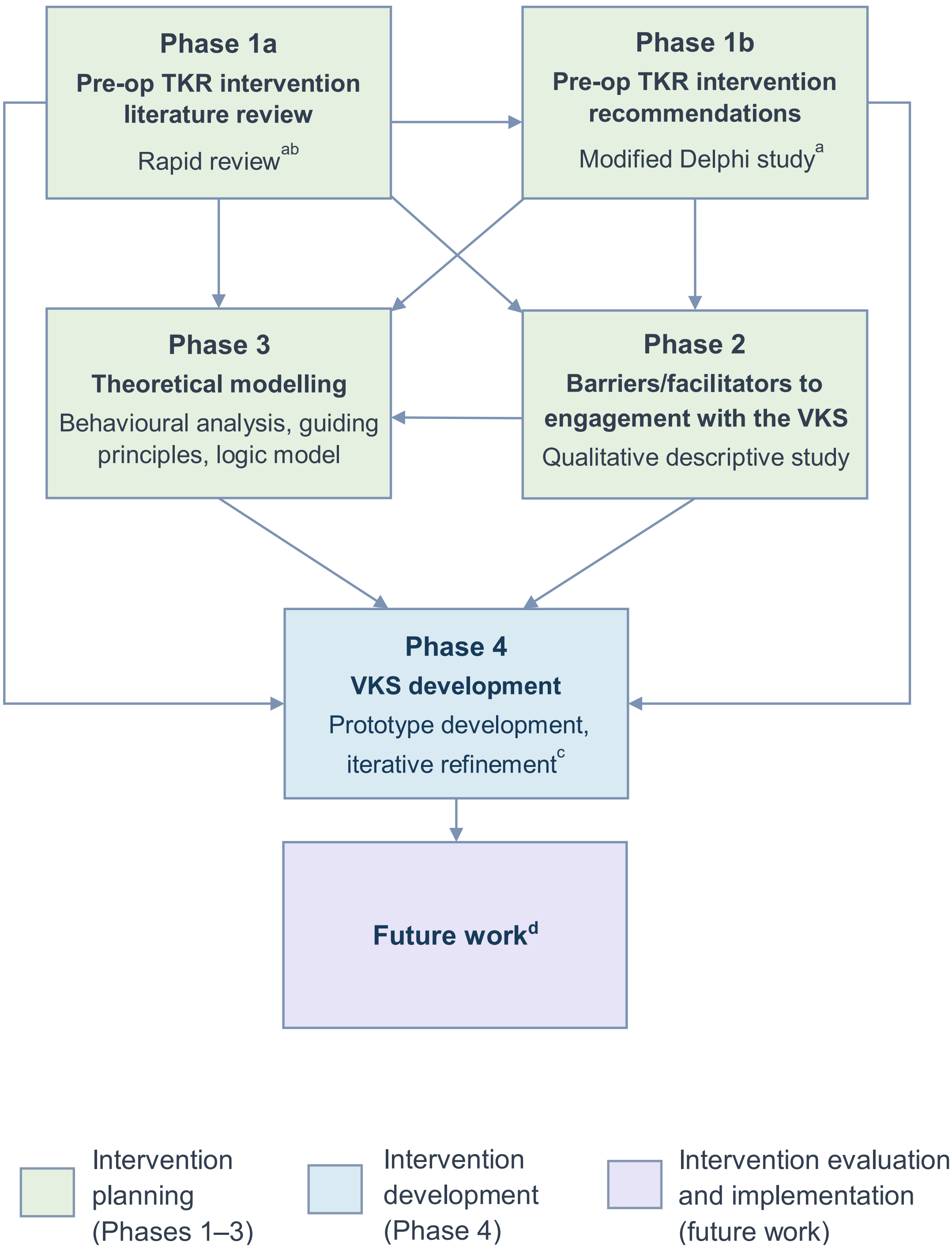


Figure 3.1: Project flow chart

Pre-op, pre-operative; TKR, total knee replacement; VKS, Virtual Knee School

[a] The design of Phase 1 may be considered exploratory sequential as the findings of the Phase 1a rapid review were used to generate the Round 1 survey used in the Phase 1b modified Delphi study.

[b] The rapid review employed a convergent segregated mixed methods design.

[c] The refinement involved user testing through the think-aloud method.

[d] A Phase 5 process evaluation was initially planned but was not conducted. A process evaluation will be incorporated into future work if appropriate.

The phase numbers correspond with the objectives listed in Chapter 1 (section 1.3).

Mixed methods designs can be considered on a continuum from *'fixed'* (the mixed methods design is pre-specified and implemented as intended) to *'emergent'* (the mixed methods design is adopted during the study conduct) (213: p.52). The design of this project was largely fixed as the overall design was pre-specified. However, the removal of the process evaluation meant the project was not implemented exactly as intended.

3.3.5 Data collection, analysis and integration

As highlighted above (section 3.3.2), rigorous collection and analysis of quantitative and qualitative data is a core characteristic of mixed methods research. This involves following best practice procedures for quantitative and qualitative research (213). Creswell and Plano Clark (213) recommend that the type of mixed methods design should guide the specific procedures employed. For example, an exploratory sequential design should ideally involve recruiting a purposive sample for the qualitative strand and a separate, larger random sample for the quantitative strand. This enables assessment of the generalisability of the quantitative feature developed from the qualitative findings. In contrast, the qualitative strand in an explanatory sequential design should ideally comprise a subsample of participants from the quantitative strand, as the purpose of the qualitative data is to explain the quantitative results. With all types of mixed methods designs, the quantitative and qualitative data are analysed separately and integrated (213). The separate analyses involve rigorous application of quantitative and qualitative analysis approaches such as descriptive statistics and thematic analysis (213). The findings of the separate analyses are interpreted to draw inferences (213, 221).

Integration is considered the defining feature of mixed methods research (213). Creswell and Plano Clark (213) describe it as the point at which *'qualitative research interfaces with quantitative research'* (p.220). Various authors have proposed principles and techniques for conducting integration. For example, Fetters et al. (212) describe integration approaches at three levels (the study design, methods and interpretation/reporting) and O'Cathain et al. (222) provide guidance on three integration techniques (the triangulation protocol, following a thread and the mixed methods matrix). Creswell and Plano Clark (213) suggest that the type of mixed methods design should determine the integration intent and procedures.

With an exploratory sequential design, the main intent of integration is to use the qualitative findings to generate a context-specific quantitative feature for subsequent evaluation (213). Integration occurs at two points (Table 3.3). The first is the generation of the quantitative feature (213). This can be classed as *'building'* (213: p.240) – a methods level integration approach in which one dataset informs collection of the other type of data (212, 213). Creswell and Plano Clark (213) suggest visually representing this process in a *'joint display'* (p.241), such as a table in which the qualitative codes/themes link to specific aspects of the quantitative feature. After the quantitative feature is developed, it is rigorously pilot tested, refined and evaluated (213). The second point of integration involves linking the qualitative findings to the results of the quantitative evaluation. This can be achieved through another joint display and/or by discussing how the qualitative findings and quantitative results relate. The conclusions drawn by interpreting the qualitative and quantitative inferences may be described as *'meta-inferences'* (221: p.101). These provide greater insights than the quantitative and qualitative inferences considered in isolation (221).

Given this project employed a complex exploratory sequential design, it involved various data collection and analysis approaches and multiple points of integration through building (Table 3.4). The findings of all the phases were integrated in the discussion to generate meta-inferences (Chapter 9, section 9.3).

Table 3.4: Project data collection, analysis and integration overview

Phase	Design	Data collection[a]	Data analysis	Building integration[b]	Chapter
1a	Rapid review (convergent segregated mixed methods)	Searches of five electronic databases and references lists to identify *'outcomes studies'* (randomised trials) and *'views studies'* (primary studies of any design exploring participants' experiences/ perspectives). Data extraction using standardised forms.	Narrative syntheses of the outcomes studies and views studies separately. Integration of the outcomes studies and views studies through tables and narrative syntheses.	N/A	4
1b	Modified Delphi study	Three online surveys with free-text and Likert scale options in Round 1 and Likert scale options only in Rounds 2 and 3.	Qualitative data: directed content analysis (223, 224). Quantitative data: descriptive statistics.	Round 1 was informed by the Phase 1a findings.	5
2	Qualitative descriptive	Online focus groups	Reflexive thematic analysis (225).	The digital trigger materials were informed by the Phase 1 findings[c].	6
3	Guiding principles; behavioural analysis; logic model	No new data collected	Guiding principles creation: PBA (178). Behavioural analysis conduct: BCW (207) and BCTTv1 (226). Logic model development: MRC process evaluation guidance (227).	All three theoretical modelling approaches were informed by the Phase 1–2 findings.	7
4	Prototype development; iterative refinement using the think-aloud method	Prototype development: no new data collected Iterative refinement: online/in-person concurrent think-aloud interviews	Prototype development: evidence-theory- and person-based approach (178, 211). Iterative refinement: bespoke approach for analysing qualitative data during PBA intervention refinement (228).	The VKS prototype development and refinement were informed by the Phase 1–3 findings.	8

BCTTv1, Behaviour Change Technique Taxonomy (v1); BCW, Behaviour Change Wheel; MRC, Medical Research Council; N/A, not applicable; PBA, person-based approach; VKS, Virtual Knee School

[a] Details of participants' characteristics were also collected in Phases 1b, 2 and 4. Only formal data collection methods (not PPI activities) are listed.

[b] In addition to the building integration, the findings of all the phases were narratively integrated in the discussion (Chapter 9, section 9.3).

[c] Due to the timeline for obtaining ethical approval, the Phase 2 topic guide was drafted prior to completion of Phase 1. It was subsequently reviewed in light of the Phase 1 findings and no changes were required.

3.3.6 Quality considerations

The quantitative and qualitative strands of a mixed methods study should be rigorously conducted in line with established quality criteria for that strand (213). For example, internal validity and credibility are important considerations for quantitative and qualitative strands respectively (213). Given that integration is a core characteristic of mixed methods research, considering the quality of the individual strands alone is not sufficient for establishing the quality of a mixed methods study (213, 229). Consensus on quality criteria and associated terminology for mixed methods research is lacking (213, 229). Based on a synthesis of existing literature, O'Cathain (229) proposed a comprehensive framework for assessing the quality of mixed methods research. The framework covers five study stages and eight domains of quality. O'Cathain (229) highlighted that this framework is time-consuming and challenging to apply in practice. Furthermore, Creswell and Plano Clark (213) argue that a design-specific approach to assessing quality is preferable to a generic approach since different designs have different logics and intents. Creswell and Plano Clark (213) also propose using *'validity'* as the overarching term when discussing quality as it is generally recognised and accepted by quantitative and qualitative researchers (p.249).

For exploratory sequential designs, Creswell and Plano Clark (213) recommend three approaches for addressing concerns about validity.

1. Transparently detailing the building process, showing how specific qualitative findings link to specific aspects of the quantitative feature.
2. Designing the quantitative feature systematically, for example by pilot testing new resources.
3. Ensuring that the quantitative evaluation phase involves a large number of participants, none of whom participated in the qualitative phase.

This project directly addressed the first two approaches. For example, an intervention planning table was created to detail the reasons for including specific features in the VKS (Chapter 8, section 8.3.3). The third approach will be addressed if a quantitative evaluation phase is conducted in the future.

3.4 Ethical and governance considerations

3.4.1 Protocols and registrations

To promote transparency and accountability, protocols covering all the project phases were developed prospectively and the studies were registered on appropriate databases (230, 231). Separate protocols were developed for Phase 1a, Phase 1b and Phases 2–4 to ensure that all relevant ethical and governance considerations were addressed whilst minimising the risk of delays. The Phase 1a rapid review was registered with PROSPERO on 3rd September 2019 (CRD42019143248). The Phase 1b modified Delphi study was not registered separately because it did not meet the criteria for a clinical trial. The protocol for Phases 2–4 initially included a process evaluation as explained in section 3.3.4; therefore, the study was considered a clinical trial. The overall project was registered on the International Standard Randomised Controlled Trial Number (ISRCTN) Registry on 24th April 2020 (ISRCTN11759773).

3.4.2 Ethical approval

Ethical approval was not required for Phase 1a because it did not involve human participants. Ethical approval for Phase 1b and Phases 2–4 was obtained from the London - Riverside Research Ethics Committee (19/LO/0813) and Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (20/YH/0095) respectively.

3.4.3 Accessibility and inclusion

Accessibility and inclusion were prioritised throughout the project. This included taking steps to make the following aspects of the research more accessible and inclusive.

- Participant procedures: for example, all focus group and interview participants were offered the opportunity to claim reimbursement for childcare, carer and/or personal assistance costs.
- PPI activities: for example, easy read documents were developed to enable an individual with a learning disability to be involved.
- VKS prototype: for example, an accessibility toolbar was included as detailed in Chapter 8 (section 8.3.5).

3.4.4 Data protection

A data management plan was created and maintained throughout the project. This detailed all the project datasets and their classification (unclassified, confidential or highly confidential); ethical and legal compliance; data storage; data sharing; data retention/deletion; and a data risk assessment. Additional details about the protection of personally identifiable data were documented in the protocols for Phase 1b and Phases 2–4. The General Data Protection Regulation (GDPR) (232), Data Protection Act 2018 (233) and University of Leeds Information Protection Policy (234) were adhered to at all times. Key steps taken to protect personally identifiable data included the following.

- Confidential and highly confidential data were stored within encrypted folders on the University of Leeds secure servers (digital data) and/or in a locked filing cabinet in the researcher's office (paper-based data).
- All participants were allocated a unique identification number, which was used to label their questionnaire data, transcripts and field notes.
- Pseudonyms are used when referring to individual participants in this thesis and all other reports/publications/presentations.
- The secure tools used to administer online surveys (Online surveys (235)) and conduct online focus groups/interviews (Blackboard Collaborate (236) and Microsoft Teams (237)) meet the University of Leeds data protection standards.
- Focus groups/interviews were recorded using encrypted digital devices and/or one of the secure videoconferencing tools specified above.
- Recordings that required transcription were transferred to 1st Class Secretarial Services, a transcription company, using their encrypted channel. A data processing agreement was in place between the University of Leeds and 1st Class Secretarial Services.
- Participants were not required to enter any personally identifiable data into the VKS prototype.

3.4.5 Project oversight

A multi-stakeholder Project Advisory Group (PAG) oversaw the project in line with agreed Terms of Reference. The PAG aimed to ensure that:

- the safety and rights of everyone involved/participating in the project were protected;
- the research was valid/credible.

The membership included the researcher, her three University of Leeds supervisors, three PPI representatives, an independent chair and a key collaborator from the West Yorkshire Association of Acute Trusts (WYAAT). One PPI representative was recruited in March 2021 to increase ethnic diversity amongst the PPI members. All other PAG members were recruited at the start of the project. A key role of the PAG was defining and agreeing the project success criteria (Appendix A). Other roles included offering advice on the research design, management and commitment of everyone involved/participating in the research; monitoring the project progress; and agreeing on/assisting with the plans for disseminating the project findings. The PAG met approximately every six months for the duration of the project (1st September 2019 to 31st May 2022). Contact between meetings was maintained via email, telephone and online meetings as appropriate.

3.4.6 Reporting

Given this project involved developing an intervention using mixed methods, and PPI was central to the project, three guidelines were selected to inform the overall reporting.

- GUIDance for the rEporting of intervention Development (GUIDED) checklist (238): a detailed 14-item checklist for reporting intervention development produced through the international consensus exercise of the INDEX study (176) detailed in Chapter 2 (Table 2.2).
- Good Reporting of A Mixed Methods Study (GRAMMS) (239): a brief six-point guideline on reporting mixed methods studies based on Creswell (240) and additional relevant literature, produced during a review of the quality of mixed methods studies in health services research.
- Guidance for Reporting Involvement of Patients and the Public (GRIPP) 2 short form (241): a brief five-point checklist for reporting PPI in research produced through systematic reviews, an international online Delphi study and a consensus meeting. The short form rather than long form version was chosen because PPI was embedded throughout the project rather than being its primary focus.

The additional guidelines used to inform the reporting of Phases 1a, 1b, 2 and 4 are detailed in Chapters 4, 5, 6 and 8 respectively. Many aspects of this project involved creating highly detailed tables. Due to the thesis word limit restrictions, table excerpts rather than the full tables are provided where appropriate.

3.5 Patient and Public Involvement

3.5.1 Overview

PPI was central throughout this project to help ensure that:

- the research procedures were acceptable and inclusive;
- patients' perspectives remained the key driving force behind the VKS design;
- the VKS is usable, accessible and engaging for a diverse range of patients awaiting TKR surgery;
- the project findings are effectively disseminated to patients and the public.

A variety of PPI consultation and coproduction activities were undertaken during the project planning and conduct. Based on the INDEX guidance (174), the term *'consultation'* is used in this thesis to describe activities in which the researcher held discussions with PPI representatives and used their feedback to guide her decision-making (p.5). The term *'coproduction'* is used when referring to activities in which PPI representatives played a direct role in making decisions (174: p.5). In line with recommended approaches for evaluating public involvement in research (242), the researcher maintained a PPI impact log throughout the project. This detailed a summary of each activity, its impact, any challenges encountered and any follow-up actions required. Role descriptions, support and reimbursement/remuneration were provided in line with guidance from the NIHR Leeds Biomedical Research Centre (BRC) and INVOLVE (now subsumed by the NIHR Centre for Engagement and Dissemination).

3.5.2 Project planning

Prior to commencing this project, two consultations were held with members of the NIHR Leeds BRC PPI group. The first consisted of a general discussion with seven PPI representatives. The second involved two PPI representatives reviewing an existing digital intervention for people with chronic joint pain. These consultations highlighted that PPI representatives were frustrated by limitations and discrepancies in pre-operative TKR care provision. They considered the Internet to be a useful resource but were concerned about online resources being unreliable and inadequately tailored to patients' individual needs. PPI representatives felt a novel digital intervention would be valuable and made specific suggestions about its development, content and design. To address these suggestions the VKS was:

- developed specifically for and with patients awaiting TKR;
- a website rather than a mobile application to maximise accessibility;
- multimedia-based, with videos of PPI representatives;
- interactive to facilitate personal tailoring.

The findings of these consultations were also incorporated into the VKS planning during the theoretical modelling reported in Chapter 7 (section 7.2).

3.5.3 Project conduct

Multiple PPI activities were undertaken during the project conduct (Table 3.5). Chapter 9 (section 9.4.3) summarises the strengths and limitations of PPI in this project.

Table 3.5: Overview of Patient and Public Involvement during the project conduct

Activity	Description	Example of impact	Further details
Reviewing documents	Two PAG PPI members and seven NIHR Leeds BRC PPI representatives reviewed the Phase 1b participant documents. Three PAG PPI members reviewed the Phase 2 and/or 4 participant documents and topic guides.	Bold 18pt text was added to the top of the Phase 2 and 4 Participant Information Sheets to explain how to request the document in large print.	Supplementary File 1 (Phase 4 Participant Information Sheet)
Survey pilot testing	Two PAG PPI members and one additional PPI representative pilot tested the Round 1 survey in the Phase 1b Delphi study.	Explanations of the roles of different health professional teams were added.	Chapter 5 (section 5.2.3.1)
PAG meetings and follow-up	Three PAG PPI members provided oversight of the study by attending PAG meetings and contributing to follow-up activities as required.	The Phase 4 recruitment procedures were amended to include a PAG PPI member sharing a WhatsApp recruitment message with contacts in her communities.	Section 3.4.5 Chapter 8 (section 8.4.2.4)
Consultations on the VKS content and exercise programme	Two PAG PPI members participated in consultations about the VKS content and exercise programme design.	Extra details were added to the educational video transcripts e.g. about sleep difficulties and psychological well-being.	Chapter 8 (section 8.3)
Consultations and coproduction activities during the VKS design, build and testing	Three PAG PPI members contributed to creating a provisional VKS template and style guide; creating the VKS designs; informing the VKS prototype build; and/or formal UAT. Two additional PPI representatives contributed to informal UAT.	Instructions on how to use the accessibility toolbar were added to the *'About the Virtual Knee School'* and *'Help'* webpages.	Chapter 8 (Table 8.8)
Filming to create VKS videos	Eight volunteer patient models were filmed to create the VKS education and exercise videos.	The VKS videos were positively evaluated by participants in the Phase 4.	Chapter 8 (sections 8.3.5 and 8.5)
Dissemination of the project findings	Two PAG PPI members reviewed the Phase 1b plain English summary. All three PAG PPI members will be invited to review additional plain English summaries and contribute to a PPI dissemination event, including as co-presenters.	The study purpose in the Phase 1b summary was rephrased to emphasise that the recommendations will help patients be better prepared for their surgery.	Supplementary File 2 (Phase 1b plain English summary)

BRC, Biomedical Research Centre; NIHR, National Institute for Health and Care Research; PAG, Project Advisory Group; PPI, Patient and Public Involvement; UAT, user acceptance testing; VKS, Virtual Knee School

Chapter 4 Rapid review of the content and delivery of pre-operative total knee replacement interventions (Phase 1a)

4.1 Introduction

This chapter provides an overview of the content and delivery of pre-operative TKR interventions through a rapid review of randomised trials and primary studies exploring patients' and/or health professionals' views of pre-operative TKR interventions. This complements the broad narrative literature review reported in Chapter 2, which provides background to the overall project. The rapid review was the first intervention planning phase for the VKS. A key purpose of the rapid review within the VKS project was to inform Round 1 of the Phase 1b modified Delphi study reported in Chapter 5.

4.1.1 Background

As detailed in Chapters 2–3 (sections 2.4.3 and 3.2), reviewing existing evidence is vital when developing a novel digital intervention and is explicitly recommended in the MRC complex intervention framework (173). A key aim of reviewing existing evidence is to identify intervention components that are likely to be effective and acceptable to users (152, 174). This was particularly important during this project due to the diversity of components that could have been included in the VKS. Reviewing existing evidence is also valuable for identifying how to optimise an intervention's delivery (243). Although the VKS delivery format was determined during this project's conception, it was important to identify how to optimise other aspects of the VKS delivery, such as the VKS exercise programme schedule.

Numerous reviews of pre-operative TKR interventions have been published (23, 28, 29, 112, 118, 123, 244). These have mostly focused on evaluating intervention effectiveness. Reviews addressing specific pre-operative TKR intervention components and/or delivery approaches have been limited in scope. Louw et al. (23) reviewed the content and delivery of pre-operative TKR/THR education but only included RCTs that assessed post-operative pain and were published between 1990 and 2011. This resulted in only four TKR studies meeting their eligibility criteria. Blasco et al. (123) and Husted et al. (118) undertook systematic reviews of pre-operative sensorimotor training and pre-operative resistance training respectively. Although their findings provide some useful insights into these exercise types, they do not specifically address additional types of exercise that could be included in pre-operative TKR exercise programmes. A systematic review by Peer et al. (244) evaluated the effectiveness of different pre-operative TKR exercise types and dosages. Only three studies reported sufficient details of the exercise dosage to meet the review's eligibility criteria.

Reviewing literature exploring stakeholders' experiences and perspectives is valuable for identifying intervention components that are likely to be acceptable and appropriate for an intervention's intended users (152). Such literature can also provide useful insights into how best to deliver interventions in specific contexts (243). Despite this, most previous reviews of pre-operative TKR interventions have not considered patients' and health professionals' views. A systematic review by Buus et al. (24) explored patients' experiences of knee replacement information provision, but only briefly addressed pre-operative education and did not consider health professionals' experiences. Conducting a novel review of the content and delivery of pre-operative TKR interventions was necessary to address the above gaps in existing literature.

Given the uncertainties in the pre-operative TKR evidence base discussed in Chapter 2 (section 2.3), it was not appropriate to rely solely on existing evidence to inform the VKS. Correspondingly, a key purpose of the review reported in this chapter was to facilitate the development of recommendations on pre-operative TKR interventions. This was achieved by using the review findings to inform Round 1 of the Phase 1b modified Delphi study reported in Chapter 5. Correspondingly, this review focused on maximising the number of intervention components and delivery approaches identified, rather than providing definitive evidence about their effectiveness. The recommendations on pre-operative TKR interventions were developed with the dual purpose of informing the VKS and providing a resource to help guide UK health professionals' decision-making on pre-operative TKR service provision. Correspondingly, a comprehensive review of pre-operative TKR intervention components and delivery approaches was required, rather than a review focused solely on digital interventions.

4.1.2 Aim and objectives

This rapid review aimed to identify and synthesise recent literature on the content and delivery of pre-operative TKR interventions (project objective 1a). It had the following two objectives.

1. To identify what pre-operative TKR intervention components and delivery approaches are associated with improved outcomes amongst patients undergoing TKR.

2. To explore the experiences and perspectives of pre-operative TKR intervention components and delivery approaches amongst patients undergoing TKR and their health professionals.

4.2 Methods

4.2.1 Overview and rationale

A wide range of review methodologies exist (245). Table 4.1 summarises the key methodologies considered for this review. These were selected because they involve structured transparent methods, which helps to minimise bias (246-250). In addition, there are relatively well-established guidelines on how to conduct these types of reviews. Methodological guidance is more limited for certain other types of reviews, such as integrative reviews (251-253).

Table 4.1: Key review methodologies considered

Review methodology	Aim	Searches[a]	Evidence included	Critical appraisal	Analysis and synthesis	Time/resource requirements[b]
Systematic review (246, 254)	Synthesise empirical evidence to answer a narrowly defined research question(s)	Comprehensive	Empirical studies that meet pre-specified eligibility criteria	Mandatory	Guided by the type(s) of empirical studies included e.g. meta-analysis, meta-ethnography	High
Rapid review (247, 255)	Synthesise evidence using streamlined systematic review methods to answer a specific research question(s) in a short timeframe	Typically limited e.g. by year of publication, due to time/resource constraints	Empirical studies and/or reviews that meet pre-specified eligibility criteria	Typically limited e.g. performed by a single reviewer, due to time/resource constraints	Typically limited e.g. narrative only, due to time/resource constraints	Low
Overview of reviews (248, 256, 257)	Synthesise systematic reviews to summarise the systematic review evidence base or answer a novel review question(s)	Comprehensive or limited e.g. to databases of reviews, based on time/resource constraints	Systematic reviews that meet pre-specified eligibility criteria[c]	Mandatory	Narrative and/or re-analysis of the results of the included systematic reviews e.g. using meta-analysis	Medium
Scoping review (250, 258-260)	Map the body of evidence to answer a broad exploratory research question(s)	Comprehensive	Empirical studies and/or reviews that meet eligibility criteria developed post-hoc	Debated	Typically descriptive numerical summary and thematic analysis	High

[a] Typical approach to conducting searches as all searches involve balancing comprehensiveness with time/resource constraints.
[b] Typical time/resource requirements in relation to systematic reviews (which are classed as having high requirements).
[c] Empirical studies may also be included if the included systematic reviews are outdated or important evidence gaps are identified.

Overview of reviews methodology was considered least suitable due to the limited information on pre-operative TKR intervention components and delivery approaches reported in existing systematic reviews. Given the present review sought to address fairly narrow questions, scoping review methodology was also considered relatively unsuitable. Of the remaining two options, rapid review methodology was chosen because it was considered the most feasible given the time/resources available. Furthermore, evidence suggests that rapid reviews generate similar conclusions to systematic reviews (261) and rapid reviews are considered appropriate for informing intervention development (243).

Rapid reviews may involve streamlining of multiple different aspects of standard systematic review methods (247, 255). The selection of streamlining approaches for this rapid review was informed by the following two resources, which provide complementary types of guidance.

- SelecTing Approaches for Rapid Reviews (STARR) decision tool (255): a consensus-based decision tool that provides high-level guidance on points to consider when planning rapid reviews.
- World Health Organization rapid review guidance (247): practical guidance on planning, conducting and using rapid reviews to inform health policy and systems.

Reviewing quantitative and qualitative evidence can provide a more in-depth understanding of a topic than reviewing a single evidence type (262, 263). In addition, preliminary literature searches indicated that studies with a range of designs would be relevant to the present review’s aim. A mixed methods approach was therefore chosen. Terminology used to describe mixed methods review designs varies (264). Joanna Briggs Institute (JBI) guidance (263) was chosen to inform this review design because the JBI is a well-established international organisation with evidence synthesis expertise (265).

The JBI guidance (263) classifies mixed methods review designs as sequential (one data type is synthesised after the other data type) or convergent (both data types are synthesised concurrently). Convergent designs are further classified as integrated (both data types are analysed in parallel by transforming one data type) or segregated (the two data types are synthesised separately then integrated). In line with the JBI guidance (263), a convergent segregated design was used for the present review because it addressed two complementary questions related to different aspects of the same phenomenon.

The JBI guidance (263) describes convergent segregated reviews as including a quantitative component and a qualitative component. The quantitative component typically addresses a question related to intervention effectiveness (263), corresponding with objective 1. The qualitative component addresses a question related to people's experiences/perspectives (263), corresponding with objective 2. Harden and Thomas (266) advocate using the term *'views studies'* within mixed methods reviews (p.262), as studies that are not qualitative can provide valuable information about people's experiences/perspectives. Preliminary literature searches for the present review concurred with this. The terms *'outcomes studies'* and *'views studies'* were therefore chosen to describe studies addressing objectives 1 and 2 respectively.

Rapid review reporting guidelines are under development but not yet available (267). This rapid review is therefore reported in line with the current Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline (268).

4.2.2 Eligibility criteria

Limiting a review's scope by type of publication, language and date is an accepted streamlining approach for rapid reviews (247, 255). In line with this, only studies published as a full text in English from January 2009 onwards were eligible. As discussed in Chapter 2 (section 2.3.1), an Enhanced Recovery Partnership Programme (ERPP) was implemented by the UK Department of Health in 2009 (103). The introduction of enhanced recovery programmes in the UK and other countries has substantially altered TKR pathways (101, 102). Correspondingly, the typical length of hospital stay (LOS) for TKR has reduced considerably since 2009 (102). The date limit of 2009 therefore also helped to ensure that the findings are relevant to current healthcare contexts. Table 4.2 provides the additional eligibility criteria.

Table 4.2: Rapid review eligibility criteria

	Outcomes studies	Views studies
Studies	Randomised trial (involve individual or cluster randomised allocation)	Primary study of any design
Participants[a]	Adults (aged ≥18 years) listed for primary TKR	Adults (aged ≥18 years) with experience of TKR care as: • a patient who is listed for and/or has undergone primary TKR • a health professional with experience of any phase of the primary TKR pathway e.g. nurses, physiotherapists etc.
Interventions/ comparator/ outcomes/ phenomena of interest	Include an intervention group that received a non-pharmacological pre-operative TKR intervention[b] Include at least one comparator group that received no pre-operative TKR interventions, standard care and/or an alternative pre-operative TKR intervention Assess at least one patient outcome (including participant-reported outcomes, performance-based outcomes, patient healthcare utilisation and patient harms)	Explore participants' experiences and/or perspectives of at least one non-pharmacological pre-operative TKR intervention component or delivery approach[bc]
Context	No limitations	No limitations

TKR, total knee replacement

[a] Studies with mixed samples were only included if they reported at least one relevant finding separately for participants who met the criteria specified and/or at least 80% of participants met the criteria specified (269).

[b] Pre-operative TKR interventions were defined as interventions delivered solely in the pre-operative phase of the TKR pathway (the period between when a patient is listed for TKR and the day they are admitted to hospital to undergo surgery (97)). Studies investigating an intervention delivered during more than one phase of the TKR pathway were excluded.

[c] The protocol stated that studies exploring participants' experiences and/or perspectives of at least one pre-operative TKR intervention would be eligible, but this was amended to the criterion shown during the study selection process to help ensure that all the included studies were directly relevant to the study aim. Studies providing purely descriptive accounts were excluded.

4.2.3 Search strategy

The researcher conducted searches of Medline (Ovid), Embase (Ovid), the Cochrane Central Register of Controlled Trials (CENTRAL) (Cochrane Library), PsycINFO (Ovid) and CINAHL (EBSCOhost) on 11th September 2019 and subsequently updated the searches to 31st December 2020. Medline, Embase and CENTRAL were chosen because the Cochrane Collaboration considers them the most important databases to search when conducting reviews of interventions (270). PsycINFO and CINAHL were chosen because they cover psychology/psychiatry and nursing/allied health respectively, aligning with this review's aim.

The searches included subject headings and text words related to TKR, the pre-operative phase and relevant interventions. Appendix B provides an example search strategy. All searches were limited to human studies published between January 2009 and December 2020. The searches of Medline, Embase, PsycINFO and CINAHL were also limited to studies published in the English language. CENTRAL does not provide the functionality to limit searches by language. The researcher also hand searched the reference lists of all eligible studies. In line with accepted streamlining approaches for rapid reviews (247), no additional sources such as grey literature were searched.

4.2.4 Study selection

All records identified were imported into Endnote X9 reference management software (271). After removing duplicates, the researcher selected studies for inclusion by screening all records based on their title and abstract and reviewing the full-text reports of all potentially relevant studies. One of the researcher's advisors (BTD) verified the study selection for a randomly selected sample of 10% of all full-text reports reviewed. This is recognised as an acceptable alternative to dual selection when conducting rapid reviews (255). The random selection of articles was achieved by numbering the articles and using the RANDBETWEEN function of Microsoft Excel 2016. Disagreements that arose during the verification and additional queries about studies' eligibility were reconciled through discussions between the researcher and her supervisors/advisors.

4.2.5 Data extraction

The researcher extracted data from all included studies using standardised forms in Microsoft Excel 2016. Two separate forms were used, one for outcomes studies and one for views studies. The data items covered general information about the study; the study characteristics; the participant characteristics; an overview of the intervention, the intervention components and the intervention delivery approaches (outcomes studies only); and the study findings. Data items related to the outcomes studies' interventions and views studies' findings were based on the Template for Intervention Description and Replication (TIDieR) checklist and guide (272). It was not always clear-cut whether/how to code intervention components and delivery approaches. For example, it was sometimes unclear whether participants' experiences/perspectives reported in views studies related to interventions delivered in the pre-operative phase. In these instances, the researcher adopted an inclusive approach to help maximise the number of intervention components and delivery approaches identified. In addition, she discussed key uncertainties with her supervisors/advisors and completed extensive cross-checking to ensure that the coding was consistent across studies.

Interventions were classified as one or more of the following intervention types: education, exercise, psychological, lifestyle and other. The term *'other'* was chosen to encompass interventions that did not fit the definitions of the additional intervention types. Examples of *'other'* pre-operative TKR interventions provided in the protocol were orthotics, nutritional supplements and acupuncture. Interventions involving a brief educational component within a different intervention type were not classed as education. Interventions that involved planned, structured, repetitive physical activity undertaken to increase/maintain physical fitness were classed as exercise rather than lifestyle interventions (132).

Outcomes studies were dichotomised into two categories:

- Studies in which a statistically significant difference in favour of the intervention group was identified for at least one outcome at one or more follow-up time points (alpha=0.05).
- Studies in which no statistically significant differences in favour of the intervention group were identified for any outcomes at any follow-up time points (alpha=0.05).

This approach was chosen to facilitate the data syntheses and the development of the recommendation items in Round 1 of the modified Delphi study (Chapter 5, section 5.2.3.1).

Members of the researcher's supervisory/advisory team (DA, CC) verified the data extraction for a randomly selected sample of 10% of the included studies. This is considered an appropriate alternative to dual data extraction when conducting rapid reviews (247, 255). The random selection was achieved by numbering the studies and using the RANDBETWEEN function of Microsoft Excel 2016. Disagreements were reconciled through discussions between the researcher her supervisors/advisors. In line with commonly used streamlining approaches for rapid reviews, primary study authors were not contacted to obtain missing data (261).

4.2.6 Methodological quality assessment

Rapid reviews typically involve some form of methodological quality assessment (247). Some review authors exclude studies that fail to meet specified methodological criteria (263, 273). However, this involves relying on an arbitrary threshold and meeting all the specified methodological criteria may not be feasible for certain types of studies (273). Given this review included studies with diverse designs and focused on maximising the number of intervention components and delivery approaches identified, exclusion of studies based on their methodological quality was not considered appropriate. The JBI mixed methods review guidance explicitly recommends assessing the quality of included studies (263). Similarly, the Cochrane Handbook for Systematic Reviews of Interventions states that the methodological quality of included studies should be assessed even if quality criteria are not used to exclude studies (274). Methodological quality assessments of all the studies included in this review were therefore undertaken to assist with interpretation of the review’s findings (274).

Methodological quality assessments in mixed methods reviews may be undertaken using different critical appraisal approaches for the different study designs included (263). The most widely used approach for RCTs is to assess risk of bias using the Cochrane risk-of-bias tool (RoB) (124), which has recently been updated to the RoB 2 (275, 276). The RoB 2 facilitates in-depth assessment of factors that may bias an RCT’s results. This is considered more specific than assessing quality, as quality assessments are not limited to constructs that may introduce bias (275). Consensus on the optimal approach for appraising qualitative studies is lacking (277). Many qualitative checklists and frameworks exist but these have been criticised for various reasons, such as failing to distinguish between different qualitative methodologies (277).

The optimal approach for appraising mixed methods studies is also debated (278, 279). A relatively widely used tool for appraising mixed methods studies is the Mixed Methods Appraisal Tool (MMAT), which was first published in 2009 and updated in 2018 (279). A key benefit of the MMAT is that it can be used to assess the quality of qualitative, quantitative and mixed methods studies. This means it can be used to appraise all types of studies included in a mixed methods review. This is an efficient approach as reviewers only need to learn how to apply a single tool and the MMAT contains a relatively small number of items (279). However, it is less comprehensive than using multiple different critical appraisal approaches. In addition, the MMAT has a checklist format, which is controversial for qualitative research as checklists are prescriptive and prioritise certain design considerations over others (277, 280). Despite these limitations, the MMAT version 18 (279) was considered appropriate for this review given that it needed to be completed largely be a single reviewer in a timely manner and studies were not excluded on the basis of quality.

The MMAT includes two screening questions to help determine whether a study is empirical. The screening questions were not used in the present review because only empirical studies were eligible. The main part of the MMAT consists of separate categories for five different study designs. Studies are assessed using all the applicable categories. For example, qualitative studies are assessed using the qualitative category only, whereas mixed methods RCTs are assessed using the qualitative, quantitative RCT and mixed methods categories. Five quality criteria are provided for each category. Each criterion is rated *'Yes'* if it is met, *'No'* if it is not met or *'Can't tell'* if insufficient information is reported to rate the criterion. Correspondingly, each study is allocated between zero and five *'Yes'* ratings for each applicable MMAT category. Receiving *'Yes'* ratings only implies a study has high methodological quality. No modifications to the MMAT were made for the purposes of the present review. However, additional notes were added to three criteria in the quantitative RCT category to ensure consistency in the assessment process. For example, criterion 2.3 of the quantitative RCT category states *'Are there complete outcome data?'* (p.4). A note was added to this criterion to define *'complete outcome data'* as more than 85% of the individuals initially allocated to groups contributing to the outcome data (281).

The researcher appraised all the included studies using the MMAT. Members of her supervisory/advisory team (DA, CC) verified the MMAT ratings for the same randomly selected 10% of studies verified at the data extraction stage. This is recognised as an acceptable alternative to dual critical appraisal when conducting rapid reviews (247, 255). Disagreements were reconciled through discussions between the researcher her supervisors/advisors. In line with the MMAT guidance and PRISMA guideline (268), no overall quality ratings were generated.

4.2.7 Data synthesis and integration

In line with the JBI guidance on convergent segregated reviews (263), the outcomes studies and views studies were synthesised separately and then integrated. The JBI guidance (263) recommends synthesising quantitative and qualitative data using meta-analysis and meta-aggregation respectively. It also highlights that narrative syntheses can be used if meta-analysis and meta-aggregation are not possible (263). Restricting the depth of data synthesis is an accepted streamlining approach for rapid reviews (247, 255); therefore, this review employed narrative syntheses only. Separate syntheses were conducted for each intervention type listed in section 4.2.5 to ensure that the findings were meaningful.

The integration involved juxtaposing the intervention components and delivery approaches from all the studies addressing the same intervention type in tables. Their findings were then narratively summarised, guided by the following questions.

- Do the findings of the outcomes studies and views studies support or contradict each other?
- Do the findings of views studies explain why particular intervention components or delivery approaches are, or are not, associated with improved outcomes?
- Which intervention components or delivery approaches investigated in outcomes studies are, or are not, explored in views studies?
- Which intervention components or delivery approaches explored in views studies are, or are not, investigated in outcomes studies?

4.3 Findings

4.3.1 Study selection

The database searches identified 3238 non-duplicate records. Hand searching identified 25 additional records. Of the 185 full-text reports assessed, 58 met the eligibility criteria. These reports covered 52 studies, of which 29 met the outcomes study criteria only, 21 met the views study only and two met the outcomes study and views study criteria (Figure 4.1).

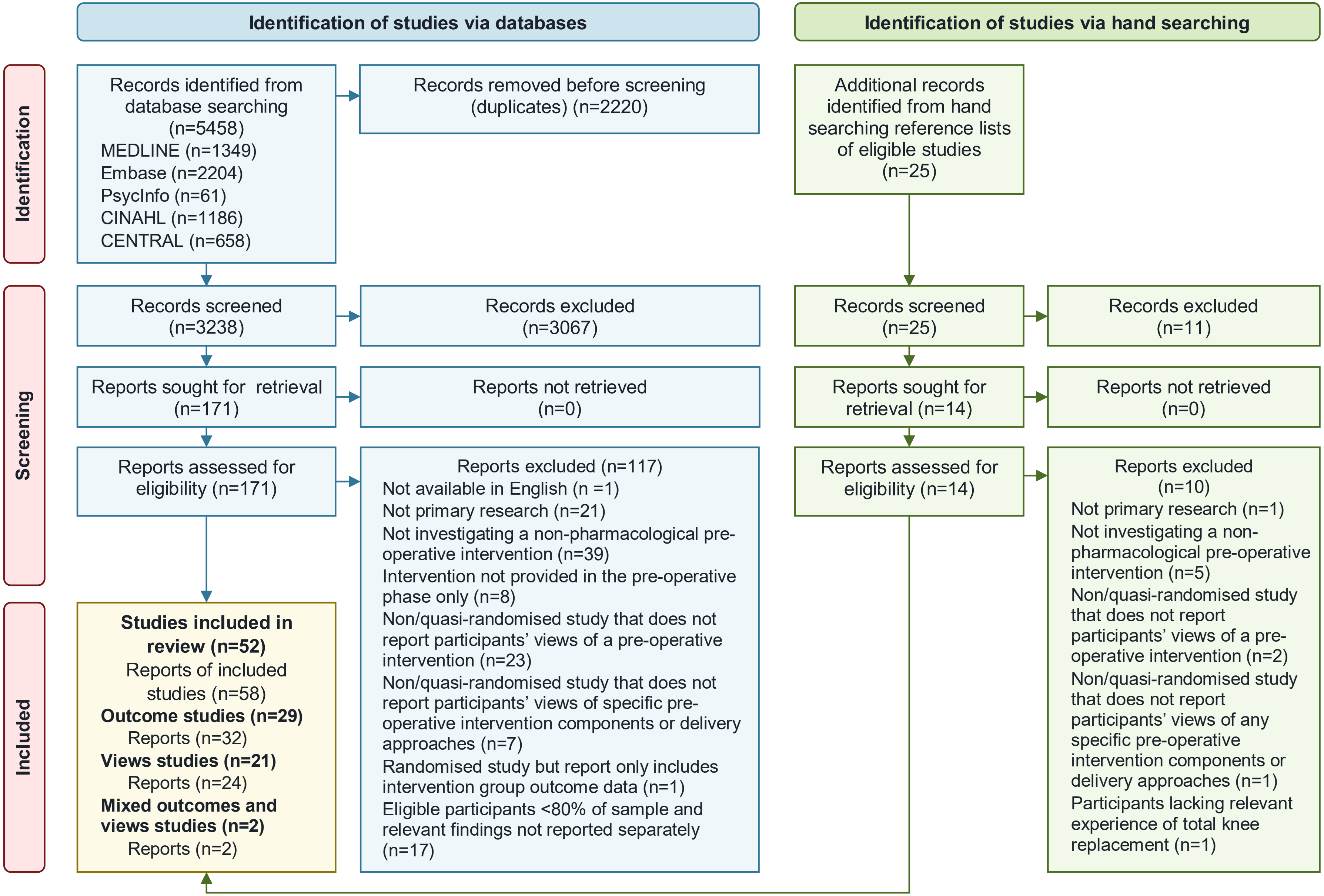


Figure 4.1: PRISMA flow diagram

The most notable excluded studies were as follows.

- Husted et al. (282): this was an embedded qualitative study that explored orthopaedic surgeons' and physiotherapists' perceptions of a *'pre-operative'* exercise programme (p.1). Despite being described as *'pre-operative'*, the exercise programme was provided to patients who were possible candidates for TKR rather than being listed for TKR. Correspondingly, the researcher and her supervisors/advisors agreed that the study did not meet the inclusion criterion of exploring participants' views of a pre-operative TKR intervention.
- Culliton et al. (183): this was an RCT of an e-learning tool. Intervention group participants received pre- and post-operative email invitations to access the tool. The researcher and her supervisors/advisors therefore agreed that the intervention did not meet the inclusion criterion of being delivered solely in the pre-operative phase. Furthermore, Culliton et al. (183) did not include any follow-up outcome assessments in the pre-operative phase; therefore, it was not possible to assess the impact of the e-learning tool pre-operatively.

4.3.2 Outcomes studies' characteristics

This section briefly summarises the characteristics of the 31 studies that met the criteria for an outcomes study. Sections 4.3.4–4.3.10 report key details of the studies' MMAT ratings, interventions and results.

The outcomes studies were conducted in a wide range of countries. Only two were UK-based. Most of the studies were two-arm RCTs (n=23). Two studies evaluated interventions classified as two intervention types. The remaining 29 studies evaluated interventions classified as a single intervention type. The most frequently evaluated intervention type was exercise (n=20). The number of randomised participants undergoing TKR ranged from 17 to 220. A variety of outcomes were assessed, including participant-reported outcomes, performance-based outcomes, healthcare utilisation and adverse events/effects. The most commonly included PROM was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (n=8). The most frequently assessed performance-based outcomes were knee range of movement (n=12) and knee extensor strength/power (n=12). The duration of follow-up ranged from immediately post-intervention to one year post-operatively. Table 4.3 summarises key characteristics of the outcomes studies. Table 4.4 provides an excerpt from the 22-page table with further details of the outcome studies' characteristics and their results.

Table 4.3: Outcomes studies' key characteristics

Citation	Country	Design[a]	Intervention type	Sample size[bc]	Follow-up[b]
Bergin et al., 2014 (283)	US	RCT	Other: Incentive spirometry	I:21[d]; C:27[d]	Hospital discharge
Blasco et al., 2020 (284)	Spain	Three-arm RCT	Exercise	H:28; D:29; C:29	6 weeks post-op
Brown et al., 2012 (285)	US	Pilot study	Exercise	I:17; C:15	3 months post-op
Brown et al., 2014 (286)	US	RCT	Exercise	I:19; C:18	2 weeks post-op
Calatayud et al., 2017 (287), Casaña et al., 2019 (288)	Spain	RCT	Exercise	I:25; C:25	3 months post-op
das Nair et al., 2018 (289)[b]	UK	Mixed methods feasibility study	Psychological	I:25; C:25	6 months post-randomisation
Doiron-Cadrin et al., 2020 (43)	Canada	Three-arm pilot study	Exercise	IP:5; T:6; C:6	Immediately post-intervention (12 weeks post-baseline)
Domínguez-Navarro et al., 2021 (290)	Spain	Three-arm RCT	Exercise	S:28; B:26; C:28	1 year post-op
Eschalier et al., 2017 (115)	France	RCT	Education	I:22; C:20	3-6 weeks post-op
Gränicher et al., 2020 (291)	Switzerland	Pilot study	Exercise	I:10; C:10	3 months post-op
Gstoettner et al., 2011 (292)	Austria	RCT	Exercise	I:18; C:20	6 weeks post-op
Huber et al., 2015a (134)	Switzerland	RCT	Exercise	I:22; C:23	1 year post-op
Jahic et al., 2018 (293)	Bosnia and Herzegovina	RCT	Exercise	I:10; C:10	1 year post-op
Leal-Blanquet et al., 2013 (46)	Spain	RCT	Education	I:42; C:50	Immediately post-intervention (4 weeks post-baseline)
Lin et al., 2019 (114)	China	RCT	Education	I:30; C:30	2 days post-op
Matassi et al., 2014 (294)	Belgium	RCT	Exercise	I:61; C:61	1 year post-op
McKay et al., 2012 (295)	Canada	Pilot study	Exercise	I:10; C:12	12 weeks post-op
Medina-Garzón, 2019 (296)	Colombia	RCT	Psychological	I:28; C:28	4 weeks post-intervention (48 days post-baseline)
Rittharomya et al., 2020 (40)	Thailand	RCT	Exercise Lifestyle	I:48; C:48	Immediately post-intervention (12 weeks post-baseline)

Skoffer et al., 2016 (297), 2020 (125)	Denmark	RCT	Exercise	I:30; C:29	1 year post-op
Soeters et al., 2018 (44)	US	RCT	Education	I:32; C:31	Hospital discharge
Soni et al., 2012 (298)	UK	RCT	Exercise Other: Acupuncture	I:28; C:28	3 months post-op
Stone et al., 2020 (299)	US	RCT	Other: Dynamic knee extension device	I:56; C:59	2 weeks post-op
Swank et al., 2011 (300)	US	RCT	Exercise	I:36; C:35	Immediately post-intervention (1 week pre-op)
Topp et al., 2009 (301)	US	RCT	Exercise	I:26; C:28	3 months post-op
Tungtrongjit et al., 2012 (302)	Thailand	RCT	Exercise	I:30; C:30	6 months post-op
Villadsen et al., 2014a (303), 2014b (304)	Denmark	RCT	Exercise	I:41; C:40	3 months post-op
Walls et al., 2010 (305)	Ireland	Pilot study	Other: NMES	I:9[d]; C:5[d]	12 weeks post-op
Wang et al., 2020 (306)	China	RCT	Exercise	I:110; C:110	1 month post-op
Wilson et al., 2016 (116)	Canada	RCT	Education	I:73; C:70	3 days post-op
Zhao et al., 2018 (307)	China	RCT	Other: Electro-acupuncture	I:30; C:30	72 hours post-op

B, strengthening plus balance/proprioceptive exercise group; C, control group; D, domiciliary group; H, hospital group; I, intervention group; IP, in-person prehabilitation group; NMES, neuromuscular electrical stimulation; post-op, post-operative; RCT, randomised controlled trial; S, strengthening group; T, tele-rehabilitation prehabilitation group; UK, United Kingdom; US, United States of America

[a] All studies involved two arms unless otherwise specified.

[b] For studies with mixed populations, details of the sample size and follow-up are only provided if the primary source reported them separately for participants listed for TKR.

[c] Sample size refers to the participants randomised unless otherwise indicated.

[d] Number of participants included in the analysis as the number of participants allocated to each group was not reported.

Table 4.4: Outcomes studies' characteristics and results table excerpt

Citation, country	Primary aim	Design	Participants[a]	Patient outcomes	Key findings[b]
Lin et al., 2019 (114), China	To investigate whether pre-op CFNB education improves post-op analgesic efficacy amongst patients undergoing TKR (and whether the education reduces nurse PCA-related workload)	**Quantitative: Two-arm RCT** Participants were recruited from a single hospital. **Control group:** Received PCA pump operation training before returning to the ward and bedside PCA education on the ward. **Intervention group:** Received the same PCA pump training and education as the control group. Also attended a nurse-led educational session the day before their TKR. The educational session focused on an educational pamphlet focused on PCA (including falls prevention).	**Control group:** N=30 Age: 66.6±6.5 Gender: 73% BMI: 26.4±4.1 **Intervention group:** N=30 Age: 66.5±8.1 Gender: 90% BMI: 26.7±4.0	Knee flexion ROM, 10 item questionnaire assessing participants' knowledge of CFNB and PCA and VAS pain scores at rest and during movement at days 1 and 2 post-op	No adverse events occurred. Significant between-group differences in favour of the intervention group were identified for: - knowledge questionnaire scores at day 1 post-op - VAS pain scores at rest and during movement at days 1 and 2 post-op. No other significant between-group differences were identified.

BMI, body mass index; CFNB, continuous femoral nerve block; PCA, patient-controlled analgesia; post-op, post-operative; ROM, range of motion; RCT, randomised controlled trial; TKR, total knee replacement; VAS, Visual Analogue Scale

[a] Age and BMI are presented as mean ± standard deviation in years and kg/m² respectively. Gender is presented as the percentage of females.

[b] Significance refers to a statistically significant difference between the intervention group and the control group with alpha=0.05.

4.3.3 Views studies' characteristics

This section briefly summarises the characteristics of the 23 studies that met the criteria for a views study. Sections 4.3.5–4.3.10 report key details of the studies' MMAT ratings and findings.

The UK was the most common location of the views studies (n=8). The studies included 10 qualitative studies, one RCT, five quantitative descriptive studies, two studies involving a quantitative descriptive component embedded in a larger study and five mixed methods studies. Four studies explored participants' views of education and at least one additional intervention type. The other 19 studies explored participants' views of a single intervention type. The most commonly explored intervention type was education (n=20). The participants who met the review eligibility criteria consisted of patients only in 12 studies, health professionals only in six studies and both patients and health professionals in five studies. The total number of participants ranged from four to 469. Table 4.5 summarises the key characteristics of the views studies. Table 4.6 provides an excerpt from the 26-page table with further details of the views studies' characteristics and their findings.

Table 4.5: Views studies' key characteristics

Citation	Country	Design[a]	Data collection method(s)[b]	Intervention type	Patient sample size[c]	Professional sample size[c]
Aunger et al., 2020 (135)[d]	UK	Mixed methods feasibility study	Sedentary behaviour booklet; questionnaire	Lifestyle	18 (I:13; C:5; T:35, T-B:16; T-C-Q:9; T-I-Q:21)	N/A
Bardgett et al., 2016 (308)	UK	Qualitative descriptive	Postal questionnaire	Education	50 (T:102)	N/A
Barnes et al., 2018 (309)	South Africa	Cross-sectional survey	Structured interviews	Education	36 (T:50)	N/A
Berg et al., 2019 (310)	Sweden	Qualitative descriptive	Semi-structured interviews	Education	11 (T:24)	N/A
Bin Sheeha et al., 2020 (311)	UK	Phenomenology	Focus group	Education Exercise Other: Acupuncture	7	N/A
Causey-Upton et al., 2017 (312)	US	Transcendental phenomenology	Semi-structured interviews	Education	4	N/A
Causey-Upton et al., 2018 (313)	US	Cross-sectional pilot survey	Online questionnaire	Education	N/A	7
Causey-Upton et al., 2020a (314), 2020b (109)	US	Explanatory sequential mixed methods	Quantitative component: online questionnaire Qualitative component: semi-structured interviews	Education	N/A	Quantitative component: 469 Qualitative component: 10
das Nair et al., 2018 (289)	UK	Mixed methods feasibility study	Semi-structured interviews	Psychological	50[e] (I:25; C:25; I-Int:11; C-Int:12)	N/A
Drew et al., 2019 (148), Judge et al., 2020 (102)	UK	Ethnography	Part 1: health professional observations/job shadowing; semi-structured interviews Part 2: patient semi-structured interviews	Education	Part 1: N/A Part 2: 13 (T:37)	Part 1: 38 Part 2: N/A

Eschalier et al., 2013 (315)	France	Survey embedded within an intervention validation study	Postal questionnaire	Education	N/A	27
Eschalier et al., 2017 (115)	France	RCT	Questionnaire	Education	42 (I:22; C:20)	N/A
Goldsmith et al., 2017 (99)	Canada	Qualitative descriptive component of a mixed methods prospective cohort study	Semi-structured interviews	Education	45	N/A
Høvik et al., 2018 (316)	Norway	Qualitative descriptive	Focus groups	Education	13	N/A
Huber et al., 2015b (317)	Switzerland	Questionnaire development and psychometric testing embedded within an RCT	Questionnaire	Education	35	N/A
Lucas et al., 2013a (318), 2013b (319)	UK	Action research study	PMG member semi-structured interviews; patient focus groups	Education	PMG members: 5 (Int:4) Focus group participants: 9	PMG members: 17 (Int:12) Focus group participants: N/A
Plenge et al., 2018 (320)	South Africa	Delphi study	Four rounds, including a Skype teleconference in Round 4	Lifestyle	N/A	33
Sharif et al., 2020 (107)	UK	Qualitative descriptive	Semi-structured interviews	Education Exercise	N/A	16
Smith et al., 2018 (321)	US	Qualitative descriptive	Open-ended structured interviews	Education	4 (T:11)	7
Snowden et al., 2020 (128)[d]	UK	Mixed methods involving a non-randomised feasibility study followed by a pilot study	Defining the intervention and TAU: healthcare professional questionnaire; health professional focus groups	Education Lifestyle	Defining the intervention and TAU: N/A Feasibility study: 12 (T:15; T-Int:13)	Defining the intervention and TAU: 12 (questionnaire), 19 (focus groups)

			Feasibility study: patient and health professional qualitative interviews Pilot study: patient and health professional qualitative interviews		Pilot study: 45 (I:20; C:25; I-Int:5; C-Int:6; T:68; T-I-Int:7; T-C-Int:7)	Feasibility study: 3 Pilot study: 5
SooHoo et al., 2011 (322)	US	Modified RAND-UCLA Delphi study	Two rounds with a face-to-face group discussion between rounds	Education	N/A	10
Specht et al., 2016 (323)	Denmark	Phenomenological-hermeneutic	Observations; semi-structured interviews	Education	4 (T:8)	N/A
Westby et al., 2018 (97)	Canada	Modified RAND-UCLA Delphi study	Three rounds, including online ratings in Rounds 1 and 3 and an anonymous online discussion forum in Round 2	Education Exercise Lifestyle	1 (T:2)	16

B, subsample of participants who provided comments in the sedentary behaviour booklets; C, control group; I, intervention group; Int, subsample of participants interviewed; PMG, Project Management Group; Q, subsample of participants who completed the questionnaire in the week prior to their surgery; RAND, research and development (Corporation); RCT, randomised controlled trial; T total number of patient participants (including patients undergoing hip replacement); TAU, treatment as usual, UCLA, University of California-Los Angeles; UK, United Kingdom; US, United States of America

[a] All RCTs, pilot studies and feasibility studies involved two arms unless otherwise specified.

[b] Only data collection methods used to provide information about participants' experiences and/or perspectives of a pre-operative intervention component/delivery approach are listed. The delivery format of questionnaires and Delphi rounds is included if reported in the primary source.

[c] Details are for the participants who met the review eligibility criteria and participated in the data collection methods listed. Additional details, including the total number of all participants, are provided in brackets where relevant.

[d] Quantitative outcome data were not presented separately for participants undergoing knee replacement; therefore, the study does not meet the criteria for an outcomes study.

[e] One additional participant was randomised but did not meet the inclusion criteria so was excluded from the analyses.

Table 4.6: Views studies' characteristics and findings table excerpt

Citation, country	Primary aim	Design	Participants[a]	Key findings
Goldsmith et al., 2017 (99), Canada	To explore patients' experience and satisfaction post-TKR	**Mixed methods: Qualitative descriptive component of a mixed methods prospective cohort study** Participants were purposively selected from a cohort study involving participants from six different sites across British Columbia. The authors were particularly interested in exploring dissatisfaction, so recruited as many participants as possible who reported dissatisfaction with their TKR on the 6-month post-op questionnaire. Data were collected using semi-structured interviews. The interviews focused on participants' experiences of TKR and their satisfaction with the outcomes. Data were analysed using a multi-step thematic coding process involving four coders and wider team discussions.	**Patients 8 months post-TKR** N=45 Age: 65 (SD not reported) Sex: 67%	Participants' views of their experiences of TKR were mainly focused on the aid/assistance they received, which the authors described as *'support'* (p.3). Participants' support expectations were formed across the care pathway. Participants whose support expectations were not met tended to report a negative experience of TKR. Participants' experiences of support were focused on three interacting areas: informational, clinical and personal. Participants felt information about preparing for TKR and post-op recovery was key. Although participants felt the pre-op education sessions and their surgeon were important sources of informational support, many participants felt the information they provided was inadequate. Additionally, some participants felt it was difficult to understand and retain the instructions provided at the pre-op education session, particularly because the session was delivered to patients undergoing TKR and patients undergoing THR together. Some participants reported that their surgeon did not have/make time to answer their questions and/or did not make an effort to treat them like an individual. Key areas in which participants wanted more information included: pain expectations, pain management and recovery trajectories. Participants felt gaining informational and emotional support from patients who had previously undergone TKR could be helpful and suggested providing *'recovery stories'* of previous patients as part of the pre-op education (p.10).

Post-op, post-operative; SD, standard deviation; THR, total hip replacement; TKR, total knee replacement

[a] Age is presented as the mean in years. Sex is presented as the percentage of females. Body mass index was not reported.

4.3.4 Outcomes studies' Mixed Methods Appraisal Tool ratings

All 31 outcomes studies were appraised using the quantitative RCT category of the MMAT (Table 4.7). The majority of studies received between one and three *'Yes'* ratings (n=28). None received *'Yes'* ratings only. This implies that all the studies present at least some methodological quality issues.

The random allocation criterion was rated *'Yes'* in 15 studies and *'Can't tell'* in the remaining 16 studies. The reports of eight studies that received *'Can't tell'* ratings for this criterion provided details about the random sequence generation but did not state whether the allocation was concealed. Lack of appropriate randomisation is an important consideration because it presents a risk of selection bias and confounding (276). Substantial between-group differences at baseline are an indicator of inadequate randomisation (276). Correspondingly, it is encouraging that most studies received *'Yes'* ratings for group comparability at baseline (n=26).

The complete outcome data criterion was rated *'Yes'*, *'No'* and *'Can't tell'* in 14, 11 and six studies respectively. As expected, studies with longer follow-up periods were generally less likely to meet this criterion. Assessing this criterion is important because missing outcome data can bias estimates of intervention effects (276). All the studies received *'No'* ratings for outcome assessor blinding. This was largely due to the inclusion of participant-reported outcomes and the inability to blind participants to the interventions investigated. Whilst this was unavoidable, it is still worth considering because lack of outcome assessor blinding has been associated with overestimation of intervention effects (324, 325). The majority of studies received *'Can't tell'* ratings for the adherence criterion. This criterion is particularly relevant for studies of pre-operative TKR exercise interventions as there is a risk that exercise may increase patients' pain, negatively affecting their adherence to the intervention (28).

Table 4.7: Outcomes studies' Mixed Methods Appraisal Tool ratings

Outcomes study	MMAT ratings: Quantitative randomised controlled trials[a]				
	Random allocation appropriately performed	Groups comparable at baseline	Complete outcome data	Outcome assessors blinded	Participants adhered to assigned intervention
Bergin et al. (283)	?	?	N	N	?
Blasco et al. (284)	Y	Y	?	N	?
Brown et al. (285)	?	?	N	N	Y
Brown et al. (286)	Y	Y	N	N	?
Calatayud et al. (287), Casaña et al. (288)	Y	Y	Y	N	?
das Nair et al. (289)[b]	Y	Y	N	N	N
Doiron-Cadrin et al. (43)	Y	?	Y	N	?
Domínguez-Navarro et al. (290)	Y	Y	N	N	Y
Eschalier et al. (115)	?	Y	Y	N	Y
Gränicher et al. (291)	Y	Y	Y	N	Y
Gstoettner et al. (292)	Y	Y	Y	N	?
Huber et al. (134)	Y	Y	N	N	Y
Jahic et al. (293)	?	Y	?	N	?
Leal-Blanquet et al. (46)	?	Y	Y	N	?
Lin et al. (114)	?	Y	Y	N	?
Matassi et al. (294)	?	Y	Y	N	Y
McKay et al. (295)	Y	Y	N	N	Y
Medina-Garzón (296)	?	Y	Y	N	?
Rittharomya et al. (40)	?	Y	Y	N	?
Skoffer et al. (125, 297)	Y	Y	N	N	Y
Soeters et al. (44)	?	Y	?	N	Y
Soni et al. (298)	Y	Y	N	N	?
Stone et al. (299)	?	Y	Y	N	?
Swank et al. (300)	?	Y	Y	N	Y
Topp et al. (301)	?	Y	Y	N	?

Tungtrongjit et al. (302)	?	Y	?	N	?
Villadsen et al. (303, 304)	Y	Y	?	N	?
Walls et al. (305)	?	?	N	N	Y
Wang et al. (306)	?	?	?	N	?
Wilson et al. (116)	Y	Y	N	N	?
Zhao et al. (307)	Y	Y	Y	N	?

MMAT, Mixed Methods Appraisal Tool; N, no; Y, yes; ? can't tell

[a] For studies with mixed populations, ratings were made specifically for participants listed for TKR.

[b] das Nair et al. (289) was also appraised using the qualitative and mixed methods categories of the MMAT (reported in Table 4.8).

4.3.5 Views studies' Mixed Methods Appraisal Tool ratings

Nineteen views studies were appraised using a single MMAT category, three were appraised using three categories and one was appraised using all five categories (Table 4.8). Given that all five MMAT categories were covered, and each includes five criteria, only key findings of the views studies' MMAT ratings are discussed below.

The most favourable ratings occurred in the qualitative category. Eleven of the 15 studies appraised using this category received *'Yes'* ratings only. These favourable ratings need to be interpreted cautiously due to the limitations of the MMAT discussed in section 4.2.6. In line with the outcomes studies, all four views studies appraised using the RCT category received *'No'* ratings for outcome assessor blinding because they included participant-reported outcomes and participants could not be blinded to the interventions investigated.

The highest proportions of *'Can't tell'* ratings occurred in the quantitative descriptive category. Six of the nine studies appraised using this category received *'Can't tell'* ratings for the representativeness of the sample. This was due to inadequate reporting about the target population and/or sample and potentially limits the external validity of the findings (326). Similarly, inadequate reporting about non-respondents led to six quantitative descriptive studies receiving *'Can't tell'* ratings for the risk of non-response bias. Non-response bias occurs when there are relevant and systematic differences between respondents and non-respondents and can substantially affect a study's findings (327).

All four studies appraised using the mixed methods category received *'Yes'* ratings for addressing divergences/inconsistencies between the quantitative and qualitative results. However, this was an arbitrary rating due to the absence of clear divergences/inconsistencies. Only two of these studies effectively integrated the different study components. This is a notable limitation given that integration is a core characteristic of mixed methods research (213).

Table 4.8: Views studies' Mixed Methods Appraisal Tool ratings

Views study	MMAT ratings: Qualitative[a]				
	Qualitative approach appropriate	Data collection methods adequate	Findings adequately derived from data	Interpretation sufficiently substantiated by data	Coherence between data sources, collection, analysis and interpretation
Aunger et al. (135)	Y	N	?	Y	Y
Bardgett et al. (308)	Y	N	Y	Y	Y
Berg et al. (310)	Y	Y	Y	Y	Y
Bin Sheeha et al. (311)	Y	Y	Y	Y	Y
Causey-Upton and Howell (312)	Y	Y	Y	Y	Y
Causey-Upton et al. (109)	Y	Y	Y	Y	Y
das Nair et al. (289)	Y	Y	Y	Y	Y
Drew et al. (148) Judge et al. (102)	Y	Y	Y	?	Y
Goldsmith et al. (99)[b]	Y	Y	Y	Y	Y
Høvik et al. (316)	Y	Y	Y	Y	Y
Lucas et el. (318, 319)	Y	Y	Y	Y	Y
Sharif et al. (107)	Y	Y	Y	Y	Y
Smith et al. (321)	Y	N	?	?	N
Snowden et al. (128)	Y	Y	Y	Y	Y
Specht et al. (323)	Y	Y	Y	Y	Y

	MMAT ratings: Quantitative randomised controlled trials[a]				
	Random allocation appropriately performed	**Groups comparable at baseline**	**Complete outcome data**	**Outcome assessors blinded**	**Participants adhered to assigned intervention**
Aunger et al. (135)	Y	?	?	N	?
das Nair et al. (289)	Y	Y	N	N	N
Eschalier et al. (115)	?	Y	Y	N	Y
Snowden et al. (128)	Y	?	?	N	Y
	MMAT ratings: Quantitative non-randomised[a]				
	Participants representative of target population	**Measurements appropriate**	**Complete outcome data**	**Confounders accounted for**	**Intervention administered as intended**
Snowden et al. (128)	N	Y	Y	Y	Y
	MMAT ratings: Quantitative descriptive[a]				
	Relevance of sampling strategy	**Sample representative of target population**	**Measurements appropriate**	**Risk of non-response bias low**	**Statistical analysis appropriate**
Barnes et al. (309)	Y	?	N	?	Y
Causey-Upton et al. (313)	N	N	Y	N	Y
Causey-Upton et al. (314)	Y	?	Y	N	Y
Eschalier et al. (315)	?	?	Y	?	Y
Huber et al. (317)	?	?	Y	?	Y
Plenge et al. (320)	N	N	Y	?	Y
SooHoo et al. (322)	Y	?	N	?	Y

Snowden et al. (128)	?	?	Y	?	Y
Westby et al. (97)	Y	Y	Y	Y	Y
	MMAT ratings: Mixed methods[a]				
	Adequate rationale for mixed methods design	**Different study components effectively integrated**	**Outputs of the integration adequately interpreted**	**Divergences and in-consistencies adequately addressed**	**Different components adhered to corresponding quality criteria**
Aunger et al. (135)	Y	N	N	Y	N
Causey-Upton et al. (109, 314)	N	N	N	Y	N
das Nair et al. (289)	?	Y	Y	Y	N
Snowden et al. (128)	?	Y	Y	Y	N

MMAT, Mixed Methods Appraisal Tool; N, no; Y, yes; ? can't tell

[a] For studies with mixed populations, ratings were made specifically for participants who met the review eligibility criteria.

[b] Reported the qualitative component of a mixed methods study, but the quantitative results are not reported in the same article; therefore, the study was appraised using the qualitative category of the MMAT only.

4.3.6 Education interventions

4.3.6.1 Outcomes studies

Five outcomes studies evaluated pre-operative education interventions, all of which were two-arm RCTs. Across all the education interventions, 26 intervention components (22 education topics, four activities/opportunities) and 27 delivery approaches were identified. The studies that identified superior outcomes in the intervention group are discussed first, followed by the study that did not identify any superior outcomes in the intervention group.

Studies that identified superior outcomes in the intervention group

Four studies identified a significant between-group difference in favour of the intervention group for at least one outcome (44, 46, 114, 115). These outcomes included the number of physical therapy visits and time taken to meet inpatient physical therapy discharge criteria (44), knowledge/change in knowledge (114, 115), change in specific beliefs (115) and pain on post-operative days one and two (114). Leal-Blanquet et al. (46) identified significant between-group differences in favour of the intervention group for post-intervention expectations/change in expectations on specific topics, but not the overall expectations scores. The interventions evaluated in these four studies varied in their content and delivery. Lin et al. (114) evaluated an intervention that focused predominantly on patient-controlled analgesia. In contrast, the other three interventions covered six (46), 10 (44) or 15 education topics (115). The most frequently included education topics were precautions (e.g. thromboembolism prophylaxis) (44, 114, 115), discharge instructions/what to expect following discharge (44, 46, 115), rehabilitation (44, 46, 115) and returning to daily activities (44, 46, 115).

A key finding for this project was that the interventions evaluated in two studies combined digital and face-to-face delivery formats. In the study by Soeters et al. (44), intervention group participants received a one-to-one physical therapy session followed by access to a web-based microsite. The intervention evaluated by Leal-Blanquet et al. (46) consisted of a DVD delivered during a nurse appointment. The delivery formats of the other two studies consisted of a booklet (115) or a single nurse-led educational session in which participants received a pamphlet (114). Across all four studies, the timing of intervention delivery ranged from one day pre-operatively (114) to four to six weeks pre-operatively (115). Only Soeters et al. (44) explicitly indicated that their intervention was personally tailored. Both Soeters et al. (44) and Leal-Blanquet et al. (46) highlighted that their interventions provided an opportunity for patients' questions to be addressed.

Study that did not identify any superior outcomes in the intervention group

Wilson et al. (116) did not identify any significant between-group differences for any outcome at any follow-up time-point. The intervention focused mainly on pain management and was personally tailored. The principal investigator (PI) delivered the intervention through a booklet and teaching session within four weeks pre-operatively, followed by a telephone call to address patients' questions within one week pre-operatively.

4.3.6.2 Views studies

Twenty views studies explored participants' experiences/perspectives of pre-operative education intervention components and/or delivery approaches. Across all these studies, 33 intervention components (29 education topics, four activities/opportunities) and 54 delivery approaches were identified. Key findings are summarised below.

Comprehensive pre-operative education is valued but may be overwhelming

Both patients and health professionals perceived numerous education topics as valuable. These addressed:

- background information e.g. knee joint anatomy (313, 314);
- what to expect e.g. pain expectations (99, 109, 321);
- preparing for surgery e.g. obtaining/using walking aids and other equipment (97, 102, 314, 318, 319);
- recovering from surgery e.g. returning to work (308).

The most frequently mentioned topics were rehabilitation (n=9) (97, 99, 102, 310, 313-315, 317-319) and recovery expectations (n=7) (97, 99, 102, 109, 310, 313, 314, 322). Although comprehensive education was valued, health professionals reported that patients receive a large volume of information, which may be difficult for patients to process (128) or lead to *'information fatigue'* (321: p.187).

Employing appropriate delivery approaches is vital

The value of pre-operative education appeared to be affected by how it was delivered. For example, patients had difficulty retaining information delivered immediately after the decision to undergo surgery was made (323) or a long time before their surgery (102). Others missed the opportunity to attend a pre-operative education class due to receiving a quick referral (102). Correspondingly, nurses in the mixed methods study by Causey-Upton et al. (109, 314) highlighted that the timing of education delivery needs to minimise the risk that patients will forget information whilst ensuring that they have sufficient time to act on the advice provided. Overall, the nurses felt that education delivery around two to four weeks pre-operatively is optimal. Patients and health professionals expressed a range of perspectives regarding other aspects of education delivery. For example, the opportunity to interact with peers was perceived as a benefit of group education (102, 109, 316, 323). However, hearing peers' stories of serious complications could frighten patients (316). Positives and negatives were also identified for different delivery formats (102, 107, 109, 148). Correspondingly, nurses in the study by Causey-Upton et al. (109, 314) suggested that education should be delivered using multiple formats to account for patients' varying needs,

Digital delivery formats are helpful for at least some patients

Notably for this project, the findings of multiple studies suggested that digital delivery formats are helpful for at least some patients. The quality indicators (QIs) developed in the consensus development studies by SooHoo et al. (322) and Westby et al. (97) recommend a range of delivery formats including video (97, 322), telehealth (97) and other electronic formats (322). Almost half the nurses in the quantitative component of the mixed methods study by Causey-Upton et al. (109, 314) stated that they would like to add online education delivery to their current pre-operative education programmes. Nurses in the qualitative component of the same study recommended providing online or other types of remote education for patients who are unable to attend face-to-face sessions (109). Health professionals in the qualitative study Sharif et al. (107) felt various virtual healthcare technologies could be used to provide pre-operative education, including websites, videos, virtual reality and mobile health interventions. The health professionals also identified benefits and potential problems related to each type of technology (107). Benefits included the opportunity to enhance patient engagement, provide more personalised care and increase efficiency. Potential problems related to lack of access to digital technologies, low digital literacy and poor compliance. In addition, the health professionals highlighted that some patients may have difficulty logging into mobile health tools and remembering their passwords (107).

Some patients perceive pre-operative education as insufficient

Patients reported insufficiencies in various aspects of pre-operative education. These included issues with the timing of education delivery, as discussed above, and inadequate education on specific topics, such as rehabilitation (99, 310) and recovery expectations (99, 102, 310). Some patients in Goldsmith et al. (99) felt that their surgeon did not provide time to answer their questions or treat them like an individual. Correspondingly, Bardgett et al. (308) reported that patients who received advice on returning to work felt it was not tailored to their individual needs. Studies conducted with health professionals suggested factors that may contribute to insufficiencies in pre-operative education. For example, health professionals in Judge et al. (102, 148) reported that they might not be able to provide information booklets due to funding cuts, whilst nurses in the study by Causey-Upton et al. (109, 314) acknowledged that pragmatic factors guide pre-operative education provision.

4.3.6.3 Integration of the outcomes studies and views studies

This section summarises the integration of the outcomes studies and views studies that addressed pre-operative education interventions. Table 4.9 provides an excerpt from the five-page table used to juxtapose the education intervention components and delivery approaches identified from all the studies.

Table 4.9: Education intervention components and delivery approaches table excerpt

Category	Intervention component or delivery approach	Leal-Blanquet et al. (46)[a]	Lin et al. (114)[a]	Soeters et al. (44)[a]	Wilson et al. (116)[b]	Eschalier et al. (115)[a]	Bardgett et al. (308)	Barnes et al. (309)	Berg et al. (310)	Bin Sheeha et al. (311)	Causey-Upton and Howell (312)	Causey-Upton et al. (313)	Causey-Upton et al. (109, 314)	Drew et al. (148) Judge et al.	Eschalier et al. (315)	Goldsmith et al. (99)	Høvik et al. (316)	Huber et al. (317)	Lucas et al. (318, 319)	Sharif et al. (107)	Smith et al. (321)	Snowden et al. (128)	SooHoo et al. (322)	Specht et al. (323)	Westby et al. (97)
Provider	Multidisciplinary team												V	V											V
	Researcher(s)				O																				
	Orthopaedic surgeon									V		V				V							V		
	Physician assistant											V													
	Nurse/nurse practitioner	O	O										V						V				V		
	Physical therapist/ physiotherapist			O									V						V						
	Occupational therapist												V						V						
	Case manager											V	V										V		
	Social worker											V	V												
	Previous patients												V						V						
	Pain management provider												V												
	Home healthcare provider												V												
	Dietetics												V												
	Anaesthetist												V												

O, intervention component/delivery approach included in an intervention investigated in an outcomes study; V, participants' experiences/perspectives of the intervention component/delivery approach reported in a views study

[a] Outcomes study in which a statistically significant difference in favour of the intervention group was identified for at least one outcome at one or more follow-up time points (alpha=0.05).

[b] Outcomes study in which no statistically significant differences in favour of the intervention group were identified for any outcomes at any follow-up time points (alpha=0.05).

Fifty-five percent of all the intervention components were identified in both outcomes studies and views studies. A large proportion of this overlap is attributable to the studies by Eschalier et al. (115, 315). The views study by Eschalier et al. (315) involved the validation of an educational booklet. The booklet was subsequently evaluated in an RCT by Eschalier et al. (115), which met the criteria for both an outcomes study and a views study. All 10 of the education topics identified in Eschalier et al. (315) were therefore included in the intervention evaluated by Eschalier et al. (115). Twenty-nine per cent of all the delivery approaches identified were noted in both outcomes studies and views studies. This relatively low percentage is at least partly due to the identification of 46 delivery approaches in the views study by Causey-Upton et al. (109, 314).

Areas of agreement were evident between the views studies and the outcomes studies that identified superior outcomes in the intervention group. For example, three of these outcomes studies' interventions were delivered using more than one format (44, 46, 114). This corresponds with the benefits of employing multiple delivery formats highlighted by nurses in the views study by Causey-Upton et al. (109, 314). Furthermore, three of the interventions addressed at least six education topics (44, 46, 115); aligning with the finding from the views studies that comprehensive pre-operative education is valued. In contrast, Wilson et al. (116), who did not identify any significant between-group differences, evaluated an intervention that focused largely on pain management. Conversely, the intervention in the study by Wilson et al. (116) addressed many delivery aspects perceived as important in the views studies. For example, it was delivered using more than one format and tailored to patients' individual needs.

4.3.7 Exercise interventions

4.3.7.1 Outcomes studies

Twenty outcomes studies evaluated pre-operative exercise interventions. Across all the exercise interventions, 28 intervention components (17 exercise types, 11 adjuncts/activities) and 85 delivery approaches were identified. The studies that identified superior outcomes in the intervention group are discussed first. The studies that did not identify any superior outcomes in the intervention group are then briefly addressed.

Studies that identified superior outcomes in the intervention group

Sixteen studies identified a significant between-group difference in favour of the intervention group(s) for at least one outcome. These outcomes included participant-reported outcomes (e.g. self-reported pain) (40, 43, 284, 285, 287, 290, 291, 293, 297, 301-304, 306), performance-based outcomes (e.g. knee extensor strength) (40, 125, 284, 287, 288, 290, 292, 294, 297, 300-304, 306) and LOS (287, 294). The more favourable outcomes in the intervention group(s) were identified at varying follow-up points, ranging from pre-operative time-points (40, 43, 284, 287, 288, 290, 291, 293, 297, 300, 301, 303) to one year post-operatively (125, 290). Amongst these 16 studies, one evaluated a combined exercise and diet control intervention (40). The other 15 evaluated interventions that were predominantly exercise-based. Fourteen interventions involved multiple exercise types, of which the most common was lower limb strengthening/resistance exercises (n=12) (43, 125, 284, 285, 287, 288, 290, 293, 294, 297, 300, 301, 303, 304, 306). The most frequently included adjunct component was completion of a logbook/calendar (n=7) (40, 43, 284, 285, 294, 300, 301). Most interventions were delivered by a physiotherapist/physical therapist(s) (n=8) (43, 125, 284, 287, 288, 290-292, 297, 303, 304) or researcher(s) (n=6) (40, 285, 294, 300, 301, 306). Eleven interventions were delivered using more than one format (40, 43, 284, 285, 291, 292, 294, 300-302, 306). The intervention schedules and intensities varied widely. The intervention was progressive in nine studies (43, 284, 285, 290, 292, 294, 297, 300, 303, 304) and tailored according to patients' needs/abilities in 10 studies (43, 125, 284, 285, 287, 288, 290-292, 297, 303, 304, 306).

Of particular relevance to this project, only two studies evaluated interventions that employed digital delivery formats. One of these was an RCT by Rittharomya et al. (40), which evaluated a 12-week exercise and diet control intervention. The PI delivered the intervention using multiple formats, including an information session with a DVD followed by remote monitoring through telephone calls or a mobile application. Rittharomya et al. (40) identified significant between-group differences in favour of the intervention group for most outcomes assessed over the intervention period. These included self-efficacy, knee pain, health-related QOL and performance-based outcomes. No significant between group differences in BMI were identified. Outcomes were not assessed beyond the end of the 12-week intervention. The other study that evaluated a digitally delivered intervention was a three-arm pilot study by Doiron-Cadrin et al. (43). The intervention groups in this study participated in an exercise programme involving multiple exercise types and adjunct components delivered either in person (in-person prehabiltation) or via an internet-based telecommunication mobile application (tele-prehabilitation). The study was underpowered to detect significant between-group differences. However, participant-reported and performance-based outcomes were assessed to evaluate the potential impact of the interventions. At the end of the 12-week programme, the only significant between-group difference was a higher proportion of success based on the Global Rating of Change Scale in both intervention groups compared to the control group (43).

Two RCTs by the same research group also involved three-arms, enabling exercise types/delivery approaches to be directly compared (284, 290). The intervention groups in the RCT by Domínguez-Navarro et al. (290) participated in an outpatient strength training programme or the same strength training programme augmented with balance training. In the RCT by Blasco et al. (284), the intervention groups participated in a strength and balance training programme that was either hospital- or home-based. At six-weeks post-operatively (primary end-point), significant between-group differences in favour of both intervention groups compared to the control group were identified for knee extensor strength by Domínguez-Navarro et al. (290) and balance by Blasco et al. (284), but no additional outcomes. Neither RCT identified any significant differences between the two intervention groups at any follow-up time point (284, 290).

Studies that did not identify superior outcomes in the intervention group

Four studies did not identify any significant between-group differences in favour of the intervention group for any outcome at any follow-up time point. All of these evaluated interventions involving multiple exercise types delivered either alone (134, 286, 295) or combined with acupuncture (298). None of the interventions employed digital delivery formats. Three of the interventions were both progressive and tailored according to patients' needs/abilities (134, 286, 295). Notably, the interventions evaluated by Brown et al. (286) and Huber et al. (134) were similar to those evaluated in studies that identified significant between-group differences in favour of the intervention group for at least one outcome – Brown et al. (285) and Villadsen et al. (303, 304) respectively. Brown et al. (286) included goal setting, behavioural contracting and feedback in the intervention evaluated, whereas none of those adjunct components were reported by Brown et al. (285). The lack of intervention benefits identified by Brown et al. (286) may be because only two outcomes were assessed, self-efficacy for exercise and outcome expectations for exercise. In addition, the results of the study by Brown et al. (285) should be interpreted cautiously as it was a small pilot study.

The key difference between the interventions evaluated by Huber et al. (134) and Villadsen et al. (303, 304) was that they were delivered for 4–12 weeks and eight weeks respectively. The flexible exercise programme duration employed by Huber et al. (134) accounted for participants' differing locations on the waiting list for TKR. The study's adherence data suggested that patients undertook the exercise programme for five weeks on average (134). The disparities in the results of Huber et al. (134) and Villadsen et al. (303, 304) may therefore have been due to the differing durations of the exercise programmes. Additional factors, such as the different co-interventions employed, may also have contributed to the disparities in the two studies' results.

4.3.7.2 Views studies

Three views studies explored participants' experiences/perspectives of pre-operative exercise intervention components and/or delivery approaches. Across these three studies, seven intervention components (six exercise types, one adjunct/activity) and eight delivery approaches were identified.

In the consensus-based study by Westby et al. (97), a proposed QI states that patients awaiting TKR should carry out a progressive, individually tailored exercise programme, involving specific exercise types and education on remaining physically active. The QI also specifies that patients should commence the exercise programme at least eight weeks pre-operatively *'to allow a physiologic training effect'* (97: p.377). Bin Sheeha et al. (311) conducted a focus group with patients at one year post-TKR. The patients generally perceived pre-operative exercise as valuable. However, three did not recommend pre-operative physiotherapy. Reasons for this included not being able to fit the recommended exercises into their schedule and believing that the exercises physiotherapists provide can be obtained online. Sharif et al. (107) conducted a qualitative study to explore NHS health professionals' perspectives of virtual healthcare technologies that could be incorporated into knee/hip replacement pre-operative care. The health professionals felt that websites could be used to provide pre-operative exercises and mobile health interventions could encourage patients to exercise. They also highlighted that remote patient monitoring could be used to track patients' attainment of their exercise goals. As discussed above (section 4.3.6.2), benefits and potential problems of the technologies were identified (107).

4.3.7.3 Integration of the outcomes studies and views studies

This section summarises the integration of the outcomes studies and views studies that addressed pre-operative exercise interventions. Table 4.10 provides an excerpt from the nine-page table used to juxtapose the exercise intervention components and delivery approaches identified from all the studies.

Table 4.10: Exercise intervention components and delivery approaches table excerpt

Category	Intervention component or delivery approach	Blasco et al. (284)[a]	Brown et al. (285)[a]	Brown et al. (286)[b]	Calatayud et al. (287)[a] Casaña et al. (288)[a]	Doiron-Cadrin et al. (43)[a]	Domínguez-Navarro et al. (290)[a]	Gränicher et al. (291)[a]	Gstoettner et al. (292)[a]	Huber et al. (134)[b]	Jahic et al. (293)[a]	Matassi et al. (294)[a]	McKay et al. (295)[bc]	Rittharomya et al. (40)[a]	Skoffer et al. (125, 297)[a]	Soni et al. (298)[b]	Swank et al. (300)[a]	Topp et al. (301)[a]	Tungtrongjit et al. (302)[a]	Villadsen et al. (303, 304) [a]	Wang et al. (306)[a]	Bin Sheeha et al. (311)	Sharif et al. (107)	Westby et al. (97)
Component: Exercise type	Single exercise type													O					O					
	>1 exercise type	OH OD	O	O	O	OI OT	OS OB	O	O	O	O	O	O		O	O	O	O		O	O			V
	Warm-up[d]		O	O	O	OI OT	OS OB		O	O			O		O		O	O		O	O			
	Upper body strength exercises		O	O																				V
	Lower limb strength/resistance exercises	OH OD	O	O	O	OI OT	OS OB			O	O	O	O	O[e]	O	O[e]	O	O	O	O	O			V
	Upper limb stretches		O	O																				
	Trunk stretches		O	O																				
	Lower limb stretches/ flexibility training		O	O					O			O			O	O[e]								
	Lower limb joint mobilisation/range of movement exercises					OI OT																		V

B, strengthening plus balance/proprioceptive exercise group; D, domiciliary group; H, hospital group; I, in-person prehabilitation group; O, intervention component/delivery approach included in an intervention investigated in an outcomes study; S, strengthening group; T, telerehabilitation prehabilitation group, V participants' experiences/perspectives of the intervention component/delivery approach reported in a views study

[a] Outcomes study in which a statistically significant difference in favour of the intervention group was identified for at least one outcome at one or more follow-up time points (alpha=0.05).

[b] Outcomes study in which no statistically significant differences in favour of the intervention group were identified for any outcomes at any follow-up time points (alpha=0.05).

[c] The control group participated in an upper body strength training programme that involved the same warm-up and delivery approaches as the intervention group's lower limb strength training programme.

[d] Warm-up included at least one of the following activities: aerobic activities e.g. cycling or walking; joint movements; and/or dynamic body weight exercises.

[e] Exercises grouped into types by the researcher (all other exercises grouped according to the primary study authors' terminology).

There were a few areas of agreement between the findings of the views study by Westby et al. (97) and the outcomes studies. Notably, the exercise QI proposed by Westby et al. (97) states that patients should perform a progressive, individually tailored pre-operative exercise programme. In line with this, 10 outcomes studies evaluated an exercise intervention that was both progressive and tailored according to patients' ability/needs (43, 125, 134, 284-286, 290, 292, 295, 297, 303, 304). Seven of these reported superior outcomes in the intervention group (43, 125, 284, 285, 290, 292, 297, 303, 304). Other than gait training, all the exercise type advocated Westby et al. (97) were employed in the intervention of at least one outcomes study. However, none of the outcomes studies combined all the exercise types recommended by Westby et al. (97) in a single intervention.

The exercise programme duration was a notable area of dissonance. The QI proposed by Westby et al. (97) states that patients should commence an exercise programme at least eight weeks pre-operatively. Conversely, 13 outcomes studies involved exercise programmes that did not last at least eight weeks (125, 134, 284, 290-295, 297, 300-302, 306). Eleven of these reported superior outcomes in the intervention group (125, 284, 290-294, 297, 300-302, 306). Another notable finding was that only two studies evaluated interventions involving digital delivery formats (40, 43), despite the potential value of these formats highlighted by Sharif et al. (107).

4.3.8 Psychological interventions

4.3.8.1 Outcomes studies

Two outcomes studies evaluated pre-operative psychological interventions. Across both psychological interventions, seven intervention components and 11 delivery approaches were identified. The studies comprised an RCT by Medina-Garzón (296) and a mixed methods feasibility study by Das Nair et al. (289). Both studies identified a significant-between group difference in favour of the intervention group for a single outcome. Medina-Garzón (296) reported that anxiety scores at four weeks post-intervention were significantly lower in the intervention group compared to the control group, but did not include any other outcomes or follow-up time points. Das Nair et al. (289) assessed multiple self-reported outcomes at four- and six-months post-randomisation, although the study was underpowered to detect significant between-group differences. In addition, two of the 25 intervention group participants withdrew prior to receiving the intervention and a further 17 did not complete the intervention as planned. Physical function scores were significantly better in the intervention group compared to the control group at the six-month follow-up. Das Nair et al. (289)

acknowledged that this finding is likely to have occurred by chance as multiple comparisons were made.

A single intervention component (motivational interviewing) was identified from the intervention evaluated by Medina-Garzón (296). Six intervention components were identified from the cognitive behavioural therapy (CBT)-based intervention evaluated by Das Nair et al. (289). The only overlap in the intervention delivery approaches identified in the studies was that both interventions were tailored to patients' individual needs. The minimal overlap may have been at least partly due to the limited details of the intervention reported by Medina-Garzón (296).

4.3.8.2 Views studies

The only views studies that addressed a psychological intervention was the aforementioned feasibility study by das Nair et al. (289). Eleven patients in the intervention group completed semi-structured interviews. Patients' experiences/perspectives of five intervention components and six delivery approaches were identified from the interview findings. Most of the patients interviewed felt that the intervention offered benefits, such as helping them to think more positively. However, some did not find the intervention useful and disagreed with the proposed interaction between mood and pain. Patients who perceived the intervention as beneficial attributed this to a range of factors. These included intervention components, such as relaxation, and delivery approaches, such as personal tailoring. Patients expressed differing opinions regarding the home versus hospital delivery and group versus individual sessions. For example, home-based sessions were perceived as preferable for pragmatic reasons, such as not needing to travel, whilst hospital-based sessions were considered more compatible with patients' work schedules.

4.3.8.3 Integration of the outcomes studies and views study

This section summarises the integration of the outcomes studies and views study that addressed pre-operative psychological interventions. Table 4.11 juxtaposes the psychological intervention components and delivery approaches identified from the studies.

Table 4.11: Psychological intervention components and delivery approaches table excerpt

Category	Intervention component or delivery approach	Medina-Garzón (296)[a]	das Nair et al. (289)[a]
Component	Motivational interviewing	O	
	Psychoeducation on mood and pain		OV
	Values-based goal setting		O
	Self-management and behavioural activation		O
	Relaxation and mindful breathing		OV
	Cognitive restructuring		OV
	Post-surgical planning		O
	Signposting to relevant services		V
	Post-op reminders of the session content		V
Provider	Nurse	O	
	Psychologist		OV
Delivery mode	Single format		O
	Face-to-face		O
	Individual		OV
	Group		V
Setting	Hospital or home, according to the patients' preference		O
	Hospital		V
	Home		V
Schedule	3 sessions over a 20 day period	O	
	Up to 10 sessions delivered once or twice weekly		O
Intensity	Session length: ~40 min	O	
	Session length: ~1 hour		O
Tailoring	Tailored to each individual's needs	O	OV

O, intervention component/delivery approach included in an intervention investigated in an outcomes study; post-op, post-operative; V, participants' experiences/perspectives of the intervention component/delivery approach reported in a views study

[a] Outcomes study in which a statistically significant difference in favour of the intervention group was identified for at least one outcome at one or more follow-up time points (alpha=0.05).

As highlighted above (section 4.3.8.1), the only similarity in the interventions evaluated by Medina-Garzón (296) and Das Nair et al. (289) was that both interventions were tailored to patients' individual needs. This aligns with the qualitative component of Das Nair et al. (289), which found patients perceived personal tailoring as beneficial. A few other areas of agreement were evident between the intervention evaluated by Das Nair et al. (289) and the study's qualitative findings. For example, the intervention evaluated by Das Nair et al. (289) was delivered at hospital or in participants' homes, according to their preference. This aligns with the qualitative finding that patients' preferences for the delivery setting varied. Patients in the qualitative component of Das Nair et al. (289) also made a few suggestions that were not included in the intervention, such as providing post-operative reminders of the session content.

4.3.9 Lifestyle interventions

4.3.9.1 Outcomes studies

The only outcomes study that evaluated a lifestyle intervention was the RCT by Rittharomya et al. (40). Five intervention components and seven delivery approaches were identified from this study's intervention. Further details of this study are provided above (section 4.3.7.1), so are not repeated here.

4.3.9.2 Views studies

Four views studies explored participants' experiences/perspectives of pre-operative lifestyle intervention components or delivery approaches. Across these studies, 12 intervention components and nine delivery approaches were identified. In the aforementioned consensus development study by Westby et al. (97), one of the proposed QIs states that patients awaiting TKR with a BMI of 27 kg/m² or over should receive weight management information and be referred to a weight management programme. Plenge et al. (320) also conducted a consensus development study that addressed multiple aspects of TKR/THR care. This included developing a prioritised list of 10 pre-operative interventions perceived to be the most important for improving post-operative outcomes. The final list included smoking cessation (ranked sixth) and alcohol cessation (ranked tenth).

Two mixed methods pilot/feasibility studies focused on pre-operative behaviour change interventions. Aunger et al. (135) conducted a feasibility study of a sedentary behaviour reduction intervention. Participants identified physical and mental benefits from engaging with the intervention. They generally reported having no problems making environmental modifications but at least some problems attaining their goals. Despite this, most participants felt that their goals were well suited to their individual circumstances. Patients expressed a range of views about other intervention components and delivery approaches. For example, some participants reported enjoying using the pedometer, whilst others reported being unable to use it successfully.

Snowden et al. (128) evaluated an intervention aimed at reducing pre-operative alcohol consumption through a non-randomised feasibility study followed by a pilot study. Patients and health professionals perceived the intervention as acceptable. However, the impact of the intervention on patients' alcohol consumption varied. Snowden et al. (128) reported patients' and health professionals' views of various intervention components and delivery approaches. The only area of overlap with Aunger et al. (135) was that health professionals commented on personal tailoring of the intervention/associated screening, which they felt was important to keep their interactions positive.

4.3.9.3 Integration of the outcomes study and views studies

This section summarises the integration of the outcomes study and views studies that addressed pre-operative lifestyle interventions. Table 4.12 provides an excerpt from the two-page table used to juxtapose the lifestyle intervention components and delivery approaches identified from all the studies.

Table 4.12: Lifestyle intervention components and delivery approaches table excerpt

Category	Intervention component or delivery approach	Rittharomya et al. (40)[a]	Aunger et al. (135)	Plenge et al. (320)	Snowden et al. (128)	Westby et al. (97)
Delivery mode	>1 format	O				
	Information/instruction sessions with a poster and DVD	O				
	Remote monitoring via telephone calls/a mobile application	O				
	Visual aids e.g. infographics or poster	O			V	
	Booklet		V[b]			
Setting	Pre-operative assessment clinic				V	
	Home and unspecified location for information/instructions	O				
Schedule	12-week programme	O				
	Additional protected time in pre-operative assessment clinic				V	
	Booster session				V	
Tailoring	Tailored to each individual's circumstances/needs		V		V	

DVD, digital video disc; O, intervention component/delivery approach included in an intervention investigated in an outcomes study; V, participants' experiences/perspectives of the intervention component/delivery approach reported in a views study

[a] Outcomes study in which a statistically significant difference in favour of the intervention group was identified for at least one outcome at one or more follow-up time points (alpha=0.05).

[b] Finding is from a study with a mixed population and is not supported with evidence specifically for participants who met the review eligibility criteria.

The integration was limited because only one outcomes study evaluated a lifestyle intervention. The main area of agreement was that the intervention evaluated by Rittharomya et al. (40) included diet control components, aligning with the QI on weight management proposed by Westby et al. (97). In addition, the intervention evaluated by Rittharomya et al. (40) was delivered using multiple formats, including a poster. Correspondingly, health professionals in the study by Snowden et al. (128) felt that visual aids are valuable.

4.3.10 Other pre-operative interventions

4.3.10.1 Outcomes studies

Five outcomes studies evaluated other pre-operative TKR interventions. Across these interventions, six intervention components and 23 delivery approaches were identified. Two studies identified a significant between-group difference in favour of the intervention group for at least one outcome. These included cognitive function in an RCT of electroacupuncture (307) and the chair rise test and stair climb test in a pilot study of neuromuscular electrical stimulation (NMES) (305). Notably, this pilot study involved 17 participants only, three of whom withdrew (305).

The remaining three studies did not identify any significant between group differences in favour of the intervention group at any follow-up time point. The interventions evaluated in these studies comprised incentive spirometry (283), a dynamic knee extension device (299) and acupuncture plus exercise (298). There were minimal similarities in the intervention components and delivery approaches of the other pre-operative TKR interventions evaluated. The most notable similarities were between the NMES and incentive spirometry interventions, as they both included self-monitoring and employed more than one delivery format (283, 305).

4.3.10.2 Views studies

The only views study that explored participants' experiences/perspectives of other pre-operative interventions was the aforementioned study by Bin Sheeha et al. (311). Two patients in this study reported finding acupuncture *"very good"* before their surgery (p.442). However, it was unclear whether their comments related specifically to acupuncture delivered in the pre-operative phase.

4.3.10.3 Integration of the outcomes studies and views study

This section summarises the integration of the outcomes studies and views study that addressed other pre-operative TKR interventions. Table 4.13 provides an excerpt from the two-page table used to juxtapose the intervention components and delivery approaches identified from the studies.

Table 4.13: Other pre-operative intervention components and delivery approaches table excerpt

Category	Intervention component or delivery approach	Bergin et al. (283)[b]	Soni et al. (298)[b]	Stone et al. (299)[b]	Walls et al. (305)[a]	Zhao et al. (307)[ac]	Bin Sheeha et al. (311)
Component	Incentive spirometry	O					
	Self-monitoring e.g. through completion of a logbook	O			O		
	Acupuncture		O				V
	Electroacupuncture					O	
	NMES				O		
	Dynamic knee extension device			O			
Provider	Physiotherapist		O				
	Acupuncturist					O	

NMES, neuromuscular electrical stimulation; O, intervention component/delivery approach included in an intervention investigated in an outcomes study; V, participants' experiences/perspectives of the intervention component/delivery approach reported in a views study

[a] Outcomes study in which a statistically significant difference in favour of the intervention group was identified for at least one outcome at one or more follow-up time points (alpha=0.05).

[b] Outcomes study in which no statistically significant differences in favour of the intervention group were identified for any outcomes at any follow-up time points (alpha=0.05).

[c] The control group received *'placebo electroacupuncture'* that involved the same provider, delivery mode and schedule as the intervention group's electroacupuncture (307: p.233).

The integration was limited because no views studies explored participants' experiences/perspectives of other pre-operative interventions in depth. The only notable finding was that patients in the views study Bin Sheeha et al. (311) felt acupuncture is helpful, whereas the outcomes study that evaluated an exercise plus acupuncture intervention did not identify any significant benefits of the intervention (298).

4.4 Discussion

4.4.1 Main findings

This rapid review identified and synthesised a wide range of evidence on the content and delivery of pre-operative TKR interventions. The 52 included studies investigated various intervention types, of which the most common were education and exercise. The majority of intervention components and delivery approaches identified were specific to particular intervention types. However, some similarities across intervention types were evident. Notably, personal tailoring was associated with improved outcomes and/or perceived as valuable for education, exercise, psychological and lifestyle interventions. This is consistent with a NICE quality standard on primary joint replacement published in March 2022, which states that pre-operative rehabilitation advice should be *'tailored to the person's individual needs, circumstances and preferences'* (328: p.7). Another similarity across intervention types was that employing more than one delivery format was associated with improved outcomes and/or perceived as valuable for education interventions, exercise interventions, a combined diet and exercise intervention and a NMES intervention. Nurses in the study by Causey-Upton et al. (109, 314) highlighted that employing a combination of delivery format helps to address patients' differing needs.

Several studies' findings indicate that digital delivery formats may be useful for providing education and/or exercise interventions (97, 107, 109, 314, 322). The suggested digital delivery formats included websites, videos, virtual reality, telehealth and mobile health interventions. Only one study considered these formats in depth. This was a qualitative study by Sharif et al. (107), which explored NHS health professionals' perspectives of using virtual healthcare technologies to deliver pre-operative knee/hip replacement care. The health professionals identified multiple potential benefits of the technologies, such as optimising patient engagement and providing more personalised care. Potential problems related to the technologies were also highlighted. These included lack of access to digital technologies and low digital literacy. As discussed in Chapter 2 (section 2.4.2), these are substantial problems as they could lead to digital interventions increasing health inequities (37, 163). Correspondingly, it is essential to take steps to mitigate these problems, such as ensuring that digital interventions are rigorously developed with extensive input from intended users (163). Despite the potential benefits of digital delivery formats, only four studies evaluated interventions delivered at least partly via digital formats (40, 43, 44, 46). All these studies presented notable limitations, such as inadequate reporting of important methodological details, lack of post-intervention follow-up and small sample sizes. Furthermore, no included studies evaluated a digital intervention delivered without health professional support. This demonstrates that the VKS developed in this project could help address an important gap in existing literature.

Of all the included studies, only two RCTs and a pilot study compared the effectiveness of different intervention components or delivery approaches (43, 284, 290). The results of the two RCTs suggest that pre-operative TKR exercise programmes are equally effective regardless of whether they include strength training only or strength plus balance training (290) and whether they are hospital or home-based (284). Correspondingly, the pilot study found that a pre-operative TKR exercise programme had similar effects when it was delivered in person or via telecommunication software (43), although a fully powered RCT is required to confirm this. These findings align with a Cochrane review of land-based exercise for people with OA (120), which demonstrated that the effects of exercise programmes on pain and function do not vary significantly for different exercise types and delivery formats.

The present review's findings demonstrate the importance of providing pre-operative TKR education on a comprehensive range of topics. Of the 32 topics identified, rehabilitation and recovery expectations appear particularly important. Education on these topics was perceived insufficient by some patients. Lack of personalised education was also highlighted as an issue, despite the importance of personalised care discussed above. Causes of perceived inadequacies in pre-operative TKR education are likely to be multifactorial. Potential contributory factors identified in this review include funding restrictions and pragmatic considerations. Previous research has suggested that delivering patient-centred TKR care may require greater acknowledgement that patients awaiting TKR typically have multiple joint problems and comorbidities, all of which interact and affect their lives in many ways (329). This review's findings also emphasise the importance of optimising pre-operative TKR education delivery. For example, providing education between two and four weeks pre-operatively was suggested to help ensure that patients have enough time to address the advice and can still remember it at the time of their surgery (109, 314).

The timing/duration of pre-operative exercise interventions was a key area of dissonance identified in this review. Multiple outcomes studies reported significant effects of exercise programmes lasting less than eight weeks, whereas the exercise QI proposed by Westby et al. (97) states that patients should commence an exercise programme at least eight weeks pre-operatively. Delivering pre-operative exercise programmes for a set duration may be challenging due to the variability in TKR waiting times. Huber et al. (134) addressed this by investigating a neuromuscular exercise programme delivered for 4–12 weeks pre-operatively depending on the participant's location on the TKR waiting list. Huber et al. (134) did not identify any superior outcomes in the intervention group compared to the control group, contrasting with a study evaluating a similar exercise programme delivered for eight weeks (303, 304). The disparities in these studies' results may have been due to the differing durations of the exercise programmes and/or other factors, such as the different co-interventions employed.

4.4.2 Comparison with previous similar reviews

This review's findings have some similarities with those of previous pre-operative TKR intervention reviews, but cover a wider range of intervention types and provide more detail about the content and delivery of interventions. A review by Louw et al. (23) identified numerous topics that may be included in pre-operative TKR education. However, the range of education delivery approaches identified was limited. For example, none of the four TKR RCTs included by Louw et al. (23) employed any of the digital delivery formats highlighted above. Buus et al. (24) explored patients' experiences of information provision before and after knee replacement through a systematic review and narrative synthesis. As in this review, Buus et al. (24) reported that patients value pre-operative information but noted problems with its content and delivery. This review provides further insights into pre-operative TKR education by also exploring health professionals' perspectives. For example, this review's findings highlight that health professionals may be concerned about overwhelming patients with a large volume of information.

Previous reviews have suggested that definitive evidence to guide the design of pre-operative TKR exercise interventions is lacking (118, 244). The present review's findings concur with this, whilst also providing information about pre-operative TKR exercise intervention components and delivery components that could help guide future research, as discussed in section 4.4.4 below. Sorel et al. (330) systematically reviewed 40 studies investigating the effectiveness of peri-operative TKR interventions targeting psychological distress, of which only two were included in the present review (116, 289). This was largely due to differing eligibility criteria regarding the timing of intervention delivery and study designs. Similarly, this review did not include any of the seven studies included in a systematic review of pre-operative TKR/THR non-surgical weight loss interventions by Seward et al. (136). This was primarily because Seward et al. (136) included single arm-case series, which did not meet this review's eligibility criteria.

4.4.3 Limitations

This review's findings need to be interpreted in light of the limitations of the included studies and review methodology. As discussed in section 4.3.4, the MMAT ratings suggest that all the included outcomes studies present at least some methodological quality issues (Table 4.7). Furthermore, many of the outcomes studies present limitations not addressed by the MMAT, such as being underpowered to detect statistically significant differences and/or using non-validated questionnaires. As highlighted in section 4.3.5, the MMAT ratings of the views studies were more variable (Table 4.8). Although many qualitative studies received favourable ratings, these need to be interpreted in light of the limitations of the MMAT. Across both the outcomes and views studies, there were a relatively high number of MMAT *'Can't tell'* ratings, reflecting limitations in the studies' reporting. Reporting limitations also meant that relevant information about intervention components and delivery approaches may have been missed. Contacting the studies' authors for clarifications would have helped address this, but was not undertaken due to the rapid review methodology employed (261).

Whilst rapid review methodology was appropriate for the present review, streamlining standard systematic review methods increases the risk of bias and errors within a review (247). For example, a study involving 280 reviewers found that the percentage of relevant studies missed with single-reviewer abstract screening was 13%, compared to only 3% with dual-reviewer screening (331). In addition, the relatively strict definition of a pre-operative TKR intervention employed in the present review led to potentially relevant studies being excluded. Another limitation of this review was that outcome studies were dichotomised according to whether they identified a statistically significant difference in favour of the intervention group for at least one outcome. This facilitated the development of Round 1 of the Phase 1b modified Delphi study reported in Chapter 5 (section 5.2.3.1), but required reliance on an arbitrary threshold (alpha=0.05) and statistically significant improvements may not be clinically relevant (332).

The intervention components and delivery approaches were described using the primary study authors' terminology where possible, leading to some inconsistency in the coding. For example, step/stair training was listed as a distinct exercise type in some studies, but as a strengthening exercise, functional exercise or warm-up exercise in others. Furthermore, Soni et al. (298) reported that stair climbing was included in their exercise circuit, but did not group the exercises into different types. This meant that the researcher had to subjectively group the exercises reported by Soni et al. (298) into different types. Subjective judgements were also frequently required when extracting data from the views studies. As discussed in section 4.2.5, actions were taken to ensure that the coding was appropriate and consistent despite the subjective judgements. For example, the researcher completed extensive cross-checking between studies and members of her supervisor/advisory team verified the data extraction for a randomly selected sample of 10% of the included studies.

4.4.4 Implications for practice and future research

This review's findings demonstrate that definitive evidence on the optimal content and delivery of pre-operative TKR interventions is lacking, highlighting the need for further research in this area. The comprehensive nature of this review enabled various considerations for designing pre-operative TKR interventions for clinical practice and future research to be identified. Key implications are that personal tailoring and employing more than one delivery format are likely to be important design elements for most types of pre-operative TKR interventions. The findings also suggest that pre-operative TKR education should cover a comprehensive range of topics, including rehabilitation and recovery expectations. Important implications for designing pre-operative TKR exercise programmes are that including balance training and hospital versus home delivery do not appear to be priorities. The latter suggests that delivering pre-operative TKR exercise programmes remotely is appropriate, supporting the rationale of digital interventions such as the VKS. The paucity of studies evaluating interventions employing digital delivery formats, despite the perceived benefits of these formats, also demonstrates that future research of pre-operative TKR digital interventions is warranted.

These tables of pre-operative TKR intervention components and delivery approaches developed in this review informed Round 1 of the Phase 1b modified Delphi study reported in Chapter 5 (section 5.2.3.1). The tables could also be used to inform future research, such as consensus development studies in other countries. This review's findings have also been integrated with all the other phases of this project. For example, exercises identified in this review were incorporated into the VKS exercise programme, as discussed in Chapter 8 (section 8.3.6). By comprehensively reviewing multiple pre-operative TKR intervention types, this review has highlighted important areas for future research. In particular, few studies of healthy lifestyle interventions were identified. Lifestyle-related factors are key modifiable predictors of poor TKR outcomes (17, 18, 93, 94); therefore, future research evaluating pre-operative healthy lifestyle interventions is warranted. This review's findings also highlight a need for future research of pre-operative TKR psychological interventions. This has been addressed to some degree by four RCTs published in 2021, after completion of this review's searches (39, 42, 142, 143). All these RCTs are discussed in Chapter 2 (section 2.3.6). Research addressing the areas of dissonance identified in this review, such as the optimal exercise programme duration, would also be valuable.

4.5 Conclusion

The review reported in this chapter achieved its aim of identifying and synthesising recent literature on the content and delivery of pre-operative TKR interventions. The findings confirm that definitive evidence to guide the design of pre-operative TKR interventions is lacking. Digital delivery formats were identified as potentially useful for providing education and/or exercise interventions. Despite this, digital delivery formats were only employed in the interventions of four included studies. None of these involved a digital intervention delivered without health professional support. This supports the rationale for the VKS project. This review's findings provide a valuable original contribution to existing literature by highlighting key considerations for designing pre-operative TKR interventions. In particular, the findings suggest that personal tailoring and employing more than one delivery format are important design elements for most types of pre-operative TKR interventions. Two included RCTs provide preliminary evidence that the effectiveness of pre-operative TKR exercise interventions is not dependent on the inclusion of balance training or hospital versus home delivery. The views of patients and health professionals suggest that pre-operative TKR education should cover a comprehensive range of topics, including rehabilitation and recovery expectations. The findings of this review have been integrated with all the subsequent phases of this project. This included using the pre-operative TKR intervention components and delivery approaches identified in this review to inform Round 1 of the modified Delphi study reported in the Chapter 5 (section 5.2.3.1).

Chapter 5 Modified Delphi study to develop recommendations on pre-operative total knee replacement interventions (Phase 1b)

5.1 Introduction

This chapter reports a UK-based modified Delphi study involving patients and professionals. The study built on the findings of the Phase 1a rapid review (Chapter 4) by developing recommendations on the content and delivery of pre-operative TKR interventions. The recommendations were developed with the dual purpose of informing the VKS development and providing a resource to help guide UK health professionals' decision-making on pre-operative TKR service provision until more robust evidence is available. The findings have been published as:

> **Anderson AM**, Comer C, Smith TO, Drew BT, Pandit H, Antcliff D, Redmond AC, McHugh GA. Consensus on pre-operative total knee replacement education and prehabilitation recommendations: a UK-based modified Delphi study. BMC Musculoskelet Disord. 2021;22(1):352. https://doi.org/10.1186/s12891-021-04160-5

5.1.1 Background

As highlighted in Chapter 2 (section 2.3.7), pre-operative TKR intervention provision varies widely across the UK and does not meet all patients' needs (31, 32, 146, 148). The VKS developed in this project aims to help address these problems. As discussed in Chapter 9 (sections 9.3.2.3 and 9.6.2), the digital delivery format of the VKS is unlikely to meet all patients' needs and the VKS is not yet ready to be implemented in practice. Other strategies for improving pre-operative TKR service provision are also needed. Providing health professionals with clear criteria to guide their decision-making is key to reducing unwarranted variations in practice and improving patient care (333). The NICE guideline on joint replacement (31) and a six-part joint replacement support package proposed by Versus Arthritis (100) provide some guidance on how to support patients awaiting TKR, but lack detail on the optimal content and delivery of pre-operative TKR interventions. For example, the NICE guideline covers the entire care pathway for primary hip, knee and shoulder replacement, so pre-operative interventions are only briefly addressed and the guidance is not tailored specifically to patients awaiting TKR (31). Similarly, the Versus Arthritis support package is not TKR-specific (100). In addition, it focuses on broad areas of support rather than providing in-depth guidance on aspects such as pre-operative education topics.

More detailed recommendations on pre-operative TKR interventions have the potential to reduce disparities in service provision, improve patient care and increase service efficiency. It is essential that such recommendations are available in a clear and concise format to facilitate their uptake in clinical practice (334). Developing prioritised recommendations was also important in this project to facilitate prioritisation of the potential VKS features, as detailed in Chapter 8 (section 8.3.3). Prioritising potential intervention features is crucial when developing a novel digital intervention to ensure that all key features are included despite time and resource constraints (152).

The Phase 1a rapid review reported in Chapter 4 confirmed that definitive evidence to guide the design of pre-operative TKR interventions is lacking. In the absence of robust evidence, recommendation development must rely at least partly on expert opinion (335). Obtaining consensus from a panel of experts is preferable to relying on a single expert's opinion for multiple reasons (335). For example, group-based decisions reflect a broader range of experiences and are likely to have greater credibility (335). Furthermore, obtaining input from a diverse range of stakeholders when planning a novel intervention is essential to maximise the chances that the intervention will have a meaningful impact in real-life settings (174). Previous studies have obtained expert consensus on various aspects of TKR care (97, 320, 322, 336, 337). However, none of these focused solely on pre-operative TKR interventions, limiting the depth of their findings in this area. The expert panels in these studies included few if any patients, despite widespread acknowledgement that patient input is key to guideline development (338). Furthermore, all these studies were conducted outside the UK; therefore, their findings cannot be directly transferred to the UK NHS context (339).

5.1.2 Aim and objectives

This modified Delphi study aimed to develop evidence- and consensus-based recommendations on the content and delivery of pre-operative TKR interventions (project objective 1b). Its objectives were as follows.

1. To develop a concise set of recommendations on pre-operative TKR interventions to guide UK health professionals' decision-making on pre-operative TKR service provision.
2. To develop a prioritised set of recommendations on pre-operative TKR interventions to inform the VKS development.

5.2 Methods

5.2.1 Overview and rationale

Expert consensus can be obtained through informal methods such as group discussions. Such methods lack scientific credibility and do not account for social pressures (335). Formal consensus methods aim to address these problems by employing structured processes (335). The main formal consensus development methods used in healthcare contexts are described below (335, 340, 341). These are often used in a modified or combined format (341).

- Delphi technique: introduced by the RAND (research and development) Corporation in the 1950s (342). This involves a panel of experts, often termed *'panellists'* (340: p.5), confidentially completing a series of remote surveys known as *'rounds'* (340: p.4). In the original *'Classical'* Delphi technique, the first round consists of open-ended questions on a specific topic (340: p.7). The responses are analysed to generate a set of statements or questions. The panellists rank or rate the statements/questions in the second round. Subsequent rounds summarise the responses to the preceding round and provide the panellists with an opportunity to reconsider their rankings/ratings. The rankings/ratings are aggregated statistically to determine the level of consensus. Rounds may continue until a pre-specified level of consensus is attained or a *'point of diminishing returns'* is reached (343: p.1221).
- Nominal group technique (NGT): published by Delbecq and Van de Ven in 1971 (344). This involves a panel of experts attending a private face-to-face meeting. The panellists confidentially generate ideas about specific questions then share them in a round robin format. A moderator leads a discussion of each idea in turn. The panellists then confidentially rank or rate the ideas. Additional rounds of discussions and ranking/ratings may occur. The rankings/ratings are aggregated statistically to determine consensus about which ideas to keep/discard.
- RAND-UCLA appropriateness method: developed by the RAND Corporation and UCLA (University of California-Los Angeles) in the 1980s (345). This may be described as a *'modified Delphi method'* (345: p.7) or *'modified NGT'* (335: p.5). The first step involves a core group of experts conducting a literature review and developing a list of clinical scenarios known as *'indications'* (345: p.3). A panel of different experts are provided with the synthesised review findings and rate the appropriateness of a specific procedure for each indication on a 1–9 scale. Two rounds of confidential ratings are typically used. The first is completed remotely. The panellists then attend a meeting to receive and

discuss a summary of the first round responses and complete the second round of ratings. The ratings are aggregated statistically to determine the appropriateness of the procedure for each indication.

- Consensus development conference: introduced by the United States National Institutes of Health in 1977 (346). This involves a panel of experts attending a face-to-face conference. Independent presenters share evidence on a specific topic in an open session. The panellists and public attendees can ask questions and discuss ideas. The panellists then meet privately in an executive session to discuss the topic further and develop a consensus statement that addresses pre-specified questions. A draft consensus statement may be reviewed in a plenary session and modified in another executive session if necessary. All the sessions are chaired.

Table 5.1 summarises key features of these consensus development methods.

Table 5.1: Main formal consensus development methods used in healthcare contexts

Method	Evidence presented	Remotely delivered survey(s)[a]	Private idea generation/ ranking/ rating	Meet face-to-face	Structured interactions	Formal feedback of group choices	Consensus based on statistical aggregation	Length of time to reach decisions	Panellist equality in decisions
Delphi technique	Optional	Yes (≥2)	Yes	No	Yes	Yes	Yes	Long	Yes
Nominal group technique	Optional	No	Yes	Yes	Yes	Yes	Yes	Short	Yes
RAND-UCLA appropriate-ness method	Yes	Yes (1)	Yes	Yes	Yes	Yes	Yes	Medium	Yes
Consensus development conference	Yes	No	No	Yes	No	No	No	Short	No

RAND, research and development (Corporation); UCLA, University of California-Los Angeles
[a] Surveys may be delivered by post, fax or the Internet.
Table based on Nair et al. (341), Murphy et al. (335) and Van de Ven and Delbecq (347).

The Delphi technique is the only one of these methods that is completed entirely remotely (341). This can enable a large number of geographically dispersed panellists to participate (348). The present study aimed to develop recommendations that are relevant throughout the UK. The Delphi technique was therefore chosen to facilitate inclusion of panellists from all four UK nations. Another benefit of the Delphi technique is that anonymity between panellists is maintained, avoiding group decisions being dominated by specific individuals (341). This was considered particularly important for this study because it included patient and professional panellists, and higher status individuals may exert stronger influences on group decisions (335). The flexibility of the Delphi technique is another important strength (340). Variants of the Delphi technique are frequently described using the term *'modified Delphi technique'* (349: p.691). Widespread consensus on what constitutes a modified Delphi technique is lacking (349), although the term is often used when the first round includes statements/questions developed from a literature review or interview/focus group findings rather than open-ended questions (340). A modified Delphi technique was chosen for this study to ensure that the methods were optimal for addressing the study aim, as detailed in section 5.2.3 below.

Various authors have developed resources for improving the rigour and/or reporting of Delphi studies (335, 349-351). The main resource used in this study was the Conducting and REporting of DElphi Studies (CREDES) reporting standard (349). This was chosen because it provides recommendations on both the conduct and reporting of Delphi studies and is the only Delphi study-specific reporting standard included on the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) Network library (352). The CREDES standard was developed during a systematic review of palliative care research (349). This presents a potential limitation of the CREDES standard when used in other specialities/disciplines. To account for this, the present study was also informed by Delphi study reporting quality indicators (QIs) proposed by Diamond et al. (350). These QIs were developed during a systematic review of consensus definitions in Delphi studies from multiple disciplines (350).

Figure 5.1 provides a flow chart summarising the study steps. Sections 5.2.2–5.2.5 provide further details of the methods employed.

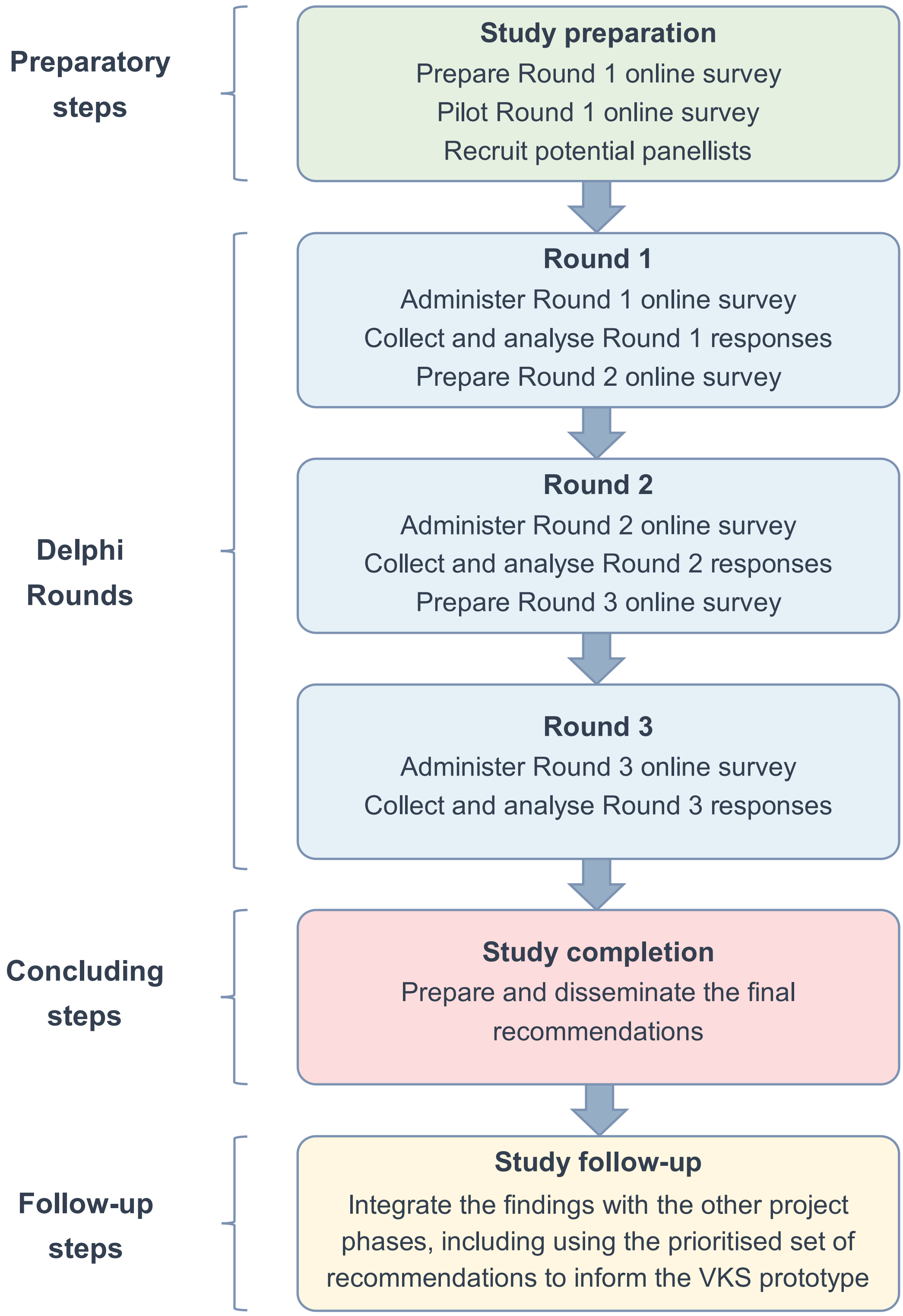


Figure 5.1: Flow chart of the Delphi process

VKS, Virtual Knee School
Flow chart steps based on the Conducting and REporting of DElphi Studies reporting standard (349).

5.2.2 Expert panel

5.2.2.1 Eligibility criteria

Although a homogenous expert panel may lead to greater agreement (335), a heterogenous panel was assembled to increase the credibility, relevance and acceptance of the findings (341, 353). To ensure that panellists could successfully complete the surveys and had relevant experience, only individuals who met the following inclusion criteria were eligible:

- adult (aged ≥18 years);
- able to communicate in English;
- able to use, and have access to, the Internet and email;
- have experience of TKR services through any the following:
  - patient who was listed for TKR;
  - patient who had undergone at least one TKR within the past two years;
  - health professional with experience of working with patients undergoing TKR in the NHS;
  - clinical commissioner with experience of commissioning orthopaedic services.

No exclusion criteria were specified to facilitate assembly of a sufficiently large and heterogenous panel.

5.2.2.2 Panel size

There is a lack of consensus on the optimal expert panel size for Delphi studies (340). Employing a larger panel increases the generalisability of the findings but requires more time and resources (340, 348). A target of 24–70 panellists was set in this study to ensure that key stakeholders were adequately represented and the panel was feasible to manage.

5.2.2.3 Sampling

A range of probability and non-probability sampling techniques may be employed in Delphi studies (340). These present different strengths and limitations (354). For example, probability sampling techniques facilitate the recruitment of a representative sample but are often very time-consuming (354). Non-probability sampling techniques are valuable for intentionally recruiting people with specific characteristics, whereas they are not appropriate when minimising the risk of selection bias is a priority (354). Recruiting appropriate experts is essential during Delphi studies; therefore, they often employ one or more non-probability sampling techniques (340). For this study, a combination of non-probability sampling techniques was chosen to help ensure that a sufficient number and diversity of panellists were recruited (340). The techniques chosen included availability sampling of patients and professionals, snowball sampling of professionals and stratified purposive sampling of a minimum number of patients and professionals from key groups (Table 5.2) (355-357). Professionals from groups not specified were also eligible as long as they met the study inclusion criteria.

Table 5.2: Sampling strategy

Panellist group	Experience of TKR	Number of panellists	Minimum group total	Maximum group total
Patient	Patient who was listed for TKR	≥6	12	35
	Patient who had undergone TKR	≥6		
Professional	Orthopaedic surgeon	≥2	12	35
	Advanced arthroplasty practitioner	≥2		
	Nurse	≥2		
	Physiotherapist	≥2		
	Occupational therapist	≥2		
	Clinical commissioner	≥2		
		Overall total	24	70

TKR, total knee replacement

5.2.2.4 Recruitment

Patients were recruited via Twitter, Facebook and in-person orthopaedic clinics at a large NHS teaching hospital in northern England. Patients were not actively encouraged to share information about the study. Patients who found out about the study via word-of-mouth were still eligible as long as they met the inclusion criteria. Professionals were recruited via Twitter, professional networks and encouraging professionals to pass information about the study onto other professionals. The study was also advertised to professionals via Facebook but no panellists reported hearing about the study via this route. One patient Facebook group, one professional Facebook group and four professional organisations assisted the recruitment. One additional patient Facebook group and three additional professional organisations were approached but did not agree to be involved in the study timeframe.

All potential participants were provided with the study Participant Information Sheet (PIS) and given the opportunity to discuss the study with the researcher in person, via telephone and/or via email. The PIS explained that the study purpose was to develop recommendations on pre-operative TKR care but did not provide details of the overall VKS project. This approach was chosen to help ensure that panellists' responses were not biased towards digital delivery formats. Details of the VKS project were still provided to individuals who requested them.

5.2.3 Data collection

Unlike in the Classical Delphi technique, the number of rounds in this study was pre-specified. This avoids the possibility of panellists agreeing simply to avoid completing further rounds (353). Systematic reviews suggest that most Delphi studies include two or three rounds (350, 358), but the optimal number of rounds is disputed (340). Three rounds were chosen for this study to increase convergence whilst minimising panellist attrition (340).

Data collection was undertaken between 13th December 2019 and 19th March 2020. Each survey was hosted using the *Online surveys* tool (235) and administered via email. This is quicker and less costly than using postal surveys (340). The *Online surveys* tool was chosen because it has been used successfully in previous Delphi studies (359, 360) and is provided by the University of Leeds. Panellists may forget the study purpose between rounds (353); therefore, each survey's introductory page provided a brief reminder of the study aim/methods and a link to the PIS. Each introductory page also included a Consent Statement that panellists were required to complete before accessing the remainder of the survey.

Rounds 1, 2 and 3 were kept open for five, four and three weeks respectively. The decision about when to close the round was based largely on optimising the response rate (348). Providing reminders also optimises response rates and appears to be acceptable to panellists (361, 362). In line with this, up to three reminders were provided to non-respondents per round. Most reminders were provided via email. This enabled inclusion of the survey hyperlink so that panellists could complete the round without needing to search for a previous email (362). Three panellists were also provided with a telephone reminder. This is a more personalised approach (362), but could not be used with all non-respondents because some opted not to provide their telephone number. Allowing non-respondents to participate in subsequent rounds helps to ensure that a sufficient number of panellists is retained (363). Rounds 2 and 3 were therefore administered to all individuals who completed Round 1. The median online time taken by panellists to complete Rounds 1, 2 and 3 was 20 minutes 18 seconds, 17 minutes 53 seconds and 16 minutes 31 seconds respectively.

5.2.3.1 Round 1

As highlighted in section 5.2.1, this study employed a modified Delphi technique to ensure that the methods were optimal for addressing the study aim. Round 1 included an initial set of pre-operative TKR intervention recommendations developed from the Phase 1a rapid review findings (Chapter 4, section 4.3). This ensured that a comprehensive range of pre-operative TKR intervention components and delivery approaches were considered whilst minimising panellist burden (362, 364). To maximise the value of the recommendations for guiding UK health professionals' decision-making on pre-operative TKR service provision, diverse pre-operative TKR intervention components and delivery approaches were considered, regardless of whether they could be addressed through a digital intervention.

Only studies included in the rapid review based on the searches conducted on 11th September 2019 were considered, as Round 1 was developed prior to the search updates. Intervention components/delivery approaches identified from these studies were included in the initial recommendations if they met one/both item inclusion criteria and no item exclusion criteria (Table 5.3). Intervention components/delivery approaches were grouped together where possible to keep the length of Round 1 manageable. The researcher discussed uncertainties about inclusion of particular intervention components/delivery approaches with her supervisors/advisors.

Table 5.3: Item eligibility criteria

Item inclusion criteria[a]	Item exclusion criteria
• Included in a pre-operative TKR intervention investigated in an outcomes study in which a statistically significant difference in favour of the intervention group was identified for at least one outcome at one or more follow-up time points (alpha=0.05) • Identified as valuable/important by at least one participant in a views study	• Adjunct component • Contradicts another intervention component/delivery approach • Dependent on another intervention component/delivery approach

TKR, total knee replacement

[a] Outcomes studies and views studies are defined in Chapter 4 (section 4.2).

The item eligibility criteria created a low threshold for including intervention components/delivery approaches in the initial recommendations. This ensured that potentially important items were not omitted from consideration. The subsequent Delphi rating process enabled unimportant items to be excluded from the final recommendations.

The initial recommendations covered the following five sections.

1. Pre-operative TKR education topics (29 items)
2. Pre-operative TKR education delivery (22 items)
3. Pre-operative TKR exercise types (14 items)
4. Pre-operative TKR exercise programme delivery (16 items)
5. Other pre-operative TKR treatments (5 items)

Panellists' interpretations of Delphi study items may vary (362). To promote a mutual understanding of the items, *'More info'* buttons, which panellists could select to display an explanation of the item, were provided where appropriate (Figure 5.2). Using this approach, rather than displaying the explanations as static text, helped to prevent the volume of text appearing overwhelming.

Recommendation 3

At a minimum, a pre-operative TKR exercise programme should include the following types of exercise:

Strengthening exercises

This part of the survey uses a table of questions, view as separate questions instead?

3.1 Leg strengthening exercises

Less info

Leg strengthening exercises aim to increase the strength and stamina of the patient's leg muscles. An example of a leg strengthening exercise is the straight leg raise. This involves the patient lying on their back with one knee straight and their other knee bent. The patient then tightens the thigh muscles of their straight leg and slowly lifts their leg upwards off the floor/bed. The patient holds their leg in the raised position for a set period of time, such as 5 seconds, and then slowly lowers it back down to the floor/bed.

	Not at all important	Not important	Neither important nor not important	Important	Very important
Please select one answer	☐	☐	☐	☐	☐

Figure 5.2: Round 1 item example with *'More info'* button selected

Various scoring systems are used within Delphi studies (348). These typically require panellists to rate the importance of, or their agreement with, each item on a Likert scale

(340, 348). An importance-based Likert scale was chosen for this study to facilitate prioritisation of the items. There is no consensus on the optimal number of Likert scale response options (365). Lozano et al. (366) suggest using between four and seven, as higher numbers improve the scale reliability and validity, but respondents may have difficulty distinguishing between large numbers of options. Correspondingly, a PAG PPI member felt that a five-point scale would be easier to complete than a scale with more response options. In line with this, panellists were asked to rate the importance of each item on a five-point Likert scale (Figure 5.2).

Each response option was displayed with a verbal label rather than a numerical one to ensure that all the options were meaningful (367). In addition, full verbal labelling may reduce *'extreme response style'* behaviours (selection of the scale endpoints only) (368: p.370). To help ensure that important items were not overlooked, free-text options were included at the end of each recommendation section, which enabled panellists to suggest additional items (348).

Round 1 included questions on panellists' characteristics, which were developed based on previous TKR-related Delphi studies (97, 369, 370) and discussions with the researcher's supervisors/advisors. To ensure that key details were obtained without overburdening panellists, separate sets of questions were provided for patient panellists (focused on their socio-demographic and clinical characteristics) and professional panellists (focused on their workplace, role and experience).

Prior to administration, Round 1 was extensively pilot tested to ensure that it was accessible, understandable and valid (348). The researcher, six of her supervisors/advisors, three physiotherapists, one nurse, two PAG PPI members and one additional PPI representative undertook the pilot testing using various devices and web browsers. None of the pilot testers joined the expert panel. The pilot testing led to minor wording/structural changes, inclusion of six additional *'More info'* explanations, inclusion of five new recommendation items and amendments to five recommendation items (Appendix C). The final version of Round 1 is available in Anderson et al. (371) (Additional File 2).

5.2.3.2 Round 2

Removing items that have reached consensus between rounds reduces the length of subsequent surveys, which may improve response rates (340). Retaining all items ensures that each item has equal opportunity of reaching as high a level of consensus and importance rating as possible (340). In this study, all the Round 1 recommendation items were retained to Round 2 to enable prioritisation of the items based on panellists' importance ratings in Round 3.

Providing feedback on the results of the preceding round is an essential component of the Delphi technique as it encourages panellists to reconsider their responses, helping to reconcile differing opinions (335, 348). Panellists are typically provided with group feedback and their individual responses (335). The restricted functionality of the *Online surveys* tool meant that providing panellists' individual responses would have required a separate survey to be created for each panellist. This was not feasible given the time and resources available. Panellists were therefore provided with group feedback only. There is no consensus on the optimal format for providing group feedback (348, 365). One option is to provide a summary statistic, with or without a measure of dispersion (348). This option is considered relatively easy to understand but risks masking divergences (372). Graphically displaying the distribution of responses avoids this and may aid panellists' interpretation (348, 365). Group feedback was therefore displayed graphically in this study.

Another consideration is whether to display the results for different stakeholder groups separately. The results of three nested RCTs suggest that providing patient and professional feedback separately leads to greater agreement than providing peer feedback only (373). A subsequent RCT did not support this, but that may have been due to the high initial level of agreement (372). Feedback on the responses of patients and professionals was therefore provided separately in this study. As explained in section 5.2.5, the ratings of all panellists were considered together when determining the final recommendations, so feedback on the ratings of the whole panel was also provided (Figure 5.3).

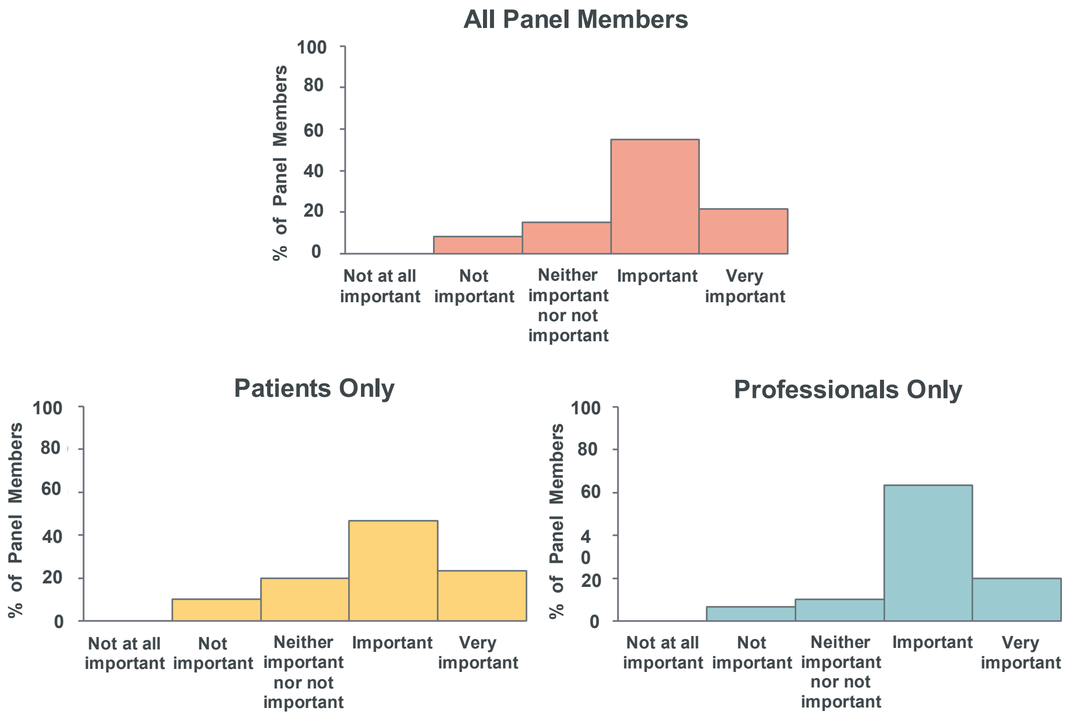
Recommendation 1

At a minimum, pre-operative TKR education should include the following topics:

Background information

This part of the survey uses a table of questions, view as separate questions instead?

1.1 Anatomy of the knee joint



More info

	Not at all important	Not important	Neither important nor not important	Important	Very important
Please select one answer	☐	☐	☐	☐	☐

Figure 5.3: Round 2 item example

New recommendation items developed from the Round 1 free-text responses were also included in Round 2. Panellists were asked to rate the importance of each item using the same five-point Likert scale as in Round 1 (Figure 5.3). To minimise panellist and researcher burden, no free-text options were provided.

5.2.3.3 Round 3

The approach used in Round 2 was repeated in Round 3. Round 3 therefore included all the Round 2 items, each accompanied by three graphical displays summarising the Round 2 importance ratings for that item. Panellists were asked to rate the importance of each item using the same five-point Likert scale as in Rounds 1 and 2.

5.2.4 Qualitative data analysis

The Round 1 free-text responses were analysed in Microsoft Excel 2016 and Microsoft Word 2016. The primary aim of the free-text data analysis was to identify additional recommendation items to include in Round 2. A secondary aim was to explore panellists' perspectives of pre-operative TKR intervention components and delivery approaches to help inform the subsequent phases of this project. The data were analysed using directed content analysis (223, 224). This is an established approach for condensing free-text Delphi survey responses into a manageable number of items for subsequent rounds (340). Content analysis is a qualitative descriptive approach and hence is appropriate for analysing data when only a limited level of interpretation is required (374). A benefit of content analysis over thematic analysis, another commonly used qualitative descriptive approach, is that content analysis can include quantification of the qualitative data (374). Content analysis approaches can be classified as conventional, directed and summative (223). Directed content analysis was chosen for this study so that the analysis could be informed by the Round 1 survey.

The content analysis was guided by the method outlined by Assarroudi et al. (224). This involved using the Round 1 survey to develop a formative categorisation matrix in which each recommendation section was considered a main category and each recommendation item was considered a potential subcategory. Table 5.4 provides an excerpt from this matrix. The full two-page formative categorisation matrix is available in Anderson et al. (371) (Additional File 3).

Table 5.4: Formative categorisation matrix excerpt

Main category	Definition	Coding rules	Anchor sample[a]	Potential subcategories
4. Pre-operative TKR exercise programme delivery	How an exercise programme could be provided to patients listed for TKR surgery	Any aspects related to how an exercise programme could be provided to patients listed for TKR surgery, excluding the type of exercise.	*"I would not have been able to get time off work to attend exercise classes beforehand …"*	Recommendations 4.1–4.9

TKR, total knee replacement

[a] The anchor samples were selected from panellists' Round 1 free-text responses.

The main data analysis phase involved identifying *'meaning units'* (224: p.51). These can be defined as:

> 'words, sentences or paragraphs containing aspects related to each other through their content and context.' (375: p.106)

One or more meaning units were identified from each Round 1 free-text response. Each meaning unit was labelled with an inductively generated code. Where possible, codes were grouped within the potential subcategories specified in the formative categorisation matrix. Codes that did not fit within the pre-specified subcategories were grouped into new, inductively generated subcategories. All the subcategories were grouped into generic categories using a mixed inductive and deductive approach. The generic categories were then reviewed to decide whether any new main categories were required. The researcher undertook all steps of the content analysis. To help ensure trustworthiness, the researcher documented the relationship between the meaning units, codes, subcategories and generic categories in a categorisation matrix. All aspects of the categorisation matrix were verified by at least one of the researcher's supervisors (GAM, CC).

Each inductively generated subcategory that related to a pre-operative TKR intervention component or delivery approach was considered a potential new item for Round 2. The approach for deciding which new items to include in Round 2 was specified *a priori* in the protocol. This stated that all new items would be included in Round 2 unless that would result in the survey requiring substantially longer than 30 minutes to complete, in which case only new items suggested by more than a threshold percentage of panellists would be included. The approach aimed to ensure that all potentially important items were considered without overburdening panellists.

5.2.5 Quantitative data analysis

The quantitative data from all rounds were analysed descriptively using Microsoft Excel 2016 and IBM ® SPSS ® Statistics 23. A range of analytical approaches may be used to determine consensus in Delphi studies (376). Agreement on the optimal approach is lacking (350). The most commonly used approaches involve descriptive statistics, such as percentage agreement or a measure of central tendency (349, 350). When percentage agreement is used, the threshold is frequently set at 70% or higher (349, 350, 377, 378); therefore, consensus in this study was defined as at least 70% of respondents rating an item as *'Important'* or *'Very important'*. The choice of analysis approach can substantially affect the overall Delphi study findings (376). Pre-specifying how consensus will be defined is therefore essential to avoid data mining and selective reporting (376). However, this may lead to some items being omitted due to narrowly missing the arbitrary consensus threshold (350). To account for this, the present study's protocol specified that the 70% threshold would be adjusted if required following discussion with the PAG. After completion of Round 3, the PAG agreed that an adjustment was not required.

In addition to calculating the percentage of *'Important'* or *'Very important'* ratings, the median and interquartile range (IRQ) were calculated. This enabled exploration of the impact of using an alternative definition of consensus and changes in the dispersion of panellists' ratings between rounds. A median of at least 4 was chosen as the alternative definition of consensus because the median is frequently used to define consensus in Delphi studies (350). In addition, the median is more appropriate for ordinal data and more robust to outliers than the mean (379).

The importance ratings were analysed for all panellists considered together and for patient and professional panellists considered separately. This approach was essential to enable development of Rounds 2 and 3. In addition, it allowed comparisons between patient and professional panellists' ratings to be made.

The final set of recommendations included all items that reached consensus in Round 3 amongst all respondents considered together. To address objective 1, a concise version of the final recommendations was developed by grouping similar items together. For example, all items about pre-operative TKR education delivery formats were grouped into a single statement.

To address objective 2, a prioritised version of the final recommendations was developed by grouping items into the following categories.

- Very important recommendations: items rated *'Very important'* by at least 70% of all respondents in Round 3, ranked according to the percentage of *'Very important'* ratings.
- Important recommendations: items rated *'Important'* or *'Very important'* by at least 70% of all respondents in Round 3 (excluding those categorised as *'Very important'*), ranked according to the percentage of *'Important'* or *'Very important'* ratings.
- Excluded recommendations: items rated *'Important'* or *'Very important'* by less than 70% of all respondents in Round 3, ranked according to the percentage of *'Important'* or *'Very important'* ratings.

5.3 Findings

5.3.1 Expert panel

The expert panel comprised 60 panellists (30 patients, 30 professionals). Rounds 2 and 3 were completed by 95% and 92% of panellists respectively. Figure 5.4 presents the flow of individuals through the study. Tables 5.5 and 5.6 present the patient and professional characteristics respectively.

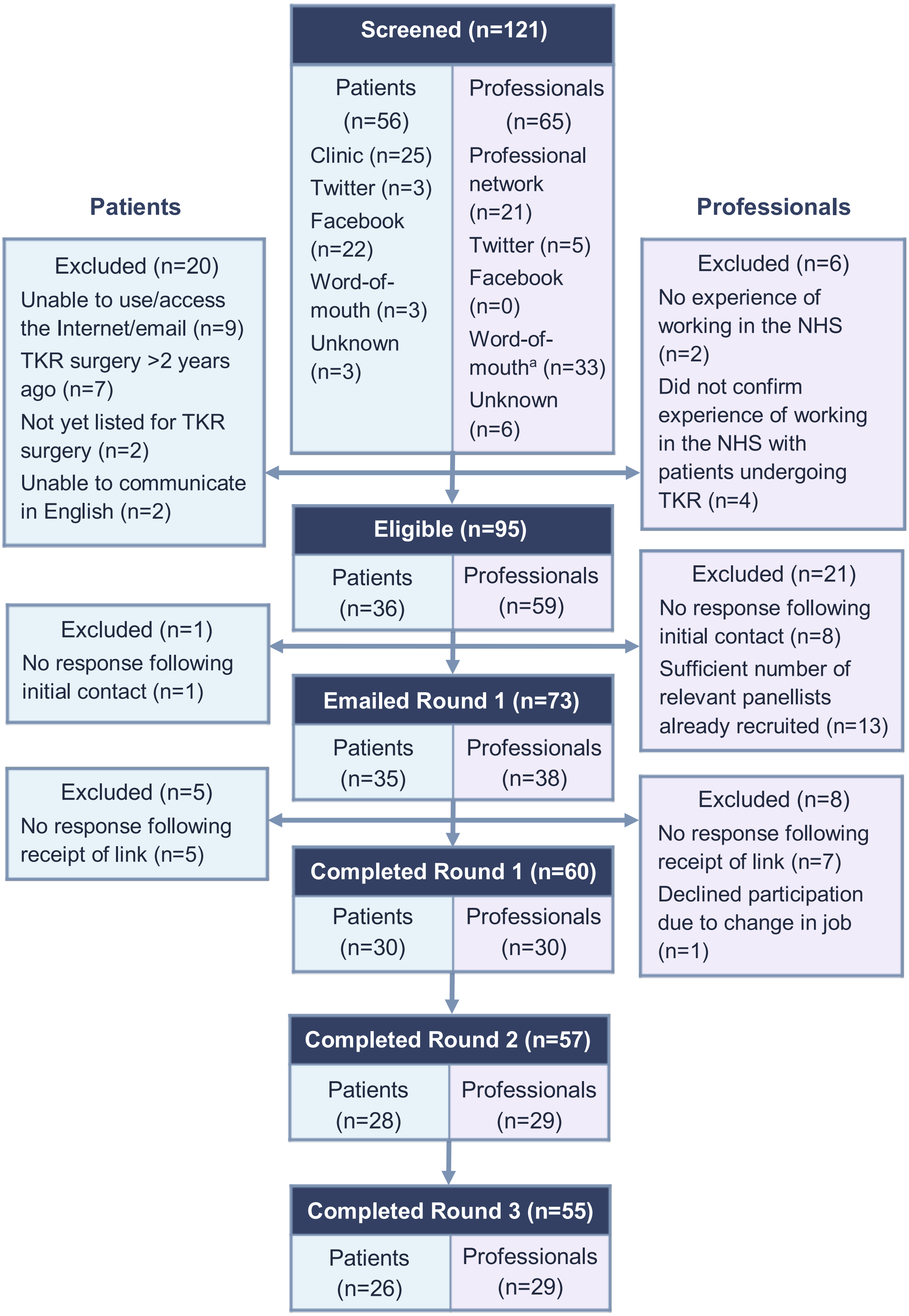


Figure 5.4: Modified Delphi study panellist flow chart

NHS, National Health Service; TKR, total knee replacement

[a] Includes professionals recruited through encouraging professionals to share the study details with other professionals.

Table 5.5: Patient panellists' characteristics

	Number of panellists (%) (n=30)
Living location	
Scotland	1 (3)
North East	3 (10)
North West	5 (17)
Yorkshire and the Humber	7 (23)
East Midlands	1 (3)
West Midlands	3 (10)
South West	1 (3)
South East	4 (13)
East of England	5 (17)
Age (years)	
40–49	4 (13)
50–59	9 (30)
60–69	11 (37)
70–79	6 (20)
Gender	
Male	10 (33)
Female	20 (67)
Ethnicity	
White British	30 (100)
Highest educational qualification	
None	4 (13)
GCSE/O Level (or equivalent)	5 (17)
A Level (or equivalent)	2 (7)
Vocational qualification (or equivalent)	10 (33)
Undergraduate degree	3 (10)
Postgraduate degree	6 (20)
Current employment status[a]	
Employed full-time	9 (30)
Employed part-time	7 (23)
Retired	13 (43)
Sick leave	2 (7)
Medically disabled	2 (7)
Experience of TKR[a]	
Listed for TKR	11 (37)
Previously undergone TKR	23 (77)

TKR total knee replacement

[a] Panellists could select more than one option

Table 5.6: Professional panellists' characteristics

	Number of panellists (%) (n=30)
Workplace location	
Scotland	2 (7)
Northern Ireland	4 (13)
Wales	2 (7)
North West	5 (17)
Yorkshire and the Humber	9 (30)
South West	3 (10)
South East	1 (3)
London	4 (13)
Current professional role[a]	
Orthopaedic surgeon	5 (17)
Advanced arthroplasty practitioner	2 (7)
Nurse	2 (7)
Physiotherapist	12 (40)
Occupational therapist	4 (13)
Rehabilitation assistant	3 (10)
Psychotherapist	1 (3)
Clinical commissioner	3 (10)
Manager	2 (7)
Researcher	2 (7)
Experience as a health professional (years)	
0–9	5 (17)
10–19	11 (37)
20–29	9 (30)
30–49	5 (17)
Workplace setting[a]	
NHS teaching hospital	18 (60)
NHS district/general hospital	7 (23)
Private Hospital or other private location(s)	5 (17)
Commissioning organisation	3 (10)
Increasing Access to Psychological Therapies	1 (3)
Currently provide clinical care to patients who are listed for/have undergone TKR	
Yes	27 (90)
No	3 (10)
Phases of the TKR pathway currently work in (n = 27)[a,b]	
Pre-operative phase	20 (74)
Acute phase	20 (74)
Post-operative phase	19 (70)
Number of patients who were listed for or had undergone TKR seen during previous week (n = 27)[b]	
0	2 (7%)
1–2	4 (15%)
3–5	2 (7%)

6–10	9 (33%)
>10	10 (37%)

TKR total knee replacement

[a] Panellists could select more than one option

[b] Only includes panellists who indicated that they currently provide clinical care to patients who are listed for/have undergone total knee replacement

5.3.2 Free-text responses

Free-text responses were provided by thirty-eight panellists (15 patients, 23 professionals). Table 5.7 provides an excerpt from the final 30-page categorisation matrix. The matrix with all the categories and codes, but not the individual meaning units, is available in Anderson et al. (371) (Additional File 5).

Table 5.7: Final categorisation matrix excerpt

Main category 2: Pre-operative TKR education delivery						
Generic category		**Subcategory**		**Codes**		**Meaning unit [Panellist]**
Generic category name	**MU**	**Subcategory name**	**MU**	**Codes**	**MU**	
Practical arrangements	6	2.9 Provide an opportunity for family member/friend to be involved	1	Impact of family/friend involvement	1	Involvement of family & friends = useful, but can make sessions rather large numbers. [Physiotherapist 691]
		Timing of delivery[a]	5	Importance of considering timing	3	Time between education (group joint school session) and operation. [Physiotherapist 676] Pre-op education needs to be timely … [Post-operative patient 688] Timing of sessions = important … [Physiotherapist 691]
				Optimal timing	2	Education pre op day best … [Surgeon 677] Timing of sessions = important (not too far away that forget critical information bu [sic] not so near that difficult to make any changes). Approx 2-4 weeks pre op = optimal [Physiotherapist 691]

MU, number of meaning units contributing to the code/category; TKR, total knee replacement

[a] New inductively generated main category defined in Round 2 as *‘At a minimum, at least some pre-operative TKR education should be delivered within 4 weeks of the patient’s TKR surgery’* (Item 2.13).

Although most codes fitted within the pre-specified subcategories, 34 new subcategories were inductively generated. Seven of these did not relate to a specific intervention component or delivery approach. These seven subcategories were grouped into a new main category, *'Planning and prioritising TKR care',* and were not considered potential new items for Round 2. Details of the new main category are provided in Anderson et al. (371) (Additional File 6).

The remaining 27 new subcategories fitted within the five pre-specified main categories and were considered potential new items for Round 2. Piloting of Round 2 by the researcher and her supervisors/advisors suggested that inclusion of all 27 items could lead to the survey taking significantly longer than 30 minutes to complete. Correspondingly, only new items proposed by at least two panellists (3% of all panellists) were included in Round 2. This led to Round 2 including 15 new items. These new items are listed in Anderson et al. (371) (Additional File 7).

Notable findings regarding panellists' perspectives of pre-operative TKR intervention components/delivery approaches included the following.

- Multiple panellists commented on the importance of tailoring pre-operative TKR education and exercise interventions to patients' individual needs. A range of considerations related to tailoring were mentioned, including age, comorbidities, disability, previous TKR, language needs, learning style, work status, motivation and personal preferences. Correspondingly, panellists highlighted positives and negatives for certain intervention components/delivery approaches. For example, a patient commented that having *"a website to refer to would be invaluable"*, whilst two professional panellists highlighted that some patients cannot access the Internet.
- Various inadequacies in current TKR care provision were noted, such as a lack of personal tailoring and inadequate guidance on pre-operative exercise. Health professionals identified pragmatic factors that could contribute to inadequacies. For example, a physiotherapist commented *"Ideally exercises would be started 6-12 weeks prior to surgery but often we don't see the patients early enough to do this in practical terms".*
- Whilst some panellists commented on the value of pre-operative TKR exercise, others expressed concerns about specific exercise types or pre-operative exercise in general. For example, a post-operative patient felt that strengthening exercises were *"key"* but it was *"probably too late for the others"*, whilst an advanced arthroplasty practitioner reported feeling *"uncertain""* about the benefits of pre-operative exercise.

5.3.3 Importance ratings overview

This section provides an overview of panellists' importance ratings. Sections 5.3.4–5.3.8 below provide further details of panellists' importance ratings for each recommendation section. Table 5.8 presents the number of recommendation items included, and the number that reached consensus, in each round. The concise set of recommendations (four pages), additional details of the importance ratings (45 pages) and prioritised set of recommendations (six pages) are available in Additional Files 8, 9 and 10 of Anderson et al. (371) respectively.

Table 5.8: Recommendation items summary

Recommendation section	Number of recommendation items					
	Round 1		Round 2		Round 3	
	Total[a]	Reached consensus[b]	Total[a]	Reached consensus[b]	Total[a]	Reached consensus[b]
Pre-operative TKR education topics	29	28	35	34	35	34
Pre-operative TKR education delivery	22	14	25	17	25	18
Pre-operative TKR exercise types	14	7	17	8	17	10
Pre-operative TKR exercise delivery	16	8	19	11	19	13
Other pre-operative TKR treatments	5	0	5	1	5	2
All recommendation items	**86**	**57**	**101**	**71**	**101**	**77**

TKR, total knee replacement

[a] Total number of recommendation items included in the round.

[b] Number of recommendation items in the round that reached consensus. Consensus was defined as at least 70% of respondents rating an item as *'Important'* or *'Very important'*.

Based on the pre-specified consensus definition of at least 70% of respondents rating an item as *'Important'* or *'Very important'*, 77 items were included in the final recommendations. If consensus had been defined as a median of at least 4, an additional four items (2.5.2; 2.5.4; 3.2; 3.9) would have been included. Amongst the 86 recommendation items included from Round 1, the number that reached consensus increased from 57 to 60 to 65 in Rounds 1, 2 and 3 respectively. Amongst the 15 items added in Round 2, the number that reached consensus increased from 11 to 12 in Rounds 2 and 3 respectively. The percentage of items for which the IRQ was zero increased from 6% to 20% to 36% in Rounds 1, 2 and 3 respectively.

Although the importance ratings of patient and professional panellists were similar, patient panellists generally provided lower ratings. This difference was most marked in Round 1. Thirteen, six and five items reached consensus amongst professional but not patient panellists in Rounds 1, 2 and 3 respectively. Three, five and one item(s) reached consensus amongst patient but not professional panellists in Rounds 1, 2 and 3 respectively. Sixteen items were prioritised as *'Very important'* and 61 as *'Important'*.

5.3.4 Pre-operative education topics

Of the 29 education topic items included in Round 1, 28 reached consensus in all three rounds. One (1.21) did not reach consensus in any round. Six new education topic items were added in Round 2, all of which reached consensus in Rounds 2 and 3. Thirty-four education topic items were therefore included in the final recommendations. All of these items reached consensus amongst patient and professional panellists in Round 3. Twelve education topic items were prioritised as *'Very important'* and 22 as *'Important'* (Table 5.9).

Table 5.9: Pre-operative education topics importance ratings summary

Pre-operative TKR education topic item[a]	% Important or Very Important rating		
	Round 1 (n=60)	Round 2 (n=57)	Round 3 (n=55)
1.1 Anatomy of the knee joint	77	91	95
1.2 Health conditions that may contribute to needing TKR surgery	77	95	91
1.3 Alternative treatment options to TKR surgery	82	91	87
1.4 Purpose of pre-operative rehabilitation	98	98	98
1.5 Patient involvement in their own management	98	100	98
1.6 Goal setting	88	93	96

1.7 Using heat and cold	87	88	85
1.8 Obtaining and using walking aids and other equipment	95	96	95
1.9 Making home preparations	98	98	100
1.10 Arranging social support	88	95	96
1.11 Arranging transport to and from the hospital	82	91	98
1.12 What to expect during the hospital stay	98	100	100
1.13 What a TKR surgical procedure involves	92	89	93
1.14 Risks of TKR surgery and how to minimise them	97	100	100
1.15 Common issues that may occur following TKR surgery which do not need to cause alarm	93	98	100
1.16 Pain expectations	97	100	100
1.17 What to expect following discharge	95	98	100
1.18 Recovery expectations	98	98	98
1.19 Pain management	100	100	100
1.20 Rehabilitation following TKR surgery	100	100	100
1.21 Complementary and alternative therapies	28	21	27
1.22 Returning to daily activities	93	100	98
1.23 Returning to driving and other types of travel	95	96	98
1.24 Returning to sports and leisure activities	90	89	96
1.25 Returning to work	88	95	95
1.26 Physical activity	95	98	100
1.27 Weight management	90	98	100
1.28 Stopping smoking	80	84	85
1.29 Avoiding alcohol misuse	73	82	87
1.30 Optimising management of diabetes	N/A	77	82
1.31 Education for other people, such as carers	N/A	82	91
1.32 Swelling	N/A	98	100
1.33 Organising help if complications occur	N/A	100	100
1.34 Returning to a normal walking pattern	N/A	93	98
1.35 Emotional well-being	N/A	89	93

N/A, not applicable because the item was not included in Round 1; TKR, total knee replacement

[a] The item in italics did not reach consensus in Round 3 and hence was excluded from the final recommendations. Items in bold were prioritised as *'Very important'*. Items in plain text were prioritised as *'Important'*.

5.3.5 Pre-operative education delivery

Of the 22 education delivery items included in Round 1, 14 reached consensus in all three rounds, one (2.12) reached consensus in Rounds 2 and 3 only and one (2.3) reached consensus in Round 3 only. The remaining six education delivery items included from Round 1 did not reach consensus in any round. Three new education delivery items were added in Round 2. Two of these items (2.13; 2.15) reached consensus in Rounds 2 and 3. The remaining item (2.14) did not reach consensus in either round. Eighteen education delivery items were therefore included in the final recommendations. All these items reached consensus amongst patient and professional panellists in Round 3. Two education delivery items (2.2.3; 2.8) were prioritised as *'Very important'* and 16 as *'Important'* (Table 5.10).

Table 5.10: Pre-operative education delivery importance ratings summary

Pre-operative TKR education delivery item[a]	% Important or Very Important rating		
	Round 1 (n=60)	Round 2 (n=57)	Round 3 (n=55)
2.1 Informed by a multidisciplinary team	75	91	96
2.2.1 Informed by members of the orthopaedic surgery team	82	93	95
2.2.2 Informed by members of the nursing team	72	86	95
2.2.3 Informed by members of the physiotherapy team	95	98	100
2.2.4 Informed by members of the occupational therapy team	80	88	85
2.2.5 Informed by members of the social work team	42	42	31
2.3 Informed by patients who have previously had TKR surgery	63	67	73
2.4 Provide examples of other patients' experiences of TKR surgery	70	77	76
2.5.1 Delivered using face-to-face group sessions	78	89	89
2.5.2 Delivered using face-to-face individual sessions	45	56	56
2.5.3 Delivered using a booklet or other written format	88	98	100
2.5.4 Delivered using a video or DVD	63	65	64
2.5.5 Delivered using a website or other electronic format	72	74	75
2.5.6 Delivered using telephone	25	18	18
2.5.7 Delivered using a PowerPoint presentation	32	23	25
2.6 Delivered using a combination of more than one format	87	93	93
2.7 Delivered through a combination of information provision and an opportunity to actively take part in tasks	78	95	96
2.8 Provide an opportunity for questions to be addressed	97	100	100

2.9 Provide an opportunity for a family member/friend to be involved	80	91	93
2.10 Tailored to each patient's needs	85	82	91
2.11 Tailored to the right or left knee	13	7	2
2.12 Received separately from patients waiting for other types of surgery	67	75	76
2.13 Delivered within 4 weeks of TKR surgery	N/A	79	84
2.14 Delivered in a hospital setting	N/A	33	22
2.15 Standardised across the UK	N/A	72	80

N/A, Not applicable because the item was not included in Round 1; TKR, Total knee replacement

[a] Items in italics did not reach consensus in Round 3 and hence were excluded from the final recommendations. Items in bold were prioritised as *'Very important'*. Items in plain text were prioritised as *'Important'*. Additional Files 2 and 7 in Anderson et al. (371) provide the exact wording of each item.

5.3.6 Pre-operative exercise types

Of the 14 exercise type items included in Round 1, seven reached consensus in all three rounds and two (3.11; 3.12) reached consensus in Round 3 only. The remaining five exercise type items included from Round 1 did not reach consensus in any round. Three new exercise type items were added in Round 2. One of these (3.15) reached consensus in Rounds 2 and 3. The remaining two items (3.16; 3.17) did not reach consensus in either round. Ten exercise type items were therefore included in the final recommendations. Two of the included items (3.11; 3.12) reached consensus amongst professional but not patient panellists in Round 3. One item (3.2) reached consensus amongst patient but not professional panellists in Round 3. Item 3.2 did not reach consensus amongst all panellists considered together; therefore, in line with the pre-specified analysis plan, it was excluded from the final recommendations. Two exercise type items (3.1; 3.3) were prioritised as *'Very important'* and eight as *'Important'* (Table 5.11).

Table 5.11: Pre-operative exercise types importance ratings summary

Pre-operative total knee replacement exercise type item[a]	% Important or Very Important rating		
	Round 1 (n=60)	Round 2 (n=57)	Round 3 (n=55)
3.1 Leg strengthening exercises	98	100	100
3.2 Arm strengthening exercises	43	51	64
3.3 Leg flexibility exercises	83	95	98
3.4 Arm flexibility exercises	27	25	29
3.5 Torso flexibility exercises	43	32	27
3.6 Balance exercises	85	95	100
3.7 Functional movement exercises	87	96	95
3.8 Functional technique exercises	80	89	91
3.9 Warm-up exercises	58	60	55
3.10 Cool-down exercises	48	44	36
3.11 Cardiovascular exercises	60	67	75
3.12 Core control exercises	60	68	76
3.13 Walking practice with walking aids	83	88	91
3.14 Training on steps	83	91	95
3.15 Practicing post-operative exercises	N/A	89	96
3.16 Water-based exercises	N/A	32	25
3.17 Exercises in which the foot does not move	N/A	39	18

N/A, Not applicable because the item was not included in Round 1

[a] Items in italics did not reach consensus in Round 3 and hence were excluded from the final recommendations. Items in bold were prioritised as *'Very important'*. Items in plain text were prioritised as *'Important'*.

5.3.7 Pre-operative exercise programme delivery

Of the 16 exercise programme delivery items included in Round 1, eight reached consensus in all three rounds, one (4.1.3) reached consensus in Rounds 2 and 3 only and one (4.7) reached consensus in Round 3 only. The remaining six exercise delivery items included from Round 1 did not reach consensus in any round. Three new exercise delivery items were added in Round 2. Two of these (4.10, 4.12) reached consensus in Rounds 2 and 3 and one (4.11) reached consensus in Round 3 only. Thirteen exercise delivery items were therefore included in the final recommendations. One of these (4.11) reached consensus amongst professional but not patient panellists in Round 3. All 13 included exercise delivery items were prioritised as *'Important'* (Table 5.12).

Table 5.12: Pre-operative exercise programme delivery importance ratings summary

Pre-operative total knee replacement exercise programme delivery item[a]	% Important or Very Important rating		
	Round 1 (n=60)	Round 2 (n=57)	Round 3 (n=55)
4.1.1 Delivered using an individual instruction session	52	53	44
4.1.2 Delivered using supervised exercise sessions	73	79	89
4.1.3 Delivered using unsupervised exercise sessions	58	72	91
4.1.4 Delivered using telephone-delivered sessions	5	9	5
4.1.5 Delivered using a booklet or other written format	87	93	93
4.2 Delivered using a combination of more than one format	87	96	91
4.3.1 Take place in the patient's own home	53	46	36
4.3.2 Take place in a clinical setting	52	47	47
4.3.3 Take place in a community setting	52	40	33
4.4.1 Include high intensity exercises	33	14	22
4.4.2 Include low to moderate intensity exercises	75	91	98
4.5 Tailored to the patient's ability	93	96	96
4.6 Be progressive	82	91	87
4.7 Each session should last a minimum of 15 minutes	63	63	80
4.8 Involve a minimum of 2 sessions per week	78	79	84
4.9 Ideally be performed for a minimum of 6 weeks	80	88	89
4.10 Tailored to each patient's needs	N/A	88	93
4.11 Provide an opportunity for peer support	N/A	65	75
4.12 Include goal setting	N/A	79	87

N/A, Not applicable because the item was not included in Round 1

[a] Items in italics did not reach consensus in Round 3 and hence were excluded from the final recommendations. Items in plain text were prioritised as *'Important'*. Additional Files 2 and 7 in Anderson et al. (371) provide the exact wording of each item.

5.3.8 Other pre-operative treatments

Of the five other treatment items included in Round 1, one (5.2) reached consensus in Rounds 2 and 3 only and one (5.1) reached consensus in Round 3 only. The remaining three other treatment items did not reach consensus in any round. No additional other treatment items were added in Round 2. Two other treatment items (5.1; 5.2) were therefore included in the final recommendations. Both these items reached consensus amongst professional but not patient panellists in Round 3 and were prioritised as *'Important'* (Table 5.13).

Table 5.13: Other pre-operative treatments importance ratings summary

Other pre-operative total knee replacement treatment item[a]	% Important or Very Important rating		
	Round 1 (n=60)	Round 2 (n=57)	Round 3 (n=55)
5.1 Patients who have a BMI of ≥27kg/m² should be referred to a weight management programme	67	67	73
5.2 Patients who have been formally diagnosed with anxiety or depression should be offered CBT-based therapy	67	74	78
5.3 Patients should be offered motivational interviewing	38	37	33
5.4 Patients should be offered neuromuscular electrical stimulation	17	5	4
5.5 Patients should be offered electro-acupuncture	8	0	0

BMI, Body Mass Index; CBT, Cognitive behavioural therapy

[a] Items in italics did not reach consensus in Round 3 and hence were excluded from the final recommendations. Items in plain text were prioritised as *'Important'*. Additional File 2 in Anderson et al. (371) provides the exact wording of each item.

5.4 Discussion

5.4.1 Main findings

This UK-based modified Delphi study built on the findings of the Phase 1a rapid review reported in Chapter 4 to develop recommendations on the content and delivery of pre-operative TKR interventions. Seventy-seven items were included in the final recommendations, of which the largest proportion are education topics (Table 5.8). Correspondingly, education topics comprise 12 of the 16 items prioritised as *'Very important'* (Table 5.9). Notably for the VKS project, pre-operative TKR education delivery via a website/other electronic format was included in the final recommendations. Education delivery using a combination of formats was also included in the final recommendations. This could counter the concerns about Internet access raised by two panellists. Pre-operative TKR exercise programme delivery via a website/other electronic format was not included in any round. However, exercise delivery using unsupervised exercise sessions was included in the final recommendations and could be supported through a digital intervention. Furthermore, data collection for this study was completed before the first COVID-19-related UK lockdown. The results do not therefore reflect the increased impetus for remote models of care that has arisen during the COVID-19 pandemic (37, 380).

Consensus in this study was defined as at least 70% of respondents rating an item as *'Important'* or *'Very important'*. An alternative approach would have been to define consensus as a median of at least 4. This would have led to the inclusion of an additional four items in the final recommendations. One of these was delivery of education using a video or DVD. This item could readily be addressed through a digital intervention; therefore, the use of videos was explored further during the Phase 2 qualitative descriptive study reported in Chapter 6. The number of items that reached consensus, and the percentage of items for which the IRQ was zero, increased in each subsequent round of this study. Repeating the Delphi rounds therefore achieved its intended purpose. Conducting additional Delphi rounds may have led to further changes, but would have risked higher participant attrition (340).

This study's expert panel consisted of 30 patients and 30 professionals, of whom 87% and 97% completed the final round respectively. The importance ratings of patient and professional panellists were similar, although patients' ratings tended to be lower. In the final round, only one item reached consensus amongst patient but not professional panellists, whilst five reached consensus amongst professional but not patient panellists. Although the reasons for this could not be explored in the present study, it is possible that patient panellists provided more conservative ratings because they felt less confident in their decision-making (381). One of the items that reached consensus amongst professional but not patient panellists states *'A pre-operative TKR exercise programme should provide an opportunity for peer support'.* This was surprising given that many of the patient panellists were recruited through a Facebook support group. Based on research conducted amongst individuals with OA (382), a potential explanation for this is that patients may have been concerned about comparing themselves to their peers.

The final recommendations state that pre-operative TKR education and exercise programmes should be tailored to each patient's individual needs and delivered using more than one format, supporting key findings from the Phase 1a rapid review reported in Chapter 4 (section 4.3). Additionally, the large number of education topics included in the final recommendations supports the rapid review finding that comprehensive pre-operative TKR education is valued. None of the items related to the setting of pre-operative TKR exercise programmes reached consensus (Table 5.12). This corresponds with an RCT included in the rapid review, which found that hospital- and home-based pre-operative TKR exercise programmes had similar effects (284). The rapid review also included an RCT by Domínguez-Navarro et al. (290) that found the effectiveness of a pre-operative TKR exercise programme was not dependent on the inclusion of balance training. Conversely, balance training was rated *'Important'* or *'Very important'* by 100% of panellists in the final round of this study. This discrepancy could be due to various factors. In particular, the exercise programme investigated by Domínguez-Navarro et al. (290) lasted four weeks only, whereas the final recommendations in this study state that pre-operative TKR exercise programmes should ideally last at least six weeks. Additionally, the RCT by Domínguez-Navarro et al. (290) was not published until after completion of this study.

5.4.2 Comparison with previous similar studies

The findings of this study expand those of previous consensus-based studies addressing TKR care (97, 320, 322, 336, 337). The most relevant previous study is the Canadian study by Westby et al. (97), which was included in the Phase 1a rapid review (Chapter 4, section 4.3). Westby et al. (97) employed a modified RAND-UCLA approach with an 18-member expert panel to develop QIs on pre- and post-operative rehabilitation for patient undergoing TKR or THR due to OA. The pre-operative TKR intervention QIs largely correspond with the recommendations developed in this study. However, this study's recommendations are more detailed. For example, the pre-operative TKR education QI developed by Westby et al. (97) specifies seven broad topic areas, whereas the present study's recommendations include 34 education topics (Table 5.9). In addition, there are disparities between the pre-operative TKR exercise QI developed by Westby et al. (97) and the present study's recommendations. For example, the QI developed by Westby et al. (97) does not mention balance exercises. Another disparity is that Westby et al. (97) did not include a pre-operative TKR psychological intervention QI, whereas CBT-based therapy is included in the present study's recommendations. These disparities are likely to be related to a combination of factors, such as differences in the studies' methodologies, expert panel compositions and healthcare contexts (97, 339).

5.4.3 Limitations

A key limitation of this study is that inclusion of items in the final recommendations was based solely on expert consensus, rather than empirical evidence. The recommendations must therefore be interpreted and revised as necessary as new evidence becomes available. The design of this study also presents limitations. Notably, items were not amended or removed between rounds, and panellists were not asked to rank any times. This provided a transparent process and enabled a prioritised set of recommendations to be developed, as all items had equal opportunity of reaching as high a level of consensus as possible (340). However, this approach meant that directly contradictory items could not be included. Correspondingly, aspects such as the optimal exercise programme duration could not be thoroughly explored. This is an important limitation given that the exercise programme duration was a key area of uncertainty highlighted in the Phase 1a rapid review (Chapter 4, section 4.4.1). Addressing this would have required a different design, such as that used by Robinson et al. (378) in their modified Delphi study of chair-based exercise. Robinson et al. (378) allowed panellists to comment on each statement and amended and removed items between rounds. Their approach facilitated exploration of aspects such as the optimal exercise programme delivery, but did not enable prioritatisation of the items. Furthermore, including free-text options for each item in this study would arguably have been inappropriate because, combined with the large number of items, it is likely to have made the surveys appear overwhelmingly long.

Panellists in this study were not provided with their individual ratings from the previous round, mainly due to the limited functionality of the *Online surveys* tool. This is a potential limitation as providing panellists with their individual ratings may help to inform their decision-making (358). This could have been addressed by providing panellists with their individual ratings in a Portable Document Format (PDF) document (359), or using Delphi-specific software such as Delphi Manager (383). Panellists' free-text comments suggested that not all panellists had read the *'More info'* explanations. An alternative approach for promoting a mutual understanding of the items would have been to use a two-part Delphi study design, in which items were defined in Part 1 then rated in Part 2 (362). However, using a two-part design would have increased the panellist and researcher burden.

The expert panel composition in this study had many strengths, such as including panellists from all four UK nations. However, it also presents limitations. Notably, the patient panellists were not fully representative of patients awaiting TKR. For example, all the patient panellists identified as White British; therefore, the final recommendations may not reflect the needs of people from minority ethnic groups. Furthermore, only individuals who could use and access the Internet and email were eligible. This may have led to digital delivery formats receiving more favourable ratings than if the panel had involved individuals who were unable to use and access the Internet and email. Only items that reached consensus amongst all panellists considered together were included in the final recommendations. This meant that professionals had a slightly greater influence on which items were included in the final recommendations, as the response rate of professional panellists was slightly higher than that of patient panellists in the final round. In addition, the arm strengthening exercises item was excluded from the final recommendations due to not reaching consensus amongst all panellists considered together, even though it did reach consensus amongst patient panellists. Correspondingly, it could be argued that arm strengthening exercises should have been included in the final recommendations due to their perceived importance amongst patients.

5.4.4 Implications for practice and future research

The recommendations developed in this study build on the NICE guideline on primary joint replacement (31) and Versus Arthritis' proposed joint replacement support package (100). For example, the NICE guideline recommends providing advice on pre-operative exercises (31) and Versus Arthritis' support package suggests patients should be offered physical activity programmes (100). The present study's findings expand on this by recommending specific types of exercise to include in pre-operative TKR exercise programmes. This study's recommendations therefore provide an appropriate resource for guiding UK health professionals' decision-making on pre-operative TKR service provision until more robust evidence emerges. The majority of recommendations could feasibly be incorporated into existing care pathways. For example, pre-operative TKR education classes and booklets could be reviewed and adapted if necessary to ensure that the recommended education topics are covered.

The concise version of the final recommendations is likely to be particularly useful for health professionals, as it is a simple four-page resource. Health professionals may also appreciate the prioritised version of the recommendations, as it could help them prioritise which changes to implement. In addition, developing a prioritised version of the recommendations was valuable because it facilitated prioritisation of intervention features when developing the VKS prototype, as discussed in Chapter 8 (section 8.3.3). This study's final recommendations and free-text comments also helped inform the Phase 2 qualitative descriptive study (Chapter 6, section 6.2.3) and Phase 3 theoretical modelling approaches (Chapter 7, section 7.2).

The CREDES standard recommends seeking endorsement of a Delphi study's output to provide external validation and promote implementation of the output in practice (349). In line with this, endorsement of this study's concise set of recommendations was sought from the Association of Trauma and Orthopaedic Chartered

Physiotherapists (ATOCP). The ATOCP committee felt that the study is of high quality and the final recommendations are valuable. However, some committee members raised concerns about implementing specific recommendations in clinical practice. The ATOCP committee therefore agreed to assist with disseminating the recommendations but not to formally endorse them. The main recommendations that ATOCP committee members raised concerns about were referral of patients with a BMI of at least 27kg/m² to a weight management programme and referral of patients with anxiety/depression to CBT-based therapy. These recommendations would apply to large numbers of patients and are not currently addressed in standard TKR pathways. These recommendations are in line with Versus Arthritis' proposed joint replacement support package, which suggests that patients should be offered self-management and mental health support (100). Versus Arthritis propose that this support could be provided through collaboration of organisations such as secondary care providers, Primary Care Networks and public health bodies (100).

In light of the challenges related to providing pre-operative TKR weight management and psychological support, future research investigating whether specific subgroups of patients benefit from such support would be valuable. The present study also highlights additional uncertainties that warrant future research, such as whether pre-operative TKR exercise programmes should include balance exercises. Furthermore, the recommendations developed in this study could be used to guide the development of pre-operative TKR interventions in other research studies.

5.5 Conclusion

The modified Delphi study reported in this chapter achieved its aim of developing evidence- and consensus-based recommendations on the content and delivery of pre-operative TKR interventions. The final recommendations cover 34 education topics, 18 education delivery approaches, 10 exercise types, 13 exercise delivery approaches and two other pre-operative treatments. This adds detail to existing guidance on pre-operative TKR care; hence providing an important original contribution to the literature. The recommendations state that pre-operative TKR education should be delivered using a combination of formats, including a website/other electronic format. They also state that pre-operative TKR exercise programmes should include unsupervised sessions, which could be supported through a digital intervention. The recommendations therefore support the rationale for the VKS project. In line with this study's objectives, two versions of the final recommendations were developed. The concise version is an appropriate resource for guiding UK health professionals' decision-making on pre-operative TKR service provision until more robust evidence emerges. The prioritised version was particularly helpful for informing the Phase 4 VKS prototype development (Chapter 8, section 8.3.3). In addition, this study's findings informed the Phase 2 qualitative descriptive study (Chapter 6, section 6.2.3) and Phase 3 theoretical modelling (Chapter 7, section 7.2).

Chapter 6 Qualitative exploration of potential barriers and facilitators to engagement with the Virtual Knee School (Phase 2)

6.1 Introduction

This chapter reports a qualitative descriptive study in which patients who were awaiting/had undergone TKR participated in online focus groups. The study built on the Phase 1 findings reported in Chapters 4–5 by exploring patients' perspectives of barriers and facilitators to engagement with the behaviours targeted by the VKS and digital features that could address the barriers/facilitators. The study was part of the intervention planning for the VKS.

6.1.1 Background

As discussed in Chapter 2 (section 2.4.3), gaining an in-depth understanding of stakeholders' perspectives is key to effective digital intervention development (38, 178). At the intervention planning stage, the person-based approach (PBA) advocates exploring intended users' perspectives of the behaviours the intervention seeks to change, including barriers and facilitators to engagement with the target behaviours (178). This can help with prioritising intervention features identified by evidence- and theory-based approaches, identifying additional features of importance to users and deciding how to implement the features (178). To help ensure the intervention will be acceptable and engaging for as broad a spectrum of intended users as possible, it is essential to consider the perspectives of diverse users and specific intervention context (178).

In line with the project rationale (Chapter 2, section 2.5), PPI representatives' suggestions (Chapter 3, section 3.5.2) and the final recommendations developed during the Phase 1b modified Delphi study (Chapter 5, section 5.3), the behaviours targeted by the VKS were:

- engagement with pre-operative TKR care in a web-based format (an essential precursor for the VKS to support other behaviour changes);
- engagement with pre-operative TKR education;
- engagement with a pre-operative TKR exercise programme;
- engagement with healthy lifestyle changes.

As discussed in Chapter 2 (section 2.3.3), psychological interventions may be included in prehabilitation programmes. In addition, the Phase 1b final recommendations state that patients awaiting TKR who have been formally diagnosed with anxiety or depression should be offered CBT-based therapy. Correspondingly, engagement with a pre-operative TKR psychological intervention could have been included as an additional target behaviour. This was decided against for the following reasons:

- engagement with a psychological intervention would not be a target behaviour for the majority of patients awaiting TKR, unlike the four target behaviours listed above;
- including a psychological intervention in the VKS, in addition to its other content, is likely to have made the VKS too complex and overwhelming for users;
- developing a psychological intervention would have required specialist expertise and additional time and resources, so was outside the scope of the VKS project;
- the PPI consultations held during the project planning, and existing literature (24, 108), suggest that not knowing what to expect is a major contributor to anxiety amongst patients awaiting TKR and this could be addressed through appropriate pre-operative TKR education.

Previous studies have provided some insights into patients' perspectives of the behaviours targeted by the VKS. However, their findings are not directly applicable to the VKS context. A Canadian study by Reid et al. (384, 385) explored patients' perspectives of a potential pre-operative TKR/THR education and prehabilitation digital intervention, but only 18% of the sample were awaiting/had undergone TKR. Similarly, in a qualitative study of orthopaedic patients' perspectives of digital features by Robinson et al. (157), only 28% of participants had experience of TKR. Furthermore, neither Reid et al. (384, 385) nor Robinson et al. (157) specifically recruited patients who varied in their confidence in using the Internet or any other indicator of digital literacy.

As highlighted by the Phase 1a rapid review (Chapter 4, section 4.3.6), numerous studies have explored patients' perspectives of pre-operative TKR education. However, none focused on exploring barriers/facilitators to engagement with pre-operative TKR education. Pellegrini et al. (127, 138, 386) and Webber et al. (387) explored barriers/facilitators to engagement with physical activity and other healthy lifestyle behaviours amongst patients who were listed for/had undergone TKR, but they considered the behaviours in the pre- and post-operative phases rather than focusing specifically on prehabilitation. In addition, the studies were based in America and Canada. To help inform the VKS, additional context-specific research was required to explore perspectives of barriers/facilitators to engagement with all the behaviours targeted by the VKS amongst a diverse sample of the intended users.

6.1.2 Aim and objectives

This qualitative descriptive study aimed to explore patients' perspectives of potential barriers and facilitators to engagement with the VKS (project objective 2). Its objectives were as follows.

1. To explore patients' perspectives of barriers and facilitators to engagement with the behaviours targeted by the VKS.
2. To explore patients' perspectives of digital features that could address barriers and facilitators to engagement with the VKS.

6.2 Methods

6.2.1 Rationale and overview

Qualitative research is particularly valuable for exploring perspectives of intended users of digital interventions in depth (152). Correspondingly, incorporating qualitative research is a core element of the PBA (178). At the intervention planning stage, this can be achieved by synthesising existing qualitative research or undertaking primary qualitative research (178). Due to the paucity of relevant research highlighted above (section 6.1.1), primary qualitative research was undertaken. Numerous qualitative methodological approaches have been described (388). These vary in their research focus (Table 6.1), although the boundaries between each approach are not clear-cut (389).

Table 6.1: Foci of commonly used qualitative approaches in health research

Approach	Research focus
Grounded theory	Generate a novel theory that explains a social process/action based on the perspectives of many participants.
Phenomenology	Understand the meaning of several participants' lived experiences of a particular phenomenon, focusing on commonalities in their experiences.
Narrative research	Explore the life story of one or a small number of participants in detail, often involving chronological ordering of their experiences.
Ethnography	Describe and interpret shared patterns, for example of behaviours and language, amongst an entire group of participants from the same culture.
Case study	Describe and analyse in detail one or more clearly defined cases, such as a person, organisation or decision process.
Qualitative description	Comprehensively summarise a specific phenomenon in a way that closely reflects participants' perspectives.

Table based on Creswell and Poth (388), Starks and Trinidad (390) and Sandelowski (391).

This study aimed to explore participants' perspectives of a phenomenon (potential barriers/facilitators to engagement with the VKS); therefore, qualitative description was identified as the optimal approach. A key distinguishing feature of qualitative description is that it involves less interpretation than other qualitative approaches (391). This is particularly valuable for gaining a direct overview of patients' experiences and perspectives in health contexts (392, 393). Correspondingly, qualitative description is well suited to mixed methods intervention development studies because it helps to ensure that the intervention being developed is grounded in the perspectives of the intended users (393, 394). Another benefit of qualitative description is its flexibility, as it is not limited to specific philosophical and theoretical orientations; or sampling, data collection and data analysis techniques (395). This facilitates tailoring of a study's procedures to its aim (396).

Due to the flexibility of qualitative description and relative paucity of literature detailing its procedures, qualitative descriptive studies may be criticised for lacking rigour (394). This can be addressed by ensuring that qualitative description is the most appropriate approach for addressing the study's aim and employing established strategies for enhancing rigour (394). Rigour in qualitative research may be described using various terms and criteria (397). The terminology and criteria proposed by Lincoln and Guba (398) were chosen for this study because they are particularly well-established and apply directly to qualitative descriptive studies (397). Lincoln and Guba (398) recommend referring to rigour in qualitative research as *'trustworthiness'* (p.290). This study employed multiple strategies to address the four trustworthiness criteria proposed by Lincoln and Guba (398) (Table 6.2).

Table 6.2: Trustworthiness criteria and strategies used to address them

Criterion[a]	Description	Strategies[b]	Section
Credibility (internal validity)	The extent to which the research findings are a true and accurate representation of the phenomenon.	Focus groups were used to encourage participants to freely express their perspectives.	6.2.3
		Rapport was established with all participants prior to the focus groups.	6.2.5
		The findings were integrated with other data sources during the Phase 3 theoretical modelling, Phase 4 VKS prototype development and discussion.	6.2.4
		The findings informed the VKS prototype and feedback on the VKS prototype was obtained through think-aloud interviews.	6.2.4
Confirmability (objectivity)	The extent to which the research findings are a true and accurate representation of the data collected.	Audio-recordings were transcribed by a transcription company then verified by the researcher.	6.2.4
		Coding was inductive and focused on manifest content.	6.2.4
		The researcher discussed the data analysis with her supervisors/advisors.	6.2.4
		The researcher used a reflexive approach, including analysing the data using reflexive thematic analysis and keeping a reflexive journal.	6.2.4; 6.2.5
		Quotes are provided to support the research themes and subthemes identified.	6.3.2
Dependability (reliability)	The extent to which the research procedures and details reported would enable replication of the study.	Detailed information is provided about the study procedures and no changes were made to the procedures during the study conduct.	6.2
		An audit trail of was maintained, including field notes, the reflexive journal and annotated NVivo files.	6.2.3; 6.2.4; 6.2.5
Transferability (external validity/ generalisability)	The extent to which the details reported are sufficient for determining whether the findings apply to other contexts.	Detailed information is provided about the study design, context and participants.	6.2; 6.3
		Maximum variation purposive sampling was used to recruit a diverse range of relevant participants.	6.2.2.1

VKS, Virtual Knee School

[a] Equivalent quantitative term provided in brackets.

[b] Strategies are allocated to the main criterion they correspond with but some strategies apply to more than one criterion.

Table based on Lincoln and Guba (398), Given (399), Bradshaw et al. (397) and Milne and Oberle (400).

Reporting of this study was guided by the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist (401). The COREQ checklist was chosen because it focuses on interviews and focus groups, in contrast to other qualitative reporting guidelines such as the Standards for Reporting Qualitative Research (402).

6.2.2 Participants

6.2.2.1 Eligibility criteria

Individuals who met the following inclusion criteria were eligible:

- adult (aged ≥18 years old);
- able to communicate in English;
- listed for primary TKR at a hospital in the UK and/or had undergone primary TKR at a hospital in the UK within the past two years;
- able to use and have access to the Internet and email.

Individuals who were unable to give informed consent were excluded to ensure that all participants could engage in the focus groups.

6.2.2.2 Sample size

Sample size in qualitative research is typically guided by the aim of achieving data saturation (403). Data saturation can be conceptualised as the point at which further data collection does not provide any new information (404). However, additional qualitative data arguably always provide some new insights (405). Various authors have defined specific types of saturation, such as code saturation and meaning saturation (406, 407). The number of focus groups required to achieve saturation depends on multiple factors, such as the study aim, saturation type and homogeneity of the sample (403, 407). A systematic review by Hennink and Kaiser (403) suggested that it is possible to achieve code/category saturation within four to eight focus groups involving a relatively homogeneous sample. This was based on studies employing empirical tests of saturation, which typically involve counting codes and rely on a relatively fixed codebook (403, 405). Such tests are incompatible with the fluid coding approach used in reflexive thematic analysis (405). Correspondingly, Braun and Clarke (405) argue that data saturation is not a valid concept for all qualitative studies, particularly those that are highly interpretative. When data saturation is referred to, Braun and Clarke (405) recommend clarifying how it is conceptualised.

Malterud et al. (408) recently proposed the concept of *'information power'* as an alternative approach for determining sample size in qualitative studies (p.1753). This is based on the assumption that the more relevant information a particular sample holds for addressing the study aim, the fewer participants are required. Malterud et al. (408) propose that information power is affected by the breadth of the study aim; the specificity of the sample relative to the study aim; the study's theoretical underpinning; the quality of the dialogue between the researcher and participants; and the analysis approach employed. Whilst information power offers a relatively flexible approach (405), it has been criticised for failing to consider factors such as the nature of the study aim and implying that data are waiting to be extracted from participants rather than acknowledging the interpretative process through which researchers generate themes (409). Furthermore, Malterud et al. (408) developed the concept of information power in relation to individual interviews and highlighted that the sample size decision-making process for other data collection methods such as focus groups presents more uncertainties.

This study involved data collection via focus groups (section 6.2.3) and employed reflexive thematic analysis with a relatively low level of interpretation (section 6.2.4). Aiming to achieve data saturation was therefore considered an appropriate approach for determining the sample size, but counting codes to assess saturation was not. Correspondingly, data saturation was assessed subjectively and conceptualised as the point at which additional data collection was considered unlikely to lead to the identification of new themes (410). Each focus group included four or five participants, which is considered an appropriate focus group size (411). Data saturation was considered to have been achieved after completion of three focus groups with 14 participants in total.

6.2.2.3 Sampling

As with other qualitative approaches, qualitative description typically involves purposive sampling (391). This involves intentionally selecting individuals with the aim of gaining information about the phenomenon of interest that is as valuable as possible (388). Furthermore, purposive sampling can enhance transferability (398). The optimal purposive sampling technique depends on the study's context and aim (391, 399). When using the PBA for intervention planning, obtaining a diverse sample is essential to help ensure that the intervention will meet the needs of as wide a spectrum of intended users as possible (178). This aligns with maximum variation purposive sampling, which involves selecting participants who differ in key characteristics (355, 399). This study employed maximum variation purposive sampling based on age, gender, experience of TKR (listed for TKR versus undergone TKR) and varying confidence in using the Internet. In line with a previous relevant study (412), confidence in using the Internet was self-rated on a four-point scale (unconfident, neither confident nor unconfident, confident, very confident). The purposive selection criteria were chosen because they may affect engagement with the behaviours targeted by the VKS (95, 127, 413). In addition, although patients awaiting TKR are the primary intended users of the VKS, inclusion of patients who had undergone TKR in the sample was considered important to find out what they wish they had known/received/engaged with pre-operatively.

6.2.2.4 Recruitment

Participants were recruited via Twitter, Facebook and emailing a brief overview of the study to patient panellists from the Phase 1b modified Delphi study (Chapter 5). Participants were not actively encouraged to share the study details. However, individuals who heard about the study via word-of-mouth were included. Recruitment via a large NHS teaching hospital was planned but could not be undertaken due to COVID-19-related restrictions.

6.2.3 Data collection

Qualitative descriptive studies usually involve data collection via interviews or focus groups (391). Focus groups are particularly valuable during PBA intervention planning because interactions between participants can lead to unanticipated discussions, providing novel insights (178). Reducing the researcher’s role in the data collection process enhances credibility (400). Furthermore, focus groups enable rapid data collection from multiple participants, provide an opportunity for participants to offer mutual support and can facilitate participation of individuals who are unwilling to be interviewed alone (411). A potential disadvantage of focus groups is that participants may not feel comfortable expressing contradictory perspectives (411). In addition, it is essential to ensure that participants do not breach each other’s confidentiality (411). In line with these considerations, the researcher collected data via focus groups and established ground rules at the beginning of each focus group. These included emphasising the importance of confidentiality and respecting each other’s views.

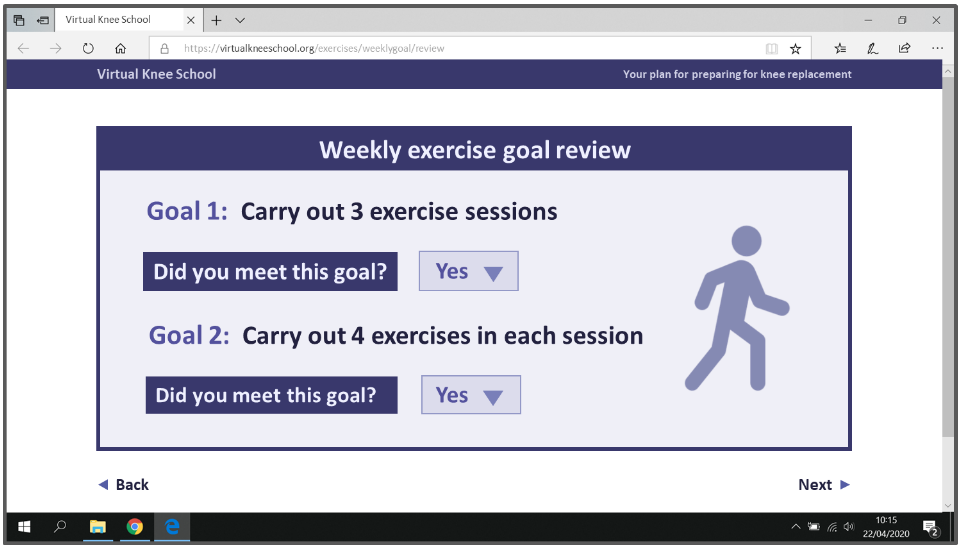
The initial intention was to conduct focus groups in person to help build rapport amongst participants and facilitate inclusion of individuals with low digital literacy (414, 415). This approach was not feasible due to COVID-19-related restrictions. Synchronous videoconferencing is a useful alternative to in-person data collection because it enables real-time interactions (416). It also offers various advantages over in-person data collection such as facilitating inclusion of participants from a wide geographical area and enabling participants to contribute from their own homes, where they may feel more relaxed (414). All focus groups in this study were conducted using Blackboard Collaborate™ (236), a secure online videoconferencing tool provided by the University of Leeds. This tool was chosen to allow participants to join the videoconference via telephone or online without needing to install specific software. Offering participants the opportunity to join via telephone was considered a priority to ensure that individuals with low digital literacy could participate. Given that some people do not feel comfortable participating in online focus groups (417), all participants were offered the opportunity to participate in a remote interview rather than a focus group, but none chose that option.

The researcher conducted all focus groups independently between 19th May 2020 and 3rd June 2020. Allocation of participants to the focus groups was mainly determined by participants' availability and their preferred time of day for participating in a focus group. This approach was chosen because holding focus groups at convenient times for patients can encourage them to participate (418). In addition, recruitment continued during the data collection phase, so not all participants had been recruited at the time of the first and second focus groups. Prior to participating in a focus group, all participants received the study PIS and videoconference joining instructions; discussed the study with the researcher; were offered the opportunity to have an individual videoconference practice joining session; and were required to complete the study eConsent Form and Questionnaire. At the beginning of each videoconference, the researcher provided a brief introduction to review key details from the PIS, explain the focus group procedures and address participants' questions. The introduction included establishing ground rules as explained above and ensuring that participants who had joined online were able to use the relevant functions of Blackboard Collaborate™ (236). Two participants received family member assistance with using Blackboard Collaborate™. To the researcher's knowledge, all other participants were alone during their focus groups. The researcher's camera was on during each videoconference. Participants who joined online could have their camera on or off according to their preference. One participant in each focus group joined via telephone.

During the focus groups, the researcher asked prompt questions guided by the Phase 2 topic guide (Appendix D). The topic guide was developed based on the study objectives and previous relevant research (412, 419). Two PAG PPI members were invited to review the topic guide. Neither suggested any changes. The topic guide was drafted prior to completion of Phase 1 (Chapters 4–5) to ensure that ethical approval was obtained in the required timeframe. The topic guide was subsequently reviewed in light of the Phase 1 findings and after each focus group. These reviews indicated that no changes to the topic guide were required. The first part of each focus group explored participants’ perspectives of preparing for TKR and the potential for websites to facilitate their preparations. Open-ended questions were used to encourage participants to discuss whatever aspects were most pertinent to them (411).

The second part of each focus group involved discussing digital trigger materials (Figure 6.1). These provided 11 examples of digital features, which may have been unfamiliar to some participants and/or not discussed spontaneously (178, 419). The researcher developed the trigger materials as static images in Microsoft PowerPoint 2016 based on intervention components and delivery approaches identified as important in Phase 1 (Chapters 4–5) and discussions with her supervisors/advisors. Two PAG PPI members provided feedback on the digital trigger materials. This led to the addition of a pain tracker to the trigger materials. The researcher shared the trigger materials on-screen during each focus group. To account for participants who joined via telephone or experienced internet connectivity problems, the research also emailed all participants the trigger materials as a PDF document prior to their focus group.

Feature 8: Goal review



Feature 10: Pain tracker

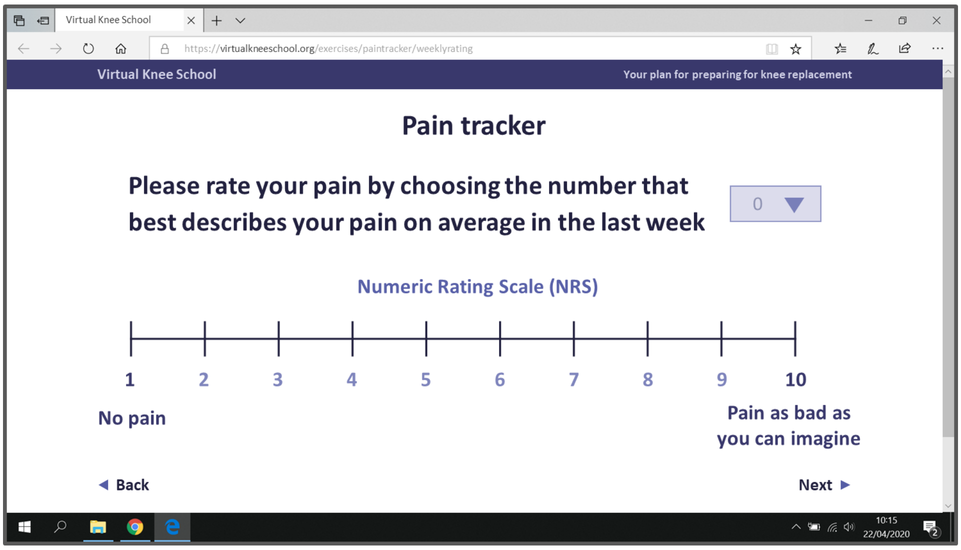


Figure 6.1: Trigger material examples

The focus groups were audio-recorded using an encrypted mobile phone and/or laptop. To help ensure confidentiality, no audio-visual recordings were made (414). The focus groups lasted 95, 110 and 101 minutes. The researcher made field notes during and/or shortly after each focus group.

6.2.4 Data analysis

Data analysis in qualitative descriptive studies typically involves qualitative content analysis or thematic analysis (389). As discussed in Chapter 5 (section 5.2.4), a distinguishing feature of qualitative content analysis is that it involves quantification of qualitative data (374). Counting the frequency of codes/categories risks removing the context of the data and failing to explain why certain codes/categories occur more frequently (374, 420). In contrast, considering context is key during thematic analysis, enabling a more detailed and meaningful understanding of a phenomenon to be gained (374, 420). This study aimed to explore participants' perspectives in depth; therefore, a thematic analysis approach was chosen.

Various thematic analysis approaches have been described. Braun and Clarke (421) classify these into three clusters: coding reliability, codebook and reflexive thematic analysis. However, they acknowledge that this typology does not fully capture all thematic analysis approaches. Coding reliability thematic analysis is underpinned by a quantitative orientation, aiming to identify objective truth and maximise reliability and accuracy. Correspondingly, the codebook is relatively fixed, multiple coders are required and themes are conceptualised as *'analytic inputs'* (421: p.237), which exist in the data prior to identification by researchers. At the other end of the spectrum, reflexive thematic analysis can be considered *'fully qualitative'* (421: p.236), embracing flexibility and subjectivity. Reflexive thematic analysis involves a fluid codebook, is well suited for a single coder and conceptualises themes as *'analytic outputs'* (421: p.9), which are actively developed by researchers. Codebook thematic analysis encompasses a number of commonly used approaches in applied health research, such as framework analysis and template analysis. These approaches are intermediate between the coding reliability and reflexive thematic analysis. They typically employ a relatively structured codebook and may involve multiple coders. However, inter-coder reliability is not prioritised. Themes in codebook thematic analysis may be conceptualised as analytic inputs, as provisional themes are often identified in the initial stages of the analysis (421).

Reflexive thematic analysis was identified as the most appropriate approach for this study because its less structured procedures can enable a more detailed and nuanced understanding of a phenomenon to be gained (421). In addition, reflexive thematic analysis can be used inductively (421). Inductive analysis is important during PBA intervention planning because it can provide novel insights into intended users' perspectives of the proposed intervention and any concerns they have about engaging with it (152, 178).

Braun and Clarke (225) described their thematic analysis approach in 2006, although they only recently labelled it as reflexive thematic analysis to differentiate it from other approaches (422). The researcher implemented the six-phase reflexive thematic analysis process as detailed below. In line with the reflexive approach (421), the phases were not followed in a strict, linear order. Throughout the analysis, the researcher held discussions with her supervisors/advisors to increase confirmability. QSR International NVivo software[3] was used to help order the data. To enhance dependability, the researcher added annotations in NVivo where appropriate and archived successive NVivo files. The analysis was underpinned by pragmatism, discussed in Chapter 3 (section 3.3.3).

1. Familiarisation with the dataset

All focus group audio-recordings were transferred to 1st Class Secretarial services as described in Chapter 3 (section 3.4.4) for intelligent verbatim transcription. After receiving each transcript, the researcher listened to the corresponding audio-recording to verify the accuracy of the transcript, make corrections where necessary and increase her familiarity with the data. The researcher then re-read the transcript to further familiarise herself with the data and start critically engaging with it.

2. Coding

In line with the considerations discussed above, the researcher coded all transcripts inductively using a fluid approach (421). To help ensure that the codes reflected participants' perspectives, the coding was mainly semantic. Field notes were referred to where appropriate.

3 The majority of the analysis was undertaken using NVivo 12. Further analysis was undertaken using NVivo Release 1 due to a software upgrade.

3. Generating initial themes

The researcher clustered codes from the entire dataset into candidate themes and subthemes. Themes/subthemes were conceptualised as a *‘pattern of shared meaning organised around a central concept’* (421: p.77). Correspondingly, the researcher sought to ensure that the themes/subthemes did not simply provide synopses of all participants’ comments on specific topics.

4. Developing and reviewing themes

The researcher critically reviewed the candidate themes/subthemes to check that they were sufficiently supported with data, clearly defined and coherent. This led to redevelopment of all the themes/subthemes and collapsing of some themes/subthemes. To facilitate the reporting, barriers and facilitators within each subtheme were grouped together with any digital features related to the barrier/facilitator. Other considerations related to a theme/subtheme were also grouped together where appropriate. For example, the influence of age on participants’ experiences/perspectives of TKR was grouped under the theme that focused on individual differences. Appendix E provides an example of the theme/subtheme coding structure in the final NVivo file.

5. Refining, defining and naming themes

The researcher further reviewed the themes/subthemes, writing a brief definition of each theme/subtheme and allocating them informative names.

6. Writing up

This phase overlapped substantially with the other phases. It involved the researcher writing an analytic narrative, supported with data extracts. In addition, the researcher entered the thematic analysis findings into tables specifying barriers and facilitators to engagement with the behaviours targeted by the VKS and design features that could address each barrier/facilitator. This approach was based on a previous evidence-, theory- and person-based intervention planning study (423) and ensured that the data were optimally structured for informing the subsequent project phases. Barriers and facilitators were defined as any factors, characteristics, perspectives or beliefs that could hinder or promote engagement with the VKS (424). A separate barriers/facilitators table was created for each of the four behaviours targeted by the VKS detailed in section 6.1.1 above. To promote transparency, each barriers/facilitators table included a column detailing whether each barrier/facilitator/feature was included in the Phase 3 behavioural analysis reported in Chapter 7 (section 7.4).

The findings of this study were integrated with the Phase 1 findings and PPI representatives' views during the theoretical modelling (Chapter 7, section 7.2) and VKS development (Chapter 8, section 8.3). This study's findings were also integrated with the findings of all the project phases in the discussion (Chapter 9, section 9.3). The process of comparing this study's findings with other data sources may be considered triangulation, an established approach for enhancing the credibility of qualitative research (216). Member checking is another approach for enhancing credibility. This involves asking participants to provide feedback on the accuracy and adequacy of their transcript and/or the analysed data (425). Given that member checking requires extra time/resources (398, 425) and feedback on the VKS prototype was obtained through think-aloud interviews, member checking was not considered justifiable for this study.

6.2.5 Reflexivity

The researcher conducted the focus groups during her full-time HEE/NIHR Clinical Doctoral Research Fellowship. The researcher is a female physiotherapist with undergraduate degrees in physiotherapy and preclinical veterinary medicine. She had experience of qualitative interviewing and facilitating group discussions, but had not previously facilitated research focus groups. The researcher discussed the study via telephone with all participants prior to their focus group to build rapport. One participant was a patient at the site where the researcher is based. Neither this participant nor any of the other participants had received clinical care from the researcher. All the participants were aware that the researcher was a physiotherapist undertaking a PhD to develop a new pre-operative TKR care website. To support reflections on how these and additional factors influenced the study, the researcher kept a reflexive journal throughout the data collection and analysis phases.

An important consideration was the researcher's dual position as a health professional and researcher. This may enhance trust with research participants and facilitate appropriate probing (400). It may also influence the data obtained, for example by encouraging participants to focus on health-related rather than broader topics (426). The researcher used prompt questions based on the topic guide (Appendix D) to help ensure that all relevant areas were fully explored in this study. Being a health professional may result in the researcher having more preconceptions about the phenomenon being explored (400). The researcher is also likely to have developed preconceptions through undertaking PPI activities, planning the VKS project and conducting Phase 1 (Chapters 4–5) (225). To help ensure that her preconceptions did not compromise her interpretation of the data, the researcher used various strategies to enhance confirmability (Table 6.2).

6.3 Findings

6.3.1 Participants

Figure 6.2 presents the flow of individuals through the study. The recruitment routes for the 14 participants who joined a focus group were Twitter (n=1), Facebook (n=6), Phase 1b (n=5) and word-of-mouth (n=2). Tables 6.3–6.4 present the characteristics of these 14 participants.

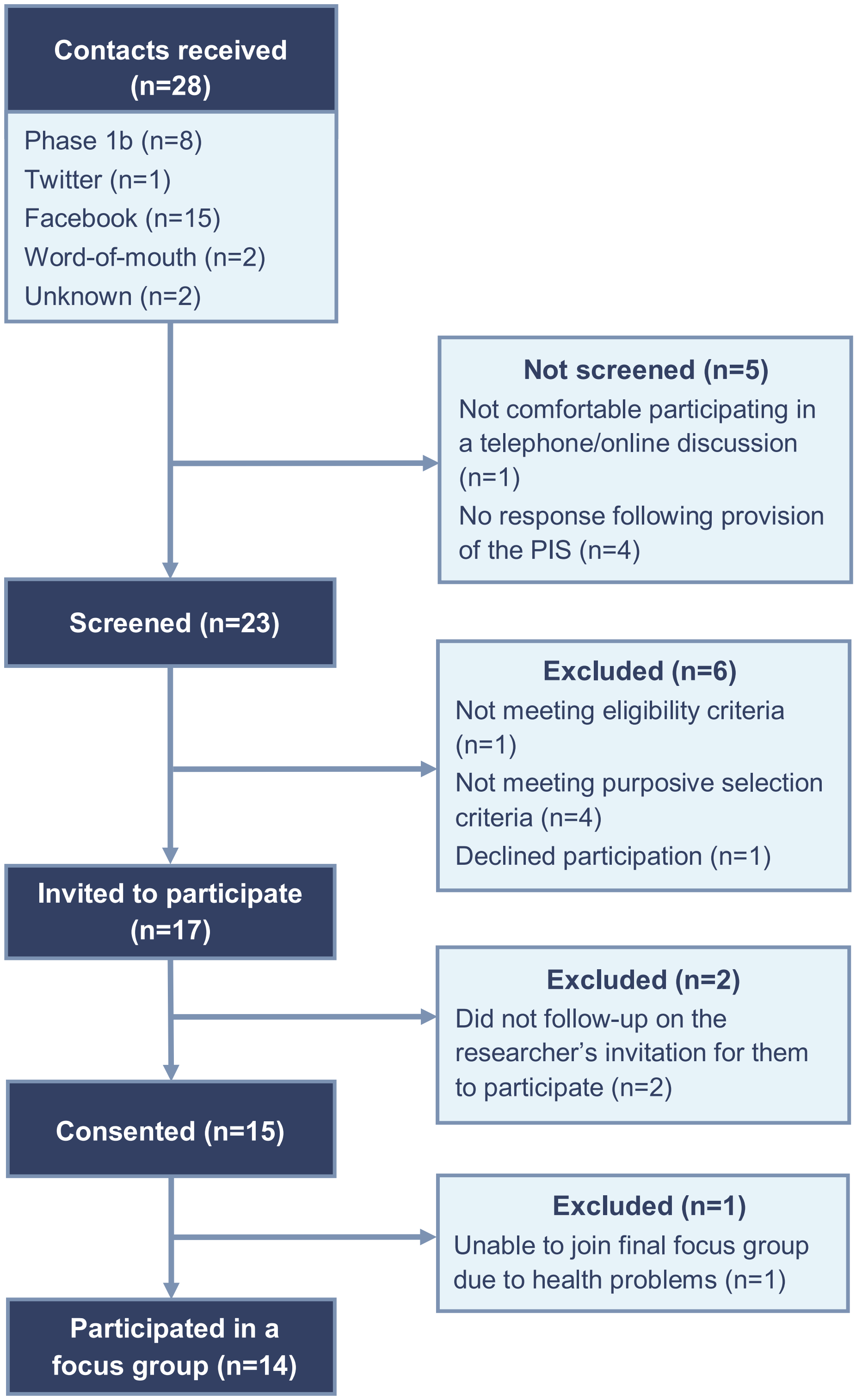


Figure 6.2: Focus group participant flow chart

PIS, Participant Information Sheet

Table 6.3: Focus group participants' key characteristics

Pseudonym[a]	Age (years)	Gender	Experience of TKR	Confidence in using the Internet
Olivia	50–59	Female	Post	Very confident
James	50–59	Male	Pre, post	Very confident
Cameron	60–69	Male	Post	Very confident
Ivy	50–59	Female	Post x 2	Confident
Luke	60–69	Male	Pre, post	Very confident
Lloyd	70–79	Male	Post	Unconfident
Rosie	60–69	Female	Pre, post	Very confident
Jacob	50–59	Male	Post	Very confident
Beatrice	70–79	Female	Pre, post	Confident
Molly	40–49	Female	Pre	Very confident
Irene	50–59	Female	Post	Confident
Dorothy	70–79	Female	Post	Confident
Harry	70–79	Male	Post	Confident
Sophia	40–49	Female	Post	Very confident

Post, previously undergone TKR; Pre, listed for TKR; TKR, total knee replacement

[a] To help ensure anonymity, participants are not listed in the order in which they participated in a focus group.

Table 6.4: Focus group participants' additional characteristics

	Number of participants (%) (n=14)
Indication for TKR[a]	
Osteoarthritis	19 (100)
Location of TKR[a]	
NHS hospital	12 (63)
Private hospital	7 (37)
Months since previous TKR[b]	
<3	3 (21)
3–6	3 (21)
6–12	2 (14)
12–24	4 (29)
≥24	2 (14)
Body mass index (kg/m²)	
18–24.9	1 (7)
25–29.9	7 (50)
30–39.9	5 (36)
≥40	1 (7)
Ethnicity	
White British	14 (100)

Disability or health condition that could affect ability to use a website or carry out gentle exercises	
Relevant disability/health condition	0 (0)
Living location	
Scotland	2 (14)
Northern Ireland	1 (7)
Wales	1 (7)
North East	1 (7)
North West	5 (36)
Yorkshire and the Humber	2 (14)
South East	2 (14)
Highest educational qualification	
None	1 (7)
GCSE/O-Level (or equivalent)	2 (14)
A-Level (or equivalent)	3 (21)
Vocational qualification	4 (29)
Undergraduate degree	2 (14)
Postgraduate degree	2 (14)
Current employment status[c]	
Employed full-time	5 (36)
Self-employed	1 (7)
Retired	8 (57)
Medically disabled	1 (7)

NHS, National Health Service; TKR, total knee replacement

[a] Participants who had undergone two TKRs/were both awaiting and had undergone TKR were counted twice (19 TKRs in total).

[b] Only includes participants who had previously undergone TKR (n=13 participants; 14 TKRs in total).

[c] Participants could select more than one option.

6.3.2 Thematic analysis overview

The reflexive thematic analysis led to the development of two intersecting themes, each with three subthemes (Figure 6.3). Each theme encapsulates a broad principle related to multiple potential barriers and facilitators to engagement with the VKS. The findings suggest that addressing these principles would help to optimise patient engagement with the VKS.

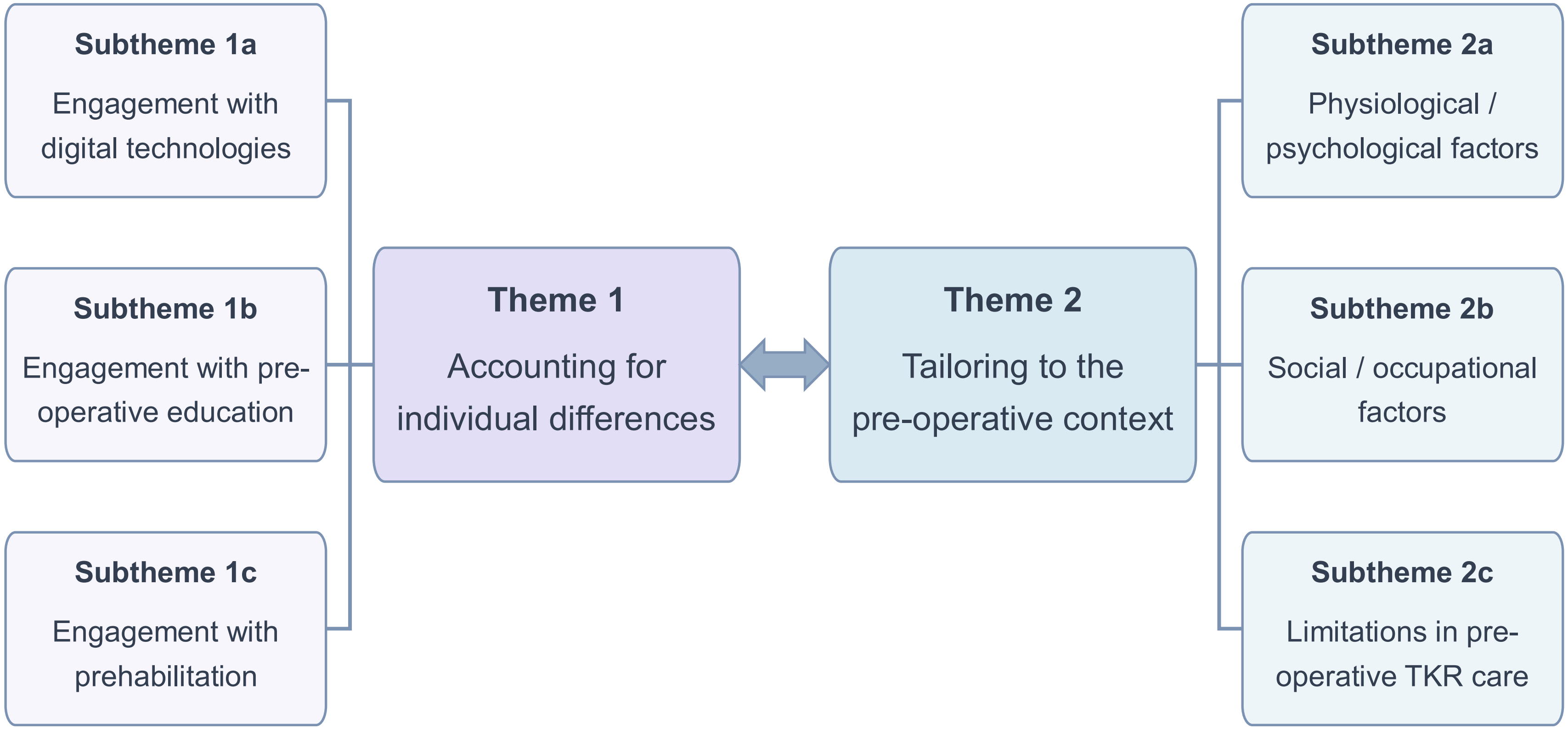


Figure 6.3: Thematic map

TKR, total knee replacement

6.3.3 Theme 1: Accounting for individual differences

Multiple participants from across all three focus groups emphasised that *"everybody's different"* (Harry). Differences in participants' individual circumstances and preferences meant their perspectives of potential barriers and facilitators to engagement with the VKS varied. This theme includes three subthemes that demonstrate the impact of individual differences on barriers/facilitators to engagement with digital technologies, pre-operative education and prehabilitation. The subthemes highlight how digital features could address the individual differences where applicable. Overall, this theme suggests that accounting for individual differences would help to optimise patient engagement with the VKS.

6.3.3.1 Subtheme 1a: Engagement with digital technologies

Participants' individual circumstances and preferences appeared to have a strong influence on their perspectives of barriers/facilitators to engagement with digital technologies. Most participants were positive about the idea of a pre-operative TKR website, with participants from one focus group suggesting that a mobile app version of the website would be valuable. Conversely, Beatrice highlighted that she is *"not up with all those sorts of apps and things"*. Beatrice felt that limited experience of using digital tools is a particularly important barrier at present due to the older demographic of patients undergoing TKR:

> "Yeah. I suppose most people, though, who have knee replacements, are much older, actually. And as time goes on, and people are much more familiar with using phones, and apps, and things, it won't be such an issue. But I think at the moment, it is quite an issue for people who are older, you know." (Beatrice)

Two other participants aged in their 70s appeared reluctant to use digital technologies due to their personal preferences. Lloyd reported being *"very happy"* to not own a watch or mobile phone, whilst Dorothy described herself as a *"paper and pencil person"*. Like other participants, Dorothy appeared more willing to use a website if it was from a UK-based credible source:

> "I also think it's helpful to have this information provided by the NHS rather than having to hunt for all sorts of other websites and as you said, many American ones, it's useful to have it all in one place and one reliable place." (Dorothy)

Even participants who were comfortable using digital technologies raised concerns about the detail/duration of website interactions. Correspondingly, participants felt that website features should be quick and simple to use. Some participants also highlighted a dislike of specific digital features as a barrier to engaging with a website. Participants' opinions were particularly divided over the idea of an exercise goal-setting feature. One participant from each focus group explicitly stated that they do not find goal setting helpful or even expressed that they *"hate goal setting"* (Luke). In addition, James highlighted that setting goals and not meeting them *"can be more of a setback than anything".* In contrast, the majority of participants felt that recording goals about engaging with an exercise programme and receiving personalised feedback would be valuable for reasons such as increasing their motivation and prompting reflections:

> "Obviously, by setting the goal, if you've not met your challenges that week, then obviously you need to work a bit harder, or wonder why you've not done it, if you know what I mean." (Molly)

Another feature that divided opinions was an educational quiz. Some participants felt a quiz would be valuable for information provision and reinforcement. Other participants disliked the idea of having to guess information, preferring passive information provision. Directly opposing preferences were also evident when discussing videos versus animations for exercise demonstrations. Most participants in two focus groups preferred videos. A key reason for this was that they valued seeing real-life people. In contrast, participants in the third focus group preferred animations and felt that using real-life people as models is suboptimal. Olivia highlighted that real-life models may even have a negative impact if patients cannot relate to them:

> "Only the real person [in the DVD] was obviously a fit, healthy person who was just going through the exercises, and I found it very patronising, that someone who was obviously fully capable of doing these exercises was showing me how to do them." (Olivia)

To account for individuals' differing preferences, participants from all three focus groups felt that a pre-operative TKR care website should be flexible. Suggestions included making website features optional and providing content such as an exercise diary in a PDF document that users could print off to avoid needing to return to the website repeatedly. Participants also highlighted that flexibility within individual website features would be valuable. For example, participants felt it would be important to be able to specify particular times for receiving email reminders to account for individuals' differing schedules. Furthermore, some participants indicated that they would prefer reminders in other formats, such as on their mobile phone or online calendar:

> "So I think something that actually pings up and says, oi, go and do, you know, ten stand and sits, now, to me, is probably more useful than having a notification coming through say in an email, that goes, open an email and it says, you should be doing this now." (Jacob)

6.3.3.2 Subtheme 1b: Engagement with pre-operative education

Participants' differing circumstances and preferences affected their willingness to engage with pre-operative education and their perspectives of specific education delivery approaches. A desire for detailed information about preparing for TKR and what to expect appeared to be an important facilitator to engagement with pre-operative education for most participants. Such information was considered valuable for making practical preparations, such as home modifications and work arrangements, and relieving participants' anxieties about their upcoming procedure. In contrast, Lloyd indicated that he did not want to receive detailed information pre-operatively:

> "I don't want to know too much about it, if I need it doing, I'll kind of just get on with it, and manage, you know, whatever comes, yeah." (Lloyd)

Differences were also evident in participants' desire to find out about the TKR surgical procedure. Most participants did not want to receive information about what would happen during their surgery. The risk of seeing graphic details was a particular concern and presented a barrier to engagement with online information. For example, James specifically recommended that patients *"stay off the Internet"* pre-operatively to avoid the risk of seeing images of surgery:

> "You can go onto something that takes you to like, it's like a scene from a horror film, and all of a sudden you're going, aah, not for me." (James)

Conversely, a few participants chose to watch a video of TKR surgery. Cameron watched a video pre-operatively because he wanted to understand what would happen whilst he was anaesthetised. Watching a video of TKR surgery post-operatively helped Irene and Ivy to understand why they had experienced so much pain/bruising, but they still felt it was best not to watch a video pre-operatively. Sophia highlighted watching an animation of TKR surgery as a useful, less graphic alternative:

> “It wasn’t obviously as graphic, it was sort of like an animation. So it just showed the knee open, but you couldn’t see anything graphic. So that was really good. But I think I would struggle with the graphics a bit.” (Sophia)

Ensuring that information delivery approaches account for individuals’ differing needs was also considered important. Participants from one focus group highlighted low literacy levels and language barriers as potential barriers to engagement with pre-operative TKR education. Suggestions for addressing this included providing pictures and videos, and keeping information as simple as possible. However, Luke reported being frustrated about receiving a large volume of simple information:

> “And they just…they told me sensible things but it took three or four hours. When, to be honest, I thought I knew a lot of it from common sense. The other thing we were given was, I think, about a 24 page booklet on what the operation would involve and how to recover. And again, it was an awful lot of simple information. So I found that a bit frustrating.” (Luke)

6.3.3.3 Subtheme 1c: Engagement with prehabilitation

As for engagement with digital technologies and pre-operative education, participants’ individual circumstances and preferences affected their perspectives of barriers/facilitators to engagement with prehabilitation. Differences in participants’ preferred exercise types and delivery modes appeared to be particularly important. For example, Beatrice reported finding exercise classes motivating, whereas Rosie indicated that she does not like the constraints of exercise classes:

> “Because I'm not good at following patterns, I'm not a, you know, I don't like to have to, I don't like classes, you know, I don't like the routine, but I do like the exercises. So doing them as I felt like it, would work for me better. Just different people have different ways of doing it.” (Rosie)

Participants also identified personal characteristics that affected their engagement with prehabilitation. For example, a tendency to overeat appeared to be a barrier to dieting, whilst having a determined personality was perceived as a facilitator to exercise:

> “So I said to myself I've got to just keep it [pre-operative exercise] going and it was just a…it's not bad language, I'm a bloody-minded person when I need to be and I just said right, I'm going to crack on with it.” (Cameron)

Lifestyle choices (e.g. being vegan) and other health issues (e.g. heart problems) were also perceived to influence engagement with prehabilitation. Participants in one group suggested signposting patients to healthy eating advice on existing credible websites, as they felt that would account for individuals’ differing needs whilst avoiding unnecessary duplication of online information:

> “And some people would say, you know, I can't do this, or I've got that, and if you just referred them to the NHS page, it covers pretty much, basically everything, and all different, you know, eventualities of being vegan, or you know, diabetic, or anything like that.” (Sophia)

Additional barriers to engagement with prehablitation related to participants’ differing environmental circumstances. Lack of access to specific equipment/facilities was identified as a barrier to engagement with exercise. Correspondingly, participants in one focus group emphasised the value of exercises that require household items only. Another environmental circumstance that presented a barrier to engagement with prehabilitation was going on holiday pre-operatively:

> “The one thing that I did do differently, and it was particularly difficult for me, because we went on holiday, got back about ten days before the operation, and it was cutting down on alcohol. Now, I'm not an alcoholic, but I do like my wine at weekends, and on holiday.” (Irene)

6.3.4 Theme 2: Tailoring to the pre-operative context

Many of the reported barriers and facilitators to engagement with the behaviours targeted by the VKS appeared to relate closely to the pre-operative context. Key pre-operative contextual features included physiological/psychological factors, social/occupational factors and limitations in pre-operative TKR care provision. This theme includes three subthemes that highlight barriers/facilitators and associated digital features that relate to these pre-operative contextual features. The findings suggest that tailoring the VKS to these contextual features would help to optimise patients’ engagement with it. Whilst this theme encompasses barriers/facilitators that appear to be common in the pre-operative TKR context, the barriers/facilitators do not apply to all individuals and may be experienced to differing degrees. Correspondingly, this theme intersects with Theme 1, *'Accounting for individual differences'*.

6.3.4.1 Subtheme 2a: Physiological/psychological factors

Certain physiological/psychological factors appeared to be particularly relevant during the pre-operative phase of the TKR pathway. Participants' pre-operative knee signs/symptoms were a key barrier to engagement with prehabilitation. Pain was the most frequently mentioned symptom across all focus groups. Loss of movement and swelling were reported. These signs/symptoms resulted in some participants having to stop certain exercises completely:

> "So there's doing a lot of stuff, like the one where you stand, and then lean down towards the chair, like a squat thing, I can't even think about doing stuff like that." (Molly)

Despite having to stop certain exercises, participants identified various strategies that enabled them to continue being physically active pre-operatively. These included using walking aids, activity pacing and performing non-weight-bearing activities:

> "I actually came across a website which said here's some really good exercises to prepare for knee operations or operations of a similar type, which were really confirming what Harry was saying about cycling and rowing and swimming, anything of that nature because they don't cause a lot of weight bearing, strangely enough, they don't cause any weight-bearing issues." (Cameron)

Knee signs/symptoms influenced the digital features that participants felt should be included in a pre-operative TKR care website. Some participants felt that a pain tracker would have limited value pre-operatively because patients' pre-operative pain levels are usually high. Despite this, Irene reported finding a pre- and post-operative pain tracker useful as her reduced post-operative pain scores highlighted *"just how successful the operation was"*. Similarly, although many participants felt that monitoring exercises/physical activity is helpful, participants in one group suggested that an activity tracker would mainly be beneficial post-operatively:

> "Because again, I think that this [activity tracker] is a post-operative thing, as opposed to a pre-operative thing. […] I wouldn't have used it pre-operatively. Because my activity was limited to trying to get around the house, because I was bone on bone, on the knee that was replaced, and I'm virtually bone on bone on the knee that's waiting to get done." (Olivia)

Prior to receiving specific advice, Luke was concerned that exercising could cause further knee damage. Overall however, participants beliefs appeared to be key psychological factors that facilitated their engagement with prehabilitation. Participants from all three focus groups seemed to be motivated to engage with pre-operative exercise and/or healthy lifestyle changes by the belief that doing so would improve their post-operative recovery. Not all participants had experience of exercising pre-operatively, but those that had felt it was highly beneficial. For example, Ivy had had both her knees replaced and attributed the greater success of her second TKR to undertaking prehabilitation:

> "And because I have done these exercises, which I've carried on doing, so on both knees, after my first operation, my recovery rate this time has been absolutely phenomenal. I really feel if I'd known about these exercises prior to the operation, I think my first knee would have gone so much better." (Ivy)

Participants also perceived other benefits of prehabilitation, such as preventing their symptoms deteriorating, loosening other joints and changing their appearance. Correspondingly, participants highlighted that they would be more motivated to engage with prehabilitation if they understood the reasons for doing so, and suggested that advice on prehabilitation should explain the benefits of specific exercises and healthy lifestyle changes:

> "I think perhaps something in place to link between weight management and, you know, the joint replacement surgery, how that has an impact on how long it will last, how well it will function." (Jacob)

6.3.4.2 Subtheme 2b: Social/occupational factors

Various pre-operative social/occupational factors presented barriers/facilitators to engagement with the behaviours targeted by the VKS. Participants highlighted how being busy with work and other distractions could prevent them from exercising or engaging with certain website features pre-operatively. In contrast, participants were highly focused on their recovery in the early post-operative phase. Correspondingly, exercise reminders were considered more helpful pre- than post-operatively:

> “Yes, I think so because once you've had the operation, you know you've got to exercise and initially all you're doing all day is exercising and taking tablets. So you know that's an easy routine to get into. I had a timetable as well. But beforehand when life was much more normal and very full, yes, I think reminders would be useful.” (Dorothy)

Social factors also presented facilitators to engagement with prehabilitation. Accountability to and feedback from health professionals appeared to be particularly important. Participants felt that seeing a physiotherapist had/would motivate them to exercise. Consultants also had a key influence, with Jacob reporting his main motivation for losing weight pre-operatively was *“a massive rollicking from the consultant”*. Correspondingly, participants felt that recording their goals/exercises on a website for health professionals to view would be valuable. Irene had previous experience of this through using a mobile app provided by her consultant:

> “You record how many times a day you do them [exercises]. So it kind of made you do it, because you kept thinking, if my surgeon sees I'm not doing it.” (Irene)

Olivia also highlighted that uptake of a new pre-operative TKR care website would depend on appropriate signposting from health professionals and publicity in health settings. However, the influence of health professionals was not always a facilitator to prehabilitation. Beatrice was surprised by a consultant’s attitude towards pre-operative exercise at a talk she attended:

> “But he [consultant] just dismissed this, somebody said something about, what about exercises beforehand, and he just dismissed it out of hand, and said, well I don't really think it makes much difference.” (Beatrice)

Rosie perceived physiotherapists as *“quite gung-ho”*, contrasting with the encouragement to exercise she received on a social media discussion group. Peer influences also appeared to be important from an educational perspective. Participants from all focus groups reported finding it helpful to chat with previous patients informally, for example via a social media discussion group or when meeting in person. Key perceived benefits included building confidence to proceed with the operation and gaining a realistic understanding of what to expect:

> “And so you can have a chat to him and find out what problems he had and how good it was and how much pain he was in. So it does give you an insight into what to expect when you are going to have the operation. So the more people you can see or meet, I think it's the better.” (Harry)

Similarly, Cameron heard a volunteer discussing their experiences of TKR surgery during a pre-operative TKR class, which he felt was *“really, really beneficial because they've been through it”* and *“they have an awful lot of empathy with you.”* Overall, participants’ desire to find out about other patients’ experiences of TKR appeared to be a facilitator to engagement with pre-operative TKR education. Despite this, participants expressed concerns about making comparisons with other patients on social media. Furthermore, some participants were reluctant to look at online information pre-operatively because they did not want to hear negative experiences:

> “I had the mother, who had gone through the experience, and there was a friend who goes to a support group that I go to, who had the horror story from hell of her experience. And if I heard it once, I heard it three dozen times, from her, of what had happened to her. So, no, I didn’t use [search engine], because I didn’t want to find out more horror stories.” (Olivia)

6.3.4.3 Subtheme 2c: Limitations in pre-operative TKR care

Participants’ experiences of pre-operative TKR care were highly varied. Whilst some had positive experiences, many participants highlighted limitations in the pre-operative care they received. These limitations presented barriers to participants’ pre-operative preparations. Being unable to access adequate pre-operative support through other sources also appeared to be a potential facilitator to engagement with a pre-operative TKR website. A key pre-operative care limitation mentioned by participants from all three focus groups was lack of guidance on pre-operative exercise:

> “But there was nothing that I got in terms of here’s exercises that you should do, or anything like that at all, it was very, very vague. That’s just what seems to be the problem, really, there's no common approach to it, everybody just seemed to sort of do their own thing.” (James)

Lloyd also identified lack of guidance as a barrier to engagement with weight loss strategies pre-operatively. Similarly, participants highlighted various deficiencies in the pre-operative TKR education they received, such as inadequate information on home preparations and post-operative pain expectations. Participants felt it would be helpful for a pre-operative TKR website to address these limitations:

> “It could be good to have a checklist of things you need to get prepared at home before you go in. Because you don't always get the information from your physio or your knee school at the hospital.” (Molly)

Participants also highlighted problems related to the timing of pre-operative TKR care delivery. Beatrice had received a comprehensive information booklet, but felt it was not provided long enough before her surgery. Dorothy did not receive any pre-operative education or prehabilitation support because she underwent TKR at short notice due to a cancellation. Both Beatrice and Dorothy felt that a resource like a website could help address these issues by providing rapid access to information.

> “But I knew nothing about what was going to happen or anything at all, no. It would be super if, as a result of this whole PhD that you're doing [interviewer name], if there could be some means of either a DVD or booklet or something, or website, of giving information to people in that position so that in a short space of time, at least you've got the knowledge.” (Dorothy)

6.3.5 Barriers and facilitators tables

All four barriers and facilitators tables were extensive, spanning 18 pages and incorporating 29 barriers and 21 facilitators in total. Table 6.5 provides an excerpt from the pre-operative TKR education barriers and facilitators table.

Table 6.5: Pre-operative education barriers and facilitators table excerpt

Barrier/*facilitator* to the target behaviour	VKS design feature(s) that could address the barrier/facilitator	Include in behavioural analysis and reason if 'No'
B10. Low literacy and language barriers Participants in one focus group highlighted that some individuals might struggle to understand detailed information and medical terminology due to reasons such as low literacy or language barriers.	**Simple language, pictures and videos** The participants who highlighted that some individuals might find it difficult to understand detailed information and medical terminology felt that using simple language, pictures and videos would be helpful.	**Barrier: Yes** **Simple language, pictures and videos: Yes**
B11. Reluctance to receive detailed pre-operative information Lloyd reported being reluctant to receive detailed pre-operative information in general. Other participants also made comments about not wanting to receive too much information, but this was mainly related to information about the TKR surgical procedure. ***F6. Desire for detailed information about preparing for TKR surgery and what to expect*** Participants from all three focus groups indicated a desire for detailed information about preparing for TKR surgery and what to expect. This related to various factors such as their anxieties about undergoing TKR surgery and wanting to be practically prepared for returning home post-operatively.	**Videos of real people performing practical tasks, including using walking aids, getting in/out of a car, getting up from a fall and going round the supermarket** Participants from all three focus groups felt that using videos to provide demonstrations of one or more of the practical tasks listed above would be useful. **Quizzes about preparing for TKR surgery and what to expect** Participants from two focus groups felt that including educational quizzes would be helpful. In contrast, other participants from two focus groups expressed a dislike of quizzes and/or a preference for passive information provision. ***"Traffic light system"* checklist about complications** Jacob suggested that it would be helpful to have a *"traffic light system"* checklist to provide education about complications and their potential level of seriousness. **Checklist about home preparations** Molly suggested that it would be helpful to have a checklist about home preparations.	**Barrier: Yes** **Facilitator: Yes** **Videos of real people performing practical tasks, including using walking aids, getting in/out of a car, getting up from a fall and going round the supermarket: Yes** **Quizzes about preparing for TKR surgery and what to expect: No** Participants' views about quizzes were very mixed, with some participants specifically disliking quizzes. It is therefore appropriate to employ alternative approaches for providing information. ***"Traffic light system"* checklist about complications: Yes** **Checklist about home preparations: Yes**

B, barrier; F, facilitator; TKR, total knee replacement; VKS, Virtual Knee School

6.4 Discussion

6.4.1 Main findings

This qualitative descriptive study explored patients' perspectives of potential barriers and facilitators to engagement with the VKS. A diverse range of barriers and facilitators were identified for each behaviour targeted by the VKS. Many of the barriers/facilitators depended on participants' individual circumstances and preferences. Others related to the pre-operative context. Participants' perspectives of digital features were also closely linked to their individual circumstances/preferences and the pre-operative context. These findings highlight the importance of ensuring that the VKS accounts for individual differences and is tailored to the pre-operative TKR context.

In many cases, participants' perspectives of barriers/facilitators and digital features were directly opposing. This presents substantial challenges for accounting for individual differences within a single digital intervention such as the VKS. Maximising an intervention's flexibility is key to addressing these challenges. Participants in this study suggested offering a choice of features and implementation options, enabling users to self-tailor the intervention. This aligns with the PBA common guiding principles discussed in Chapter 7 (section 7.3.2). Offering users choices has the benefit of increasing users' autonomy, which may enhance their intrinsic motivation to engage with the intervention (178, 203). However, offering too many choices may be onerous and overwhelming for users, potentially presenting a barrier to their engagement with the intervention (427).

Computer-tailoring is another approach for accounting for individual differences. This involves employing computer algorithms to determine what intervention content a particular user receives, and/or how they receive it, based on an assessment of their individual characteristics (428, 429). A meta-analysis by Lustria et al. (430) found web-based interventions that employed computer-tailoring had greater effects on health outcomes than those that did not. The included studies' tailoring strategies were heterogeneous, reflecting diversity in the interventions' features, formats and degrees of interactivity. There is ongoing uncertainty about the optimal computer-tailoring strategies for digital health interventions (427, 430). Avoiding unnecessarily complex computer-tailoring is important due to the significant resources/technical expertise such tailoring requires (427). The goal-setting feature in this study's trigger materials provided an example of computer-tailoring. Participants' perspectives of this feature varied widely, largely due to their strongly held beliefs about the value of goal setting itself. Some participants particularly liked the idea of receiving personalised feedback, highlighting the potential benefits of computer-tailoring.

The meta-analysis by Lustria et al. (430) found no significant differences in effect sizes between web-based interventions that were mainly self-guided and those involving extensive expert guidance. This is a particularly relevant finding for this project given that the VKS was designed to be fully automated, as discussed in Chapter 2 (section 2.5). Despite this, health professional influences were identified as important facilitators to engagement with prehabilitation in this study. Even in fully automated digital interventions, these facilitators can be addressed to some degree by strategies such as providing tailored feedback (178) and introducing the intervention developers on a *‘meet the team’* page (427: p.3). Another key strategy identified in this study was signposting to the website by health professionals.

This study’s findings suggest that peer influences can also affect engagement with pre-operative TKR education and prehabilitation. Whilst peer support and a desire to find out about other patients’ experiences were facilitators, concerns about making comparisons with other patients and hearing negative experiences presented barriers, particularly to engagement with online information. The lack of unanimous enthusiasm for peer support aligns with the Phase 1b modified Delphi study, in which the item on offering peer support in a pre-operative TKR exercise programme did not reach consensus amongst patient panellists (Chapter 5, section 5.3.7). This study’s findings about peer influences highlight the potential value of online TKR peer support groups and the importance of moderating such groups. Including patient stories is another approach for providing examples of patients’ experiences in digital interventions. As detailed in Chapter 7 (section 7.3.2), providing patient stories that model how to overcome barriers to behaviour change is recommended by the PBA common guiding principles (178). Patient stories can feasibly be included in fully automated digital interventions, unlike moderated online discussion groups. However, patient stories cannot provide social support, which is a key element of online discussion groups (431).

Another key facilitator to engagement with prehabilitation identified in this study was patients’ beliefs about the benefits of pre-operative exercise and healthy lifestyle changes, particularly in relation to optimising their post-operative recovery. This corresponds with the proposal that the pre-operative phase presents a teachable moment, as discussed in Chapter 2 (section 2.3.5) (129). The limitations in pre-operative care identified in this study align with those highlighted in the Phase 1a rapid review (Chapter 4, section 4.3.6.2) and Phase 1b modified Delphi study (Chapter 5, section 5.3.2), and suggest that current TKR services are failing to capitalise on patients' pre-operative willingness to engage with health behaviour changes.

6.4.2 Comparison with previous similar studies

The barriers and facilitators to engagement with pre-operative TKR education and prehabilitation identified in this study are largely consistent with those suggested by previous research. For example, previous studies have highlighted that some patients are reluctant to watch the TKR surgical procedure (385, 432), patients' knee signs/symptoms are a key barrier to physical activity (138, 387, 433) and patients may be motivated to engage in physical activity by beliefs about its benefits (138). The present study builds on these findings by identifying potential approaches for addressing specific barriers/facilitators, such as providing an animation of TKR surgery, including non-weight bearing exercises in pre-operative TKR exercise programmes and explaining the benefits of specific exercises. This study also helps to explain some unexpected findings of previous studies. Pellegrini et al. (138) reported it was *'surprising'* that over a quarter of patients who were awaiting/had undergone TKR in their study were not interested in receiving any form of social support during a TKR weight loss programme (p.5). The present study's findings suggest that this may have been due to patients being concerned about making comparisons with other patients or hearing *"horror stories"* about TKR.

The importance of accounting for individual differences highlighted in this study, corresponds with the findings of previous studies exploring orthopaedic patients' perspectives of digital interventions. Reid et al. (384) showed participants a mock-up of a pre-operative TKR/THR education and prehabilitation digital intervention to help elicit their perspectives of digital features. Participants' preferences regarding voiceovers, real-life videos/animations and quizzes varied. As in this study, the majority of participants felt that real-life videos are particularly valuable. The present study expands this finding by highlighting that videos may have a negative impact if patients cannot relate to the models. A qualitative study by Robinson et al. (157) suggested that orthopaedic digital interventions should include interactive customisable features. The present study's findings largely concur with this, although they also emphasise that digital features should be quick and simple to use. Participants in the study by Robinson et al. (157) felt that orthopaedic digital interventions should include specific pre-operative sections. This aligns with the importance of tailoring to the pre-operative context highlighted in the present study, which identified numerous barriers/facilitators related to the pre-operative context and potential strategies for addressing them.

6.4.3 Limitations

Restrictions related to the COVID-19 pandemic meant that this study had to be conducted entirely remotely and recruitment through the NHS was not possible. This made recruiting a diverse sample of participants more challenging than anticipated. Diversity was obtained in certain characteristics, such as age, gender and educational level, but was limited in other characteristics. Only one participant was unconfident in using the Internet and no participants had a disability/health condition that affected their ability to use a website. Important barriers/facilitators related to low digital literacy and accessibility may therefore have been overlooked. In addition, all participants were White British. A qualitative study by Bove et al. (434) identified differences in Black and White patients' perspectives of post-TKR rehabilitation, with some Black participants reporting negative interactions with healthcare providers. Correspondingly, patients' ethnicity may influence their perspectives of barriers/facilitators to engagement with pre-operative TKR care.

Another limitation was that only one participant was awaiting her first TKR. Although an additional four participants were awaiting TKR on their second knee, their perspectives are likely to have been influenced by previously having undergone TKR. Participants who were not awaiting TKR at the time of the study may have been unable to fully recall the barriers/facilitators they experienced to engagement with pre-operative TKR education and prehabilitation. Relying on recruitment through community approaches such as social media, rather than the NHS, may have led to the recruitment of individuals who were particularly interested in and enthusiastic about this study's topic, increasing the risk of self-selection bias (326). Notably, 43% of the participants were recruited through a Facebook group. This may partly explain why most participants felt that peer support/education is valuable. Most participants also appeared enthusiastic about the concept of prehabilitation. Knowing that the researcher was a PhD student developing a pre-operative TKR care website may have encouraged participants to express positive views about pre-operative TKR education, prehabilitation and digital interventions, as they may not have wanted to criticise the study's aim.

As discussed in section 6.2.2.2, the sample size was based on the subjective assessment of saturation. Whilst this aligned with the study design and data analysis approach, further data collection may have provided important additional insights. A scoping review comparing online and in-person qualitative research found that participants' responses during online research tended to be briefer with fewer contextual details (415). Correspondingly, this study's remote data collection approach may have limited the depth of information obtained. This did not appear to be a substantial issue as the focus groups lasted at least 95 minutes and participants appeared to be willing to share their perspectives in detail.

6.4.4 Implications for practice and future research

This study's findings highlight various limitations in current pre-operative TKR care provision. Lack of guidance on pre-operative TKR exercise is a key area to address. A participant in this study commented on a consultant's negative attitude towards pre-operative exercise. Exploring health professionals' beliefs about prehabilitation and countering any misconceptions may therefore be necessary to fully embed provision of pre-operative exercise guidance in TKR pathways. Additional pre-operative TKR care limitations identified in this study include lack of guidance on weight loss and inadequate information on topics such as home preparations. Problems with the timing of pre-operative TKR care delivery were also noted, as highlighted in a previous UK-based study (102). This demonstrates the importance of ensuring that sources of pre-operative TKR education and prehabilitation support are rapidly accessible. This study's findings suggest that providing a pre-operative TKR website could help to address limitations in current care provision. They also demonstrate the importance of providing pre-operative TKR care using alternative delivery formats, such as paper-based resources, to account for patients' differing needs and preferences.

This study highlights barriers and facilitators to consider when designing pre-operative TKR interventions both for clinical practice and future research, and identifies design features that could help address the barriers and facilitators. This study's findings also demonstrate the importance of ensuring that pre-operative TKR interventions account for individual differences and are tailored to the pre-operative TKR context. These considerations were addressed in the Phase 3 theoretical modelling (Chapter 7, section 7.2) and Phase 4 VKS prototype development (Chapter 8, section 8.3). In light of this study's limitations, future research is required to explore barriers/facilitators to engagement with pre-operative TKR care amongst specific groups, such as people with low digital literacy, people from minority ethnic groups and people with negative attitudes towards pre-operative TKR education, prehabilitation and/or digital interventions.

6.5 Conclusion

The qualitative descriptive study reported in this chapter achieved its aim of exploring patients' perspectives of potential barriers and facilitators to engagement with the VKS. A diverse range of barriers and facilitators were identified. These reflect two key principles, which if addressed could help to optimise patient engagement with the VKS. The first principle suggests that the VKS should account for the impact of individual differences on engagement with digital technologies, pre-operative education and prehabilitation. The second principle highlights the importance of tailoring the VKS to pre-operative contextual features, including physiological/psychological factors, social/occupational factors and limitations in pre-operative TKR care provision. This study's findings were particularly useful for informing the Phase 3 theoretical modelling (Chapter 7, section 7.2) and Phase 4 VKS prototype development (Chapter 8, section 8.3). In addition, this study's findings provide a valuable original contribution to the literature by highlighting principles, barriers/facilitators and design features to consider when developing other pre-operative TKR digital interventions. The findings also have broader implications for clinical practice and future research. These include demonstrating the need for TKR services to provide rapidly accessible sources of pre-operative TKR education and prehabilitation support in a range of delivery formats. Exploring barriers/facilitators to engagement with pre-operative TKR care amongst specific groups, such as people with low digital literacy, is an important area for future research.

Chapter 7 Theoretical modelling to guide the Virtual Knee School design, description and evaluation (Phase 3)

7.1 Introduction

This chapter reports the rationale, methods and findings of the theoretical modelling approaches used to guide the design, description and evaluation of the VKS. These approaches comprised creating guiding principles, conducting a behavioural analysis and developing a logic model. Each approach built on the findings of Phases 1–2 (Chapters 4–6). This study was the final intervention planning phase for the VKS. As discussed in Chapter 3 (section 3.3.4), user testing is considered a type of evaluation activity (38). Correspondingly, the term *'evaluation'* is used to refer to the user testing of the VKS prototype and potential future evaluation of the VKS after this project's completion. Chapter 8 (sections 8.3–8.4) explains how the theoretical modelling approaches described in this chapter informed the VKS development and its evaluation through user testing. Chapter 9 (section 9.6.2) provides details of how the theoretical modelling approaches could inform future evaluation of the VKS through a randomised feasibility study.

7.1.1 Background

As discussed in Chapter 2 (section 2.4.3), incorporating theory during complex intervention development is widely recommended (170, 174) and supported by systematic reviews of digital interventions (179-181). Correspondingly, an evidence-, theory- and person-based approach was chosen to develop the VKS, as detailed in Chapter 3 (section 3.2.3). This involved following guidance from the following two approaches.

- Person-based approach (PBA) (178), which involves using intervention-specific and common guiding principles to inform decisions throughout the intervention development and evaluation process. This helps to ensure that the intervention has a coherent focus and is acceptable, meaningful and engaging for users.
- MRC framework for developing and evaluating complex interventions (2006 version) (173), which recommends:
    - drawing on and/or developing relevant theory to gain a theoretical understanding of how the intervention is expected to work and increase the chances that it will prove effective when evaluated;
    - modelling the intervention's process and outcomes to help inform the intervention design and evaluation;

- describing the intervention thoroughly to ensure that it can be replicated and implemented as intended.

The recommendations in the 2006 version of the MRC framework align with more recently published guidance. Both the updated MRC/NIHR framework for developing and evaluating complex interventions (170) and the INDEX guidance (174) recommend drawing on existing theories and articulating programme theory. Programme theory explains how an intervention is anticipated to achieve its aims in particular contexts (170, 174). Correspondingly, an intervention's programme theory typically details key elements of the intervention, its proposed causal mechanisms and relevant contextual features, and highlights potential interactions between them (170, 174). The MRC process evaluation guidance (227) also emphasises the importance of clearly describing an intervention and its proposed causal mechanisms, which it highlights is an essential prerequisite for planning a process evaluation.

Incorporating theory is particularly important when developing behaviour change interventions (207, 435). Gaining a theoretical understanding of an intervention's target behaviours helps to ensure that key influences on behaviour are identified and addressed (207, 435). Characterising behaviour change interventions' active components using standardised terminology facilitates intervention replication and implementation (226). It also aids synthesis of components from different interventions in systematic reviews (226). Identifying the proposed causal mechanisms of behaviour change interventions is important for understanding why interventions are/are not effective, how they can be refined and how more effective interventions can be developed (226, 435, 436). Given that the VKS is a digital behaviour change intervention, and its development was guided by the PBA (178) and MRC complex intervention framework (173), it was essential to undertake comprehensive theoretical modelling to guide the VKS design, description and evaluation.

7.1.2 Aim and objectives

This study aimed to use theoretical modelling to guide the design, description and evaluation of the VKS (project objective 3). It had the following three objectives.

1. To create guiding principles for the VKS to ensure that it has a coherent focus and is acceptable, meaningful and engaging for users.
2. To use behaviour change theory to systematically analyse each behaviour targeted by the VKS, code potential VKS features and map the features to findings from PPI consultations and Phases 1–2.

3. To develop a diagrammatic representation of the VKS, including its proposed causal mechanisms and intended outcomes.

7.2 Overview

Numerous previous studies have demonstrated how theory can be successfully incorporated during evidence-, theory- and person-based digital intervention development by combining three approaches: creating guiding principles, conducting a behavioural analysis and developing a logic model (211, 423, 437-441). These approaches were used to address objectives 1, 2 and 3 respectively. The researcher implemented all three approaches by drawing on multiple sources (Table 7.1) and refined the findings based on discussions with her supervisors/advisors. The guiding principles and behavioural analysis were created/conducted concurrently. Their findings were compared and integrated in the logic model. Figure 7.1 summarises how the theoretical modelling approaches were integrated. The GUIDance for the rEporting of intervention Development (GUIDED) checklist discussed in Chapter 3 (section 3.4.6) informed the study reporting.

Table 7.1: Theoretical modelling key sources

Code	Source	Chapter
PPI-C	Patient and Public Involvement consultations held during the project planning.	3
RR (study citation)	Findings from the Phase 1a rapid review studies.	4
DR (item number)	Final set of recommendations developed in the Phase 1b modified Delphi study.	5
DC	Free-text comments provided by patients and/or professionals in the Phase 1b modified Delphi study.	5
FG	Focus group findings from the Phase 2 qualitative descriptive study.	6

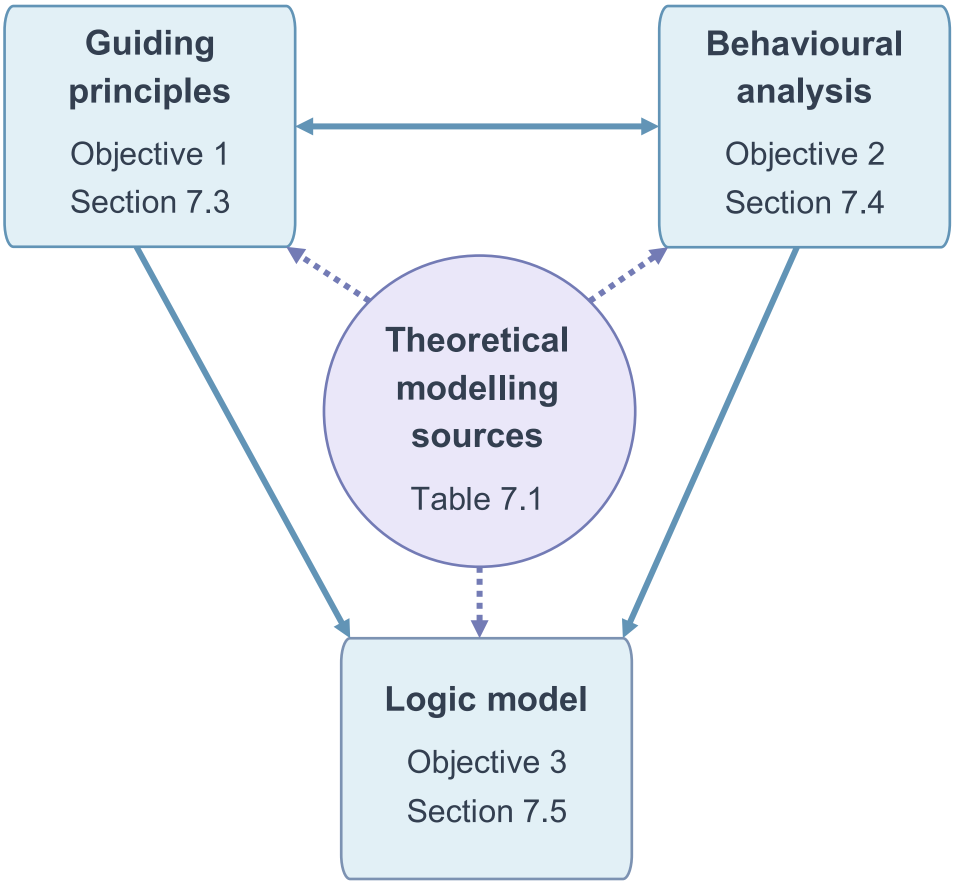


Figure 7.1: Theoretical modelling approaches

7.3 Guiding principles

7.3.1 Rationale and overview

VKS guiding principles were created to address objective 1. Creating guiding principles is a core element of the PBA (178). Guiding principles summarise two key considerations for the intervention development and evaluation process.

- Key intervention design objectives: these state the intervention's purpose in terms of the main user needs and other context-specific factors it seeks to address.
- Key intervention features: these are aspects of the intervention that aim to address the design objectives e.g. specific content, delivery approaches and implementation strategies.

Guiding principles provide a useful quick reference for prioritising intervention features and development activities (177). This helps to ensure that the development process remains focused on optimising how acceptable, meaningful and engaging the intervention is for users (177). Correspondingly, guiding principles complement more detailed theoretical modelling approaches such as the behavioural analysis described in section 7.4 below (178).

7.3.2 Methods

The VKS guiding principles were created by following the steps recommended by Yardley et al. (178) (Table 7.2).

Table 7.2: Recommended steps for creating guiding principles

Step	Describe the intervention context
1	State the objectives of the intervention in terms of behaviour and outcomes.
2	Briefly describe relevant aspects of users and their context.
3	Identify key behavioural issues, needs or challenges the intervention must address.
	Create guiding principles
4	Describe key intervention design objectives.
5	Describe key features of the intervention needed to achieve each objective.

The VKS objectives developed during step 1 were primarily informed by existing literature on pre-operative TKR interventions (Chapter 2, section 2.3) and PPI consultations held during the project planning (Chapter 3, section 3.5.2). The VKS outcome objective was defined in terms of what the VKS aims to provide. Potential patient outcomes were addressed in the logic model (section 7.5). The VKS behavioural objective was based on the VKS target behaviours detailed in Chapter 6 (section 6.1.1). During steps 2–3, the sources listed in Table 7.1 were used to identify considerations related to the intended VKS users' characteristics, context and needs. Considerations that could potentially be addressed through the same design objective/digital features were grouped together. Considerations that could not be addressed through a fully automated digital intervention, such as direct social support, were excluded. Each group of considerations developed in steps 2–3 was used to inform the development of a VKS guiding principle during steps 4–5.

Yardley et al. (178) have created a set of common guiding principles that can be drawn on to help optimise engagement with most digital behaviour change interventions (Table 7.3).

Table 7.3: Common guiding principles

CGP	Intervention design objective	Key intervention features
1	To promote user autonomy.	Offering users choice where possible (e.g. of goals, tools, timing, method of implementation).
2	To promote user competence.	Providing clear structure and (optional) guidance, examples, stories modelling successfully overcoming barriers, graded goal-setting, minimising conscious effort and lifestyle disruption where possible.
3	To promote a positive emotional experience and sense of relatedness.	Using positive (autonomy-supportive) language throughout, giving rationale for advice, acknowledging and addressing concerns.
		Ensuring all communications provide something interesting, enjoyable, relevant, and helpful for the user.
		Reciprocating intervention usage by providing immediately rewarding feedback.
		Following best practice to maximise accessibility, usability, and trust.

CGP, common guiding principle
Table reproduced from Table 3 in Yardley et al. (178) (https://doi.org/10.2196/jmir.4055) under the terms of the Creative Commons Attribution 2.0 International License (442). Modified by making minor formatting/wording amendments for clarity and consistency.

Yardley et al. (178) compiled the list of common guiding principle intervention features based on their practical experience of developing digital interventions. Yardley et al. (178) mapped the intervention features to intervention design objectives linked to constructs from Self-Determination Theory (SDT) (203). SDT is a meta-theory that proposes humans have three basic psychological needs. These include the needs for:

- autonomy (self-direction and ownership of one's actions);
- competence (confidence in one's own ability);
- relatedness (feeling connected to others).

SDT proposes that addressing these three needs enhances intrinsic motivation – motivation arising from personal interest/enjoyment/satisfaction in the activity (203). Being intrinsically motivated is believed to support maintenance of health behaviour changes (203, 443). Yardley et al. (178) identified SDT as particularly relevant to digital interventions because users typically require the motivation and confidence to use them independently (178).

The VKS development and refinement was informed by both the VKS guiding principles and the common guiding principles. Correspondingly, the VKS guiding principles were designed to be complementary to the common guiding principles. Individual VKS guiding principles and common guiding principles are referred to as *‘VGP-number’* and *‘CGP-number’* respectively in the remainder of this thesis.

7.3.3 Findings

Virtual Knee School objectives (step 1)

As discussed in Chapters 2 and 3 (sections 2.3 and 3.5.2), supporting patients to engage with pre-operative TKR education and prehabilitation could improve patient outcomes pre- and post-operatively. However, current UK pre-operative TKR intervention provision is variable, inefficient and does not meet all patients’ needs. In line with these considerations and the VKS target behaviours detailed in Chapter 6 (section 6.1.1), the VKS objectives were as follows.

- Outcome objective: to provide a patient-centred, widely accessible and cost-effective pre-operative TKR education and prehabilitation resource.
- Behavioural objective: to support patients listed for primary TKR to engage with pre-operative TKR care in a web-based format, pre-operative TKR education, a pre-operative TKR exercise programme and healthy lifestyle changes.

Users’ characteristics, context and needs (steps 2–3)

Six groups of considerations related to the intended VKS users’ characteristics, context and needs were identified. The source of each consideration is provided below using the codes detailed in Table 7.1.

1. Pre-operative TKR intervention provision and digital delivery

There are substantial discrepancies in current UK pre-operative TKR intervention provision [PPI-C; FG]. Some patients do not receive sufficient pre-operative TKR education and prehabilitation support or do not receive it long enough before their surgery [PPI-C; DC; FG]. These inadequacies may encourage patients to engage with web-based pre-operative TKR care [FG]. However, some patients may not be able to access websites [PPI-C; DC]. Even patients who can access websites may be reluctant to use them [FG]. Some patients have concerns about the reliability of websites and/or the detail/duration of website interactions [PPI-C; FG]. Furthermore, patients’ experience of using digital tools and preferences for digital features vary widely [FG].

2. Pre-operative TKR education concerns

Although some patients want to find out what happens during TKR surgery, others may be concerned about receiving information about the TKR surgical procedure, particularly due to the risk of seeing graphic details of surgery [RR (310); DC; FG]. In addition, patients may have concerns about hearing *"horror stories"* of TKR [FG]. Hearing such stories may impair patients' ability to learn [RR (316)]. Patients may also be concerned about making comparisons with other patients [FG]. On the other hand, for some patients, a desire to find out about other patients' experiences of TKR may be a facilitator to engagement with pre-operative TKR education [RR (99); FG].

3. Pre-operative TKR education preferences and needs

Patients' preferences for pre-operative TKR education vary widely, with some patients wanting to receive as much pre-operative information as possible, whilst others do not want to receive detailed information [RR (310); FG]. Patients' learning styles also differ [RR (109)]. In addition, patients may have low literacy and/or face language barriers [RR (109); DC; FG]. Correspondingly, some patients need simple information, but others find large volumes of simple information frustrating [FG]. Some patients value educational videos, especially of practical tasks such as how to use walking aids [FG]. Key topics that patients want information on include understanding what to expect, pain management and rehabilitation [PPI-C; RR (99, 102, 310, 317, 321); DR (1.12; 1.14–1.20); DC; FG].

4. Pre-operative TKR exercise misconceptions and motivating factors

Some patients may be concerned that exercising will cause further knee damage [PPI-C; FG]. Patients may also believe that pre-operative exercises are not important/beneficial [RR (311); DC]. This belief may be reinforced by health professionals [DC; FG]. Conversely, patients may be particularly motivated to perform pre-operative TKR exercises by the belief that doing so will improve their post-operative recovery and a sense of personal responsibility for their own recovery [RR (99); DC; FG]. Patients may also be motivated to engage with pre-operative exercises by setting goals/receiving tailored feedback and monitoring their exercise completion [FG]. Correspondingly, goal setting was identified as an important element of pre-operative TKR exercise programmes during the Phase 1b modified Delphi study [DR (4.12)].

5. Pre-operative TKR exercise preferences and needs

Patients listed for TKR surgery typically have severe knee signs/symptoms, which can prevent them from exercising [DC; FG]. Patients' engagement with pre-operative exercises may also be limited by a lack of guidance, being busy with other commitments/distractions and additional personal preferences/circumstances such as a dislike of certain exercise types, having other health issues and not being able to access specific equipment/facilities [PPI-C; RR (311); FG]. Patients' preferences for exercise videos versus exercise animations vary [FG]. Some patients particularly value exercise videos with real-life models, but videos may have a negative impact if patients cannot relate to the models [FG].

6. Pre-operative healthy lifestyle change motivating factors, needs and preferences

Patients may be motivated to make pre-operative healthy lifestyle changes by the belief that doing so will improve their post-operative recovery, a sense of personal responsibility for their own recovery and strategies such as self-monitoring and reflection [RR (99, 128, 135); FG]. As for pre-operative exercise, patients' engagement with healthy lifestyle changes may be limited by a lack of guidance [FG]. However, credible sources of healthy lifestyle guidance that account for individuals' differing needs/preferences are already available [FG].

Guiding principles (steps 4–5)

Six VKS guiding principles were developed (Table 7.4), corresponding with the six groups of considerations detailed above.

Table 7.4: Virtual Knee School guiding principles

VGP	Intervention design objective	Key intervention features
1	To provide a cost-effective, credible source of pre-operative TKR education and prehabilitation that is widely/immediately accessible, easy to use and engaging for a wide range of users.	Being fully automated.
		Emphasising that the VKS is evidence-based, developed by a team of UK-based experts and linked to the NHS.
		Ensuring all sections can be accessed rapidly during any session.
		Providing clear instructions on how to use the VKS, including a *'Help'* page at a minimum.
		Ensuring that the navigation and features are simple and quick to use.
		Providing PDF versions of key content/digital tools that users can download and print out, including a PDF exercise booklet and the documents listed under VGP-4 at a minimum.
2	To address users' potential concerns about pre-operative TKR education.	Emphasising that the VKS does not include any graphic details of TKR surgery.
		Providing brief information about TKR surgery only, without any graphic details.
		Ensuring that a range of appropriately moderated patient stories are provided, which are unlikely to be interpreted as *"horror stories",* and highlighting that everyone's preparations for/recovery from TKR surgery are different.
3	To account for users' varying pre-operative TKR education preferences and needs.	Providing pre-operative TKR education in accessible and engaging formats, ensuring key information is kept brief, but more detailed information is available for users who wish to access it.
		Providing information using simple language, avoiding medical terms where possible.
		Providing a glossary of medical terms.
		Providing key information using pictures and videos where appropriate, including videos related to understanding what to expect, pain management and rehabilitation (including using walking aids) at a minimum.
4	To address users' potential misconceptions about pre-operative TKR exercise and build their motivation to engage with the VKS exercise programme.	Providing reassurance that performing pre-operative exercises is safe for people with severe knee arthritis.
		Explaining the potential benefits of performing pre-operative exercises, including for post-operative recovery.
		Including patient stories modelling how other patients have benefitted from performing pre-operative TKR exercises.
		Providing features designed to motivate users to engage with the VKS exercise programme, including an online goal-setting feature that provides personalised feedback, a PDF goal-setting and recording sheet and a PDF exercise diary at a minimum.
5	To ensure that users with severe knee signs/symptoms and varying	Providing a flexible pre-operative TKR exercise programme that is tailored to the needs of users with severe knee signs/symptoms and does not require non-household equipment or facilities.

	personal preferences and circumstances can safely engage with the VKS exercise programme.	Providing clear guidance about how to safely select, perform and progress exercises, including videos of relatable patient models demonstrating exercises at a minimum.
6	To ensure that users know how to make healthy lifestyle changes and build their motivation to do so.	Explaining the potential benefits of making healthy lifestyle changes, including for post-operative recovery.
		Including brief guidance on making healthy lifestyle changes, with signposting to credible sources of further guidance.

NHS, National Health Service; PDF, Portable Document Format; TKR, total knee replacement; UK, United Kingdom; VGP, Virtual Knee School guiding principle; VKS, Virtual Knee School

7.4 Behavioural analysis

7.4.1 Rationale and overview

To address objective 2, a behavioural analysis was conducted. In an intervention development context, behavioural analysis refers to the process of using behaviour change theory to systematically analyse an intervention's target behaviours, code intervention features and map the features to the evidence base (423, 438). This helps to clearly describe the proposed intervention, ensure that all the proposed features are supported by adequate evidence/theory and check that potentially important behavioural targets/intervention components are not overlooked (423, 437). A large number of behaviour change theories, models and frameworks exist (207, 435). Using a single or small number of theories/models to inform an intervention means that potentially important influences on behaviour may be missed (207). Furthermore, many frameworks are limited in terms of comprehensiveness, coherence and linking to an overarching model of behaviour (207). To overcome these limitations, Michie et al. (207) synthesised 19 existing behaviour change frameworks to develop a new framework, the Behaviour Change Wheel (BCW).

The BCW is underpinned by the Capability, Opportunity, Motivation, Behaviour (COM-B) model of behaviour (207). This model is based on the assumption that, for an individual to perform a behaviour, they must have the required physical and psychological capability; physical and social opportunity; and reflective and automatic motivation. The COM-B model proposes that any of these six components could be targeted to change a behaviour. A key advantage of the COM-B model is that it addresses context by including physical and social opportunity (207). The COM-B model forms the inner layer of the BCW. The middle layer consists of nine intervention functions. These are relatively broad categories describing how an intervention may support/discourage a behaviour. The outer layer of the BCW includes seven policy categories, which indicate how authorities could support an intervention's implementation (Figure 7.2).

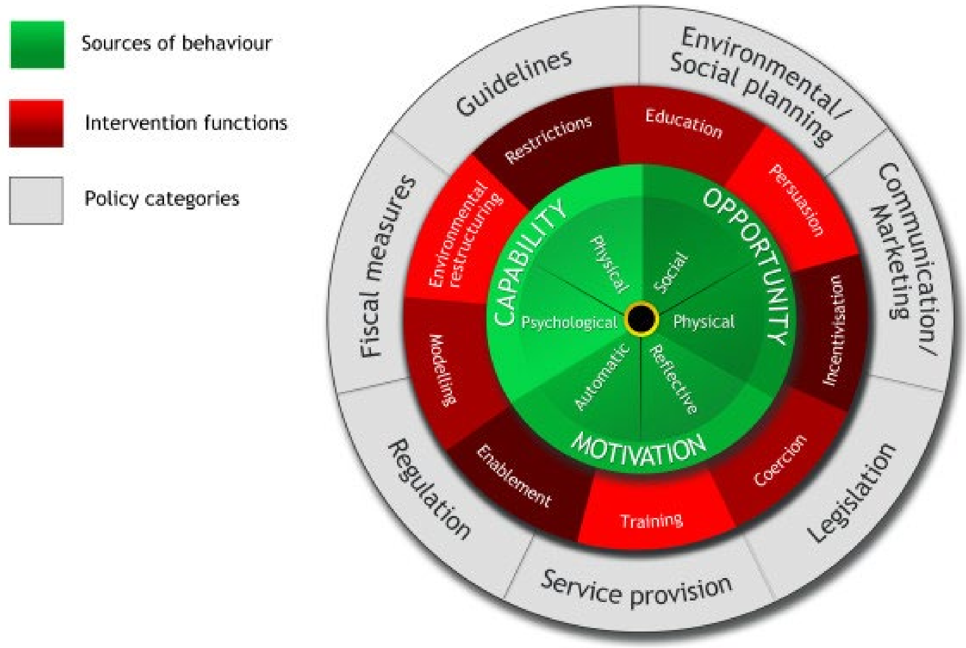


Figure 7.2: Behaviour Change Wheel

Figure reproduced without modification from Figure 2 in Michie et al. (207) (https://doi.org/10.1186/1748-5908-6-42) under the terms of the Creative Commons Attribution 2.0 International License (442).

BCW intervention functions can be linked to specific behaviour change techniques (BCTs) – the smallest *'active ingredients'* of behaviour change interventions (226: p.84). Key characteristics of BCTs are that they aim to influence behaviour and are *'observable, replicable and irreducible'* (226: p.82). Through an international consensus process, Michie et al. (226) developed a standardised approach for classifying BCTs known as the Behaviour Change Technique Taxonomy (v1) (BCTTv1). The BCTTv1 includes 93 distinct BCTs organised into 16 clusters. Using the BCW and BCTTv1 to conduct a behavioural analysis provides a systematic and transparent process for identifying and describing an intervention's behavioural targets and active components (207, 226, 438). Furthermore, the NICE guidance on individual level behaviour change interventions recommends the COM-B model for explaining how an intervention works (444). Correspondingly, the BCW and BCTTv1 have been widely used to conduct behavioural analyses during previous evidence-, theory- and person-based digital intervention development studies (211, 423, 437-441) and were chosen for this study.

Most of the above studies used the BCW and BCTTv1 alone or combined with the Theoretical Domains Framework (TDF) (445, 446) or Normalisation Process Theory (NPT) (447). The TDF is an integrative theoretical framework developed through a synthesis of 33 psychological theories (445). Although the TDF was developed for implementation research, it has been applied in other areas including the development of patient-focused behaviour change interventions (440, 448). The original TDF included 12 domains (445). It was subsequently refined to include 14 domains (446). These cover 84 constructs and have been mapped to the COM-B model (446). The TDF is valuable for comprehensive and detailed analysis of behaviours (448, 449). However, it is a relatively complex framework, which is time-consuming to apply (449).

Normalisation Process Theory (NPT) is a theory of action that aims to explain how interventions are implemented (put into action), embedded (normalised) and integrated (sustained) (447). It has four key constructs (coherence, cognitive participation, collective action, reflexive monitoring). These address the work that people need to do to implement an intervention. NPT considers organisational level factors and is particularly useful for addressing how interventions are implemented in clinical practice (205). The behavioural analysis in this study aimed to analyse multiple behaviours performed by patients and provide a clear description of potential VKS features, rather than providing a particularly in-depth analysis or considering implementation of the VKS by health professionals in clinical practice. Correspondingly, investing additional time in applying the TDF or NPT was not a priority. This study's behavioural analysis therefore employed the BCW and BCTTv1 alone.

7.4.2 Methods

The methods used to conduct the behavioural analysis were based on previous evidence-, theory- and person-based digital intervention development studies (211, 423, 438). '*Behavioural analysis tables'* (423: p.7) were developed for each of the four VKS target behaviours listed in Chapter 6 (section 6.1.1). Potential barriers and facilitators to engagement with the target behaviours and features that could address the barriers/facilitators were identified from the sources listed in Table 7.1. This led to identification of a large number of barriers/facilitators; therefore, additional studies reporting barriers/facilitators to engagement with the VKS target behaviours were not reviewed. Barriers/facilitators that could be addressed through the same digital features were grouped into sets. The lists of features were supplemented by feature ideas from the researcher and discussions with her supervisors/advisors.

The behavioural analysis table for engagement with healthy lifestyle changes was divided into separate sections for the following three healthy lifestyle changes: increase physical activity/reduce sedentary behaviour; improve weight management/diet; and reduce alcohol consumption. A section related to smoking cessation was not included because no barriers/facilitators to smoking cessation were identified from any of the sources listed in Table 7.1.

Each potential VKS feature was mapped to COM-B model components and intervention functions from the BCW (207) and BCTs from the BCTTv1 (226). Previous relevant studies were used to help resolve uncertainties in the coding (211, 423, 438). A key uncertainty was whether to code BCTs from the social support cluster for signposting to health professionals/family members/friends. Although the VKS does not provide social support directly, coding BCTs from the social support cluster was considered appropriate based on previous relevant studies (211, 438). Similarly, providing printable documents was coded as BCT 12.5 *'Adding objects to the environment'* (226: Supplementary Table 3) based on a previous study (438).

The behavioural analysis tables were compared to the BCW and BCTTv1 to check for any potentially important behavioural targets or intervention components that had not been identified through the process outlined above. To assist identification of additional relevant BCTs, the BCTs included in the tables were compared to the BCTs identified in a systematic review of digital-based structured self-management programmes for people with OA by Safari et al. (450). Policy categories were not considered because this study focused on the behaviours targeted by the VKS rather than implementation of the VKS in clinical practice. The behavioural analysis tables and VKS guiding principles were developed concurrently and compared to check for inconsistencies.

7.4.3 Findings

Tables 7.5 and 7.6 provide a summary of the behavioural analysis tables and excerpts from the tables respectively.

Table 7.5: Behavioural analysis tables summary

Target behaviour	Number of sets of barriers/facilitators	Table length (pages)
Engage with pre-operative TKR care in a web-based format	5	2
Engage with pre-operative TKR education	5	2
Engage with a pre-operative TKR exercise programme	11	5
Engage with healthy lifestyle changes	20	8

TKR, total knee replacement

Table 7.6: Behavioural analysis tables excerpts

Set of barriers/*facilitators* to the target behaviour [barrier/facilitator/VKS feature source(s)[a]]	**Potential VKS feature(s) that could address the barriers/facilitators**	**Target component(s) (BCW)**	**Intervention function(s) (BCW)**	**Behaviour change technique(s) (BCTTv1)**
Target behaviour: engage with pre-operative TKR care in a web-based format				
W1. Limited experience of using digital tools/low digital literacy [RR (107); FG]	Simple navigation, including menu pages with links to other sections/pages.	Physical opportunity	Environmental restructuring	12.1 Restructuring the physical environment
	Introductory section that provides clear instructions about how to use the VKS and emphasises that it is easy to use, even for people who have limited experience of using digital tools. *'Common questions'* and *'Help'* pages available to assist users with using the VKS.	Psychological capability Reflective motivation	Education Persuasion	4.1 Instruction on how to perform the behaviour 15.1 Verbal persuasion about capability
Target behaviour: engage with pre-operative TKR education				
Ed5. Concerns about finding out about "horror stories" of TKR surgery Concerns about making comparisons with other patients' experiences of TKR surgery *Desire to find out about other patients' experiences of TKR surgery* [RR (99, 316); DR (2.4); DC; FG]	Introductory section that: • explains that the VKS provides examples of other patients' experiences of TKR surgery to help users understand what to expect; • explains that everyone's preparations and recovery are different.	Psychological capability Reflective motivation	Education Persuasion	5.6 Information about emotional consequences
	Information about TKR surgery provided through appropriately moderated patient stories, which are unlikely to be interpreted as "horror stories".	Social opportunity Reflective motivation	Persuasion Modelling	6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source

Target behaviour: engage with a pre-operative TKR exercise programme				
Ex9. Setting exercise goals and not meeting them *Setting exercise goals, reviewing exercise goals and receiving feedback about exercise goals* [PPI-C; DR (1.6, 4.12); DC; FG]	Exercise goal setting, review and feedback feature that includes: • information about goal setting, including its benefits and how to set achievable goals; • suggestions about how to adapt goals if they are not met; • encouraging feedback; • goal setting and recording sheet that users can download and print out.	Psychological capability Physical opportunity Reflective motivation	Education Persuasion Environmental restructuring Enablement	1.1 Goal setting (behaviour) 1.2 Problem solving 1.4 Action planning 1.5 Review behaviour goal(s) 1.6 Discrepancy between current behaviour and goal 2.2 Feedback on behaviour 2.3 Self-monitoring of behaviour 5.1 Information about health consequences 10.4 Social reward 12.5 Adding objects to the environment
Target behaviour: engage with healthy lifestyle changes (increase physical activity and reduce sedentary behaviour)[b]				
HL2. Forgetfulness [RR (135)]	Guidance on setting activity reminders, for example on a mobile phone.	Physical opportunity	Environmental restructuring	7.1 Prompts/cues
	Information about the benefits of habit formation and suggestions about how to make being more active/less sedentary a habit.	Psychological capability Reflective motivation Automatic motivation	Education Persuasion Training	4.1 Instruction on how to perform a behaviour 8.1 Behavioural practice/rehearsal 8.3 Habit formation
Target behaviour: engage with healthy lifestyle changes (improve weight management and diet)				
HL12. Other health issues or lifestyle choices [FG]	Signposting to credible websites that provide weight management advice that accounts for other health issues or lifestyle choices.	Psychological capability	Education	5.1 Information about health consequences 9.1 Credible source
	Guidance on seeking health professional advice about other health issues that may present a barrier to weight management.	Social opportunity	Enablement	3.2 Social support (unspecified) 9.1 Credible source

Target behaviour: engage with healthy lifestyle changes (reduce alcohol consumption)				
HL20. Not realising how much alcohol they are consuming *Identifying and reflecting on their alcohol consumption* [RR (128)]	Guidance to support the user to monitor and reflect on their current alcohol consumption, identify barriers to reducing their alcohol consumption and identify strategies for addressing the barriers.	Psychological capability Reflective motivation	Education Enablement	1.2 Problem solving 1.4 Action planning 2.3 Self-monitoring of behaviour
	Alcohol consumption screening feature that provides personalised feedback.	Reflective motivation	Persuasion	2.2 Feedback on behaviour 5.1 Information about health consequences

BCTTv1, Behaviour Change Technique Taxonomy (v1) (226: Supplementary Table 3); BCW, Behaviour Change Wheel (207); Ed, set of barriers/facilitators to engagement with pre-operative TKR education; Ex, set of barriers/facilitators to engagement with a pre-operative TKR exercise programme; HL, set of barriers/facilitators to engagement with healthy lifestyle changes; TKR, total knee replacement; VKS, Virtual Knee School; W, set of barriers/facilitators to engagement with pre-operative TKR care in a web-based format

[a] Table 7.1 provides the codes for the sources.

[b] Only includes details related to increasing physical activity in general rather than engaging with a pre-operative TKR exercise programme.

The potential VKS features included in the behavioural analysis tables targeted all six COM-B model components and employed six BCW intervention functions: education, persuasion, training, environmental restructuring, modelling and enablement. Three BCW intervention functions were not included: incentivisation, coercion and restrictions. These three intervention functions involve creating an expectation of external consequences or imposing external rules. This may reduce intrinsic motivation (203, 443). Correspondingly, these functions were not considered appropriate for the VKS. The potential VKS features employed 25 BCTs covering 12 of the 16 BCTTv1 clusters (Table 7.7).

Table 7.7: Behaviour change techniques employed in the potential Virtual Knee School features

Cluster[a]	Behaviour change technique[a]
1. Goals and planning	1.1 Goal setting (behaviour)
	1.2 Problem solving
	1.4 Action planning
	1.5 Review behaviour goal(s)
	1.6 Discrepancy between current behaviour and goal
2. Feedback and monitoring	2.2 Feedback on behaviour
	2.3 Self-monitoring of behaviour
3. Social support	3.1 Social support (unspecified)
4. Shaping knowledge	4.1 Instruction on how to perform a behaviour
5. Natural consequences	5.1 Information about health consequences
	5.6 Information about emotional consequences
6. Comparison of behaviour	6.1 Demonstration of the behaviour
	6.2 Social comparison
	6.3 Information about others' approval
7. Associations	7.1 Prompts/cues
8. Repetition and substitution	8.1 Behavioural practice/rehearsal
	8.3 Habit formation
	8.7 Graded tasks
9. Comparison of outcomes	9.1 Credible source
10. Reward and threat	10.4 Social reward
12. Antecedents	12.1 Restructuring the physical environment
	12.2 Restructuring the social environment
	12.5 Adding objects to the environment
	12.6 Body changes (assistive aids)
15. Self-belief	15.1 Verbal persuasion about capability

[a] Clusters and behaviour change techniques are from the Behaviour Change Technique Taxonomy (v1) (226: Supplementary Table 3).

Fourteen BCTs identified in the systematic review of digital-based structured OA self-management programmes by Safari et al. (450) were not employed in any of the potential VKS features (Appendix F). The researcher compared the behavioural analysis tables with these 14 BCTs and with the BCTTv1 directly. These comparisons did not lead to the inclusion of any additional BCTs in the behavioural analysis tables. This was primarily due to the large number of BCTs already included in the tables. These BCTs were identified using a rigorous process and supported by the sources listed in Table 7.1; hence ensuring their contextual relevance. The effectiveness of BCTs is influenced by how they are delivered and contextual features (451). Correspondingly, the researcher and her supervisors agreed that implementing the BCTs already included in the behavioural analysis tables well was more of a priority than including additional BCTs, which are likely to have been less relevant to the VKS context. For example, an additional BCT identified by Safari et al. (450) was 1.7 *'Review outcome goals'* (226: Supplementary Table 3). The potential VKS features already employed BCT 1.5 *'Review behaviour goal(s)'* (226: Supplementary Table 3). BCT 1.5 was considered more of a priority to include in the VKS because many Phase 2 participants felt that setting goals about their engagement with an exercise programme would be helpful (Chapter 6, section 6.3). In addition, there is greater evidence supporting behavioural goal setting than outcome goal setting for improving exercise adherence amongst individuals with musculoskeletal conditions (452, 453).

Comparison of the behavioural analysis tables and VKS guiding principles did not reveal any major inconsistencies. However, the behavioural analysis tables included a large number of barriers/facilitators to engagement with healthy lifestyle changes. This suggests that adding further healthy lifestyle change-related features to the VKS guiding principles could have had some merit. This was decided against because providing in-depth support with multiple healthy lifestyle changes, in addition to the other VKS content, is likely to have made the VKS too complex and overwhelming for users.

7.5 Logic model

7.5.1 Rationale and overview

A logic model of the VKS was developed to address objective 3. Logic models are diagrams representing an intervention and its proposed causal mechanisms (227, 454). Although their content varies, they typically detail an intervention's intended delivery mechanisms, components, mechanisms of action and outcomes (227). Developing a logic model of an intervention is *'highly recommended'* by the MRC process evaluation guidance (227: p.58). Key benefits of logic models include:

- transparently describing an intervention and its proposed causal mechanisms;
- helping to identify potential contradictions and areas of uncertainty in the proposed causal mechanisms;
- clearly conveying complex inter-relationships;
- facilitating communication about the intervention between the research team and other stakeholders;
- providing a framework for planning a process evaluation (227, 455, 456).

There is substantial variability in how logic models are conceptualised and applied (456). In response to this, Rehfuess et al. (456) proposed a taxonomy of logic models for systematic reviews and health technology assessments (HTAs). Mills et al. (454) have also proposed a typology of logic models, which has broad applicability to healthcare research (Table 7.8).

Table 7.8: Logic model taxonomy/typology

Taxonomy/ typology	Elements	Name	Overview
Rehfuess et al. (456) taxonomy	Type	System-based	Focuses on describing the interactions of the intervention in the context of a broader system.
		Process-orientated	Focuses on describing the causal pathways between the intervention and its intended outcomes.
	Approach	A priori	Developed as close to the conception of a systematic review/HTA as possible. Not changed during the review/HTA process.
		Staged	Developed and then refined at pre-specified points during the systematic review/HTA process.
		Iterative	Developed and then repeatedly refined throughout the systematic review/HTA process.
Mills et al. (454) typology	Type	Type 1	Lists logic model factors but not relationships between factors. Excludes the intervention context.
		Type 2	Lists logic model factors but not relationships between factors. Includes the intervention context.
		Type 3	Lists logic model factors and relationships between them. Excludes the intervention context.
		Type 4	Lists logic model factors and relationships between them. Includes the intervention context.

HTA, health technology assessment

Rehfuess et al. (456) highlight that a system-based logic model is usually appropriate for a systematic review or HTA, but the optimal type depends on the nature of the intervention and research question. Given this project focused primarily on developing rather than assessing the VKS, and one of the purposes of the VKS logic model was to describe its proposed causal mechanisms, a process-orientated logic model was developed. An iterative approach was chosen to provide maximum flexibility for refining the logic model. Furthermore, an iterative approach is particularly valuable for theory generation rather than theory testing (456).

According to the typology proposed by Mills et al. (454), Type 3 and 4 logic models are most appropriate for describing an intervention’s causal mechanisms. Type 4 models offer the advantage of incorporating contextual moderators, which can have a key influence on an intervention’s success, and help to model the dynamic nature of complex interventions (454). A Type 4 logic model was therefore developed in this study.

7.5.2 Methods

The development of the VKS logic model was primarily guided by the MRC process evaluation guidance (227). It was also informed by the guidance on developing Type 4 logic models proposed by Mills et al. (454) and logic models of other digital interventions developed using an evidence-, theory- and person-based approach (211, 423, 438). The researcher drafted the logic model components as follows.

- Problems: the overall problem the VKS seeks to address was based on existing literature on pre-operative TKR interventions (Chapter 2, section 2.3) and PPI consultations held during the project planning (Chapter 3, section 3.5.2). The overall problem was hypothesised to contribute to various pre- and post-operative problems for patients, which were identified from the sources listed in Table 7.1. This included reviewing the outcome measures employed in the Phase 1a rapid review outcomes studies (Chapter 4) and identifying concerns raised by PPI representatives during the project planning (Chapter 3) and participants in Phases 1b–2 (Chapters 5–6). To ensure that potentially important problems were not overlooked, the wider TKR literature discussed in Chapter 2 was also considered.
- Objectives: the VKS outcome and behavioural objectives were identified based on the findings of step 1 of the creation of the VKS guiding principles (section 7.3.3).

- VKS features and intervention processes: key VKS features were identified from the VKS guiding principles (Table 7.4). These were linked to COM-B model target components based on the behavioural analysis tables (section 7.4.3).
- Mechanisms: potential causal mechanisms were identified in line with the MRC process evaluation guidance (227). This states that mechanisms may include participant responses (how participants engage with the intervention), mediators (intermediate processes that influence outcomes) and unintended pathways/consequences. The intended participant responses and mediators were based on the VKS behavioural objective detailed in section 7.3.3. In line with a previous relevant study (438), only key mediators (the health-related behaviours the VKS seeks to change) were listed. The key potential unintended consequence of the VKS that needs to be avoided was identified based on existing literature related to digital interventions (Chapter 2, section 2.4.2) and the sources listed in Table 7.1.
- Patient outcomes: potential pre- and post-operative patient outcomes were identified based on the pre- and post-operative problems for patients discussed above.
- Contextual moderators: potential contextual moderators were identified from the sources listed in Table 7.1, the findings of steps 2–3 of the creation of the VKS guiding principles (section 7.3.3) and the behavioural analysis findings (section 7.4.3). In line with the MRC process evaluation guidance (227), the contextual moderators were considered to have the potential to influence the causal mechanisms of the VKS and the patient outcomes.

Logic models risk being *‘unintelligible when overcrowded’* (457: p.41). To minimise this risk, relationships between factors within each component of the logic model were included, but relationships between most of the different components were excluded.

7.5.3 Findings

Figure 7.3 presents the VKS logic model. A brief narrative summary is provided below.

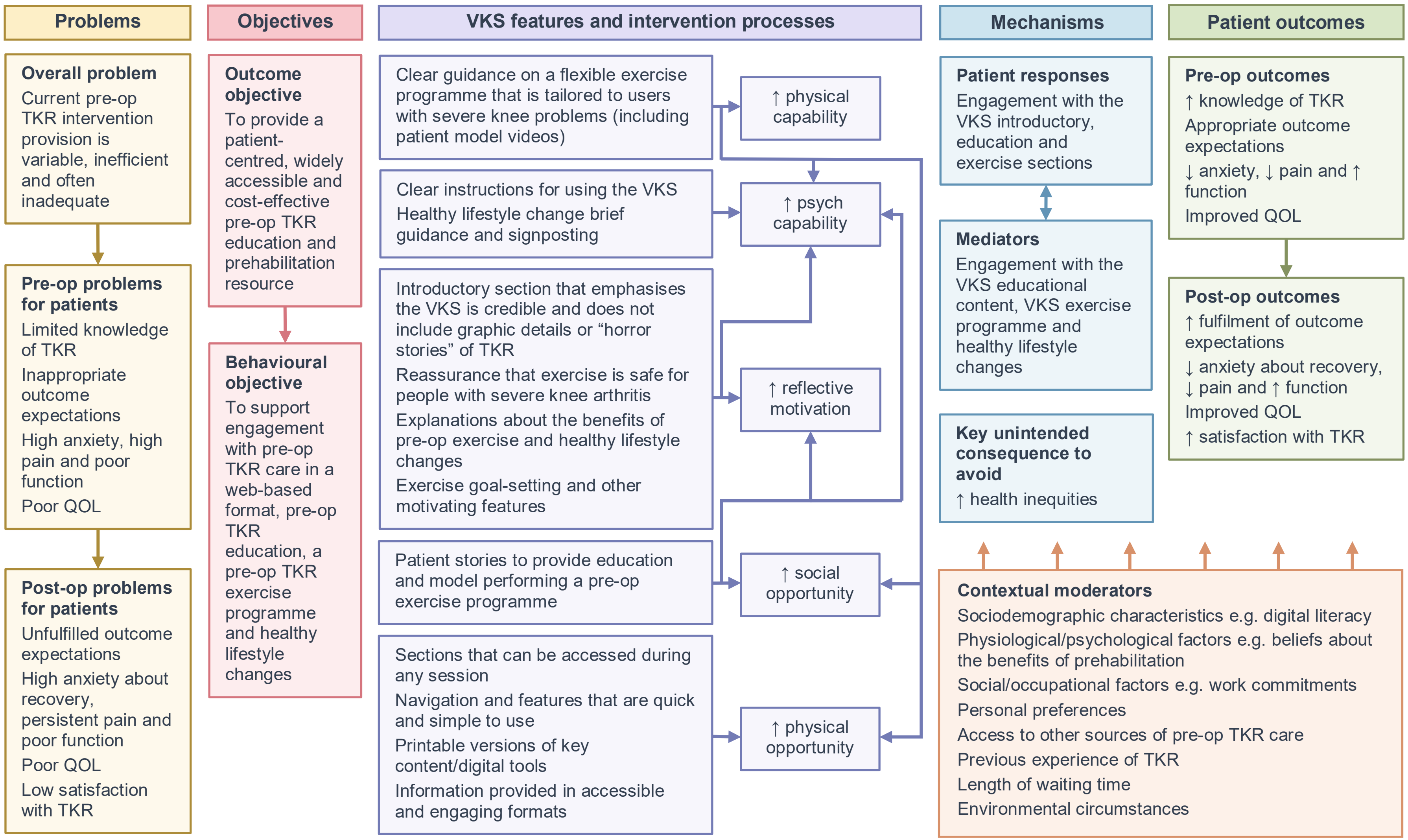


Figure 7.3: Virtual Knee School logic model

Post-op, post-operative; pre-op, pre-operative; psych, psychological; QOL, quality of life; TKR, total knee replacement; VKS, Virtual Knee School
Due to space limitations, relationships between factors in different columns of the logic model are not shown.

The overall problem the VKS seeks to address is that current UK pre-operative TKR intervention provision is variable, inefficient and often inadequate. This may contribute to multiple pre- and post-operative problems for patients, such as poor QOL. The VKS aims to address these problems by providing a patient-centred, widely accessible and cost-effective pre-operative TKR education and prehabilitation resource, and supporting patients to engage with its four target behaviours. The key VKS features target all components of the COM-B model except for automatic motivation. For example, providing brief guidance/signposting on healthy lifestyle changes aims to increase patients' knowledge about how to initiate and maintain healthy lifestyle changes; hence influencing patients' psychological capability.

Intended patient responses to the VKS are engagement with its introductory, education and exercise sections. Engagement with these sections is proposed to dynamically interact with the VKS mediators: engagement with the VKS educational content, VKS exercise programme and healthy lifestyle changes. For example, engaging with the VKS exercise section may prompt the patient to try the VKS exercises. Successfully performing the exercises may encourage the patient to engage with the VKS exercise section again. Given that some patients are not able to access websites or engage with them effectively, the key unintended consequence the VKS needs to avoid is increasing health inequities.

The VKS mediators are proposed to improve multiple pre- and post-operative patient outcomes, such as improving patients' QOL. Numerous contextual moderators may influence the VKS causal mechanisms and patient outcomes. For example, social support may facilitate patients' engagement with the VKS and its target behaviours. This may positively influence their outcomes. The contextual moderators may also affect patient outcomes independently of the VKS. For example, social support may improve patient outcomes by decreasing loneliness and increasing patients' confidence when discharged home (458, 459).

Overall, the VKS logic model provides a transparent diagrammatic representation of the VKS, including its proposed causal mechanisms and intended outcomes. The logic model and its implications, along with the other two theoretical modelling approaches, are discussed further below.

7.6 Discussion

7.6.1 Main findings

This study integrated three theoretical modelling approaches to help guide the design, description and evaluation of the VKS. Each theoretical modelling approach provided inter-related and complementary insights. Six VKS guiding principles were created (Table 7.4), which concisely summarise the key design objectives and features of the VKS. The VKS guiding principles provided a useful quick reference for ensuring that the VKS development reported in Chapter 8 remained focused on optimising how acceptable, meaningful and engaging the VKS is for users. They were also particularly helpful for informing decisions during the VKS user testing process, which enabled the VKS to be evaluated and refined. Conducting a behavioural analysis provided more in-depth insights into the behaviours targeted by the VKS. This facilitated the development of detailed lists of potential VKS features. The logic model integrated the VKS guiding principles and behavioural analysis findings and provided a diagrammatic representation of the VKS (Figure 7.3). The logic model includes the VKS's proposed causal mechanisms and intended outcomes; therefore, it will be particularly valuable for informing future evaluation of the VKS, as discussed in Chapter 9 (section 9.6.2).

The VKS guiding principles collectively address the two broad principles identified during the Phase 2 qualitative descriptive study – *'Accounting for individual differences'* and *'Tailoring to the pre-operative context'* (Chapter 6, section 6.3). In addition, they complement the PBA common guiding principles proposed by Yardley et al. (178) (Table 7.3). For example, the intervention design objective of VGP-5 is:

> 'To ensure that users with severe knee signs/symptoms and varying personal preferences and circumstances can safely engage with the VKS exercise programme.'

This accounts for the influence of individual differences on engagement with exercise and highlights the importance of tailoring the VKS exercise programme to patients' pre-operative knee signs/symptoms. VGP-5 intervention features include providing a flexible exercise programme and clear guidance, which address CGP-1 (*'To promote user autonomy'*) and CGP-2 (*'To promote user competence'*) respectively (178: Table 3).

As discussed in section 7.3.2, the common guiding principles link to the three psychological needs postulated by SDT. Based on a review of 208 behaviour change mobile apps, Villalobos-Zúñiga and Cherubini (460) identified 12 features that can address these three psychological needs. The goal-setting feature specified in VGP-4 incorporates three of these features: goal setting, log/self-monitoring and activity feedback. One further feature (reminders) was included in the behavioural analysis, but was not considered a high enough priority to specify in the VKS guiding principles. The additional eight features identified by Villalobos-Zúñiga and Cherubini (460) were not included in the VKS guiding principles or behavioural analysis. In light of the findings of this study and Phases 1–2, all eight of the additional features were considered unimportant or inappropriate for the VKS. For example, one of the additional features was peer comparison (e.g. through a *'leader board'*) (460: p.16). This was considered inappropriate for the VKS given that the Phase 2 findings highlighted that some patients are concerned about making comparisons with other patients.

The potential VKS features identified in the behavioural analysis targeted all six COM-B model components and employed six BCW intervention functions and 25 unique BCTs (Table 7.7). As discussed in section 7.4.3, 14 additional BCTs were identified in a systematic review of digital-based structured OA self-management programmes by Safari et al. (450) but were not considered a priority for the VKS. Across the eight studies included by Safari et al. (450), the most commonly employed BCT clusters were goals and planning; feedback and monitoring; and shaping knowledge. Similarly, in a systematic review of digital physical activity interventions for people with OA, Berry et al. (461) found the largest proportions of BCTs identified were in the goals and planning; feedback and monitoring; and social support clusters. Including BCTs from these latter three clusters is explicitly recommended in the NICE guidance on individual level behaviour change interventions (444). The potential VKS features cover all three of these clusters. Whilst this supports the proposed VKS features, it is important not to focus simply on the BCTs included, as numerous other factors affect the effectiveness of BCTs. These include interactions between BCTs, the BCT delivery approaches and the context in which the BCTs are implemented (451).

7.6.2 Comparison with previous similar studies

This study supports the growing body of evidence that demonstrates how creating guiding principles, conducting a behavioural analysis and developing a logic model can be successfully incorporated during evidence-, theory- and person-based digital intervention development (211, 423, 437-441). Similarly to this study, Band et al. (423)

and Bradbury et al. (211) compared their behavioural analysis tables to the BCW (and NPT) and did not identify any additional important behavioural targets or intervention components. This highlights how drawing on multiple sources when conducting a behavioural analysis is a valuable and comprehensive approach. A key difference between this study and previous similar studies is that previous studies have not specified any unintended consequences to avoid or contextual moderators in their logic models (211, 423, 437-441). Both these components are important to consider when conducting a process evaluation (227). Correspondingly, they were considered a priority to include in the VKS logic model because one of its key purposes is to inform a future process evaluation. Furthermore, as discussed in section 7.5.1, Type 4 logic models, which include contextual moderators and relationships between logic model factors, arguably model the dynamic nature of complex interventions more effectively than other types of logic models (454).

To the researcher’s knowledge, the combination of theoretical modelling approaches employed in this study has not previously been used to develop a pre-operative TKR digital intervention. However, similar theoretical modelling approaches have been applied to web-based interventions for people with joint pain. Clarkson et al. (462) used the PBA to develop a web-based joint pain self-management intervention and integrate it with a social network support tool. In line with the VKS guiding principles, the guiding principles developed by Clarkson et al. (462) address accessibility, motivation, goal setting and credibility/trustworthiness. An important difference is that Clarkson et al. (462) listed *‘Provide references for all information’* as a key intervention feature to enhance trust in the intervention (462: Table 2). In contrast, including references in the VKS was decided against to help ensure that the volume/complexity of text was not overwhelming.

Pearson et al. (412) drew on principles of persuasive technology and human-centred design to develop a web-based prototype of Enabling Self-management and Coping with Arthritic Pain through Exercise (ESCAPE-pain) – a rehabilitation programme for people with chronic joint pain. This included mapping the findings of focus groups and think-aloud interviews to the BCTTv1 (226). Whereas the VKS behavioural analysis covered 12 of the 16 BCT clusters, the qualitative findings of Pearson et al. (412) covered eight clusters only. This is likely to be at least partly because this study’s behavioural analysis involved mapping detailed features to the BCTTv1, whereas Pearson et al. (412) mapped broader subthemes such as *‘Credibility’* and *‘Exercise’* (412: Table 4), rather than detailed features.

7.6.3 Limitations

An important limitation of all three theoretical modelling approaches is that they involved subjective judgements. For example, as discussed in section 7.4.2, it was not always clear-cut how to code the digital features during the behavioural analysis. To help address this, multiple sources of guidance and previous relevant studies were referred to. In addition, the researcher refined the findings of all the approaches based on discussions with her supervisors/advisors. The perspectives of patients were incorporated through the sources used to inform each theoretical modelling approach (Table 7.1), such as the PPI consultations held during the project planning. However, patients were not directly involved in the decision-making processes. This could have been addressed by asking PPI representatives to directly review and contribute to the theoretical modelling approaches and/or by conducting primary research. For example, Bennett et al. (463) demonstrated how a three-stage process involving a behavioural analysis, focus group and modified nominal group technique (NGT) was valuable for identifying, refining and prioritising BCTs/intervention content for a self-management intervention for people with hypermobility spectrum disorders and hypermobile Ehlers-Danlos syndrome. Using a similar approach in this study would have required substantial additional time/resources and was not considered a priority because patients' perspectives were incorporated during all the other project phases.

As discussed in section 7.4.1, employing the BCW was appropriate for the behavioural analysis of this study; however, it is a relatively simple approach. Employing an additional framework or theory, such as the TDF (445, 446), NPT (447) or Social Cognitive Theory (464), would have provided a more in-depth understanding of the VKS's target behaviours and may have led to the identification of extra potential VKS features. Mapping the potential VKS features to the BCW and BCTTv1 provided a clear description of the features using standardised terminology. Whilst this approach offers benefits, it has been criticised for being too prescriptive and failing to account for the variability in how patients respond to behaviour change interventions (465). For example, contextual features such as culture may have an important influence on the effectiveness of behaviour change methods (466).

Although developing a Type 4 logic model helped with capturing the complexity of the VKS, it is still a simplified representation of the VKS. For example, only key VKS features and their target COM-B model components were included. This meant that automatic motivation was not listed in the logic model even though it was addressed by potential VKS features included in the behavioural analysis tables. In addition, space limitations meant that it was not possible to include the relationships between most of the different model components. A further limitation of the logic model is that only the health-related behaviours the VKS seeks to change were listed as mediators. Changes in the COM-B model components could also potentially be classed as mediators but were listed as *'intervention processes'* based on a previous relevant study (438: Figure 1).

7.6.4 Implications for practice and future research

The findings of the theoretical modelling approaches highlight important considerations for developing pre-operative TKR interventions and potential approaches for addressing them. These findings guided the Phase 4 VKS prototype development and refinement reported in Chapter 8 and could help inform the development of other pre-operative TKR interventions for use in clinical practice and future research. The logic model also highlights multiple problems that pre-operative TKR interventions could address, along with corresponding intended patient outcomes of the VKS. Refining the large number of problems/patient outcomes identified could be an important objective of a future feasibility study of the VKS, as detailed in Chapter 9 (section 9.6.2). As discussed above (section 7.6.3), a limitation of the logic model is that only health-related behaviours were listed as mediators. A more detailed understanding of the proposed causal mechanisms of the VKS could be obtained in the future by coding the VKS content using the TDF discussed in section 7.4.1. Another option would be to link the BCTs in the VKS features to mechanisms of action based on the Theory and Techniques Tool – an interactive online resource that provides hypothesised links between 74 BCTs and 26 mechanisms of action (467, 468).

As reported in section 7.4.2, no barriers/facilitators to smoking cessation were identified from any of the sources listed in Table 7.1. In their survey of 299 patients awaiting surgery, McDonald et al. (131) found participants' confidence ratings were notably lower for stopping smoking compared to the other three healthy lifestyle changes investigated. This suggests that patients may face substantial pre-operative barriers to smoking cessation. To the researcher's knowledge, no studies have specifically explored barriers/facilitators to smoking cessation amongst patients awaiting TKR, although a qualitative study published in Danish in 2004 may have considered this to some degree (469). Addressing this gap should be a priority for future research because smoking is associated with an increased risk of complications and mortality post-TKR/THR (18). Furthermore, smoking cessation was identified as an important education topic in the final recommendations developed in the Phase 1b modified Delphi study (Chapter 5, section 5.3.4),

7.7 Conclusion

The study reported in this chapter achieved its aim of using theoretical modelling to guide the design, description and evaluation of the VKS. Each study objective was addressed through a different theoretical modelling approach. All three approaches were integrated and built on the findings of Phases 1–2 (Chapters 4–6). Six VKS guiding principles were created in line with the PBA. These provide a concise summary of the key design objectives and features of the VKS. An in-depth understanding of the behaviours targeted by the VKS was gained by conducting a behavioural analysis using the BCW and BCTTv1. The behavioural analysis enabled a detailed list of potential VKS features to be developed and characterised using standardised terminology. The potential VKS features targeted all six COM-B model components and employed six BCW functions and 25 BCTs. The VKS guiding principles and behavioural analysis findings were integrated in a logic model. This provides a transparent diagrammatic representation of the VKS, including its proposed causal mechanisms and intended outcomes. As detailed in Chapter 8 (sections 8.3–8.4), this study’s findings played a key role in informing the VKS development and its evaluation through user testing. The findings will also be particularly valuable for guiding future evaluation of the VKS, as discussed in Chapter 9 (section 9.6.2). This study provides a useful original contribution to the literature by demonstrating how three theoretical modelling approaches can be integrated when developing a novel pre-operative TKR digital intervention. In addition to their use in this project, the findings could help inform the development of other pre-operative TKR interventions for clinical practice and future research.

Chapter 8 Virtual Knee School prototype development and iterative refinement using the think-aloud method (Phase 4)

8.1 Introduction

This chapter reports how a prototype version of the VKS was developed by integrating the findings of Phases 1–3 (Chapter 4–7). It then describes how the prototype was iteratively refined by evaluating how patients use it and exploring their perspectives of it. This was achieved through concurrent think-aloud interviews with patients who were awaiting/had undergone TKR. This study was the final phase of the overall project.

8.1.1 Background

As discussed in Chapter 3 (section 3.2.3), an evidence-, theory- and person-based approach was chosen to develop the VKS. This approach involves conducting multiple intervention planning activities and integrating their findings to develop a prototype version of the intervention (178). Even when comprehensive intervention planning is undertaken, important barriers to engagement with the intervention and its target behaviours may be overlooked or insufficiently addressed (211, 228). Correspondingly, it is vital to ask intended users to try using the prototype and explore their experiences and perspectives of doing so (177, 178). Iteratively refining the prototype based on the feedback obtained helps to ensure that the intervention is acceptable, meaningful and engaging for users (178). Furthermore, obtaining feedback on intervention prototypes is consistent with the recommendations on developing and evaluating digital behaviour change interventions proposed by Michie et al. (38) (Chapter 2, Table 2.2). These recommendations emphasise that evaluation should be embedded throughout the development cycle. Michie et al. (38) highlight that this can be achieved through approaches such as user testing.

A key purpose of obtaining user feedback is to evaluate a prototype's usability (470). According to the International Organization for Standardization (ISO) 9241-11:2018 standard (471), usability encompasses the effectiveness, efficiency and satisfaction with which users can achieve their objectives when using a website or other product, system or service. The ISO 9241-11:2018 standard also highlights that usability is specific to particular users in a particular context (471). In addition to considering usability, the person-based approach (PBA) involves exploring intended users' perspectives of an intervention prototype more broadly (178, 439). For example, in-depth qualitative research is used to explore whether the prototype is acceptable, persuasive and supportive of the desired behaviour changes (178). This comprehensive approach often leads to the identification of multiple potential changes that could be made to refine the prototype (211, 228). Correspondingly, it is essential to employ a transparent process for prioritising which changes to implement (228).

8.1.2 Aim and objectives

This study aimed to develop a prototype version of the VKS and iteratively refine it by evaluating how patients use it and exploring their perspectives of it (project objective 4). Its objectives were as follows.

1. To develop a prototype version of the VKS.
2. To evaluate the usability of the VKS prototype.
3. To explore patients' perspectives of the VKS prototype.
4. To prioritise and implement changes to the VKS prototype.

8.2 Overview

Comprehensively and transparently describing the intervention development process is important for multiple reasons (238). These include enabling stakeholders to assess the quality of an intervention and its applicability to their specific context; improving understanding of the advantages/disadvantages of different intervention development approaches; and assisting identification of how various approaches contribute to the development of effective/ineffective interventions (238). This chapter therefore provides a detailed description of how the VKS prototype was initially developed (section 8.3) and subsequently refined (sections 8.4–8.5).

Reporting of this study was primarily guided by the GUIDance for the rEporting of intervention Development (GUIDED) checklist (238) described in Chapter 3 (section 3.4.6). In line with this, the TIDieR checklist and guide (272) was referred to when describing the VKS prototype. Additionally, the reporting of the qualitative component was informed by the COREQ checklist (401) discussed in Chapter 6 (section 6.2.1).

8.3 Prototype development

8.3.1 Overview and rationale

In line with using an evidence-, theory- and person-based approach, the VKS development was informed by multiple sources. These included the Phase 1–3 findings (Chapter 4–7) and the PAG PPI member consultations and coproduction activities discussed below. To ensure compliance with all applicable guidelines/regulations, the following resources were also referred/adhered to.

- British Standards Institution (BSI) Publicly Available Specification (PAS) 277:2015 (472): a code of practice for developing safe and effective health and wellbeing apps. This addresses a range of considerations such as legal/regulatory compliance, functionality, security/privacy and safety.
- Web Content Accessibility Guidelines (WCAG) 2.1 (473): a technical standard for making web-based content more accessible. This is based on four accessibility principles, which state that web-based content must be perceivable, operable, understandable and robust.
- Public Sector Bodies (Websites and Mobile Applications) Accessibility Regulations 2018 (474): a set of regulations that aims to ensure public sector body websites and mobile applications are accessible for disabled people. These regulations can be met by including an accessibility statement on the website/mobile application and ensuring it adheres to the WCAG 2.1 AA standard (473).
- University of Leeds website regulations (475): a set of regulations that apply to websites associated with the University of Leeds. These regulations cover aspects such as the website terms of use, privacy and branding.

As recommended by the BSI PAS 277:2015 (472), a VKS risk register was developed to document potential risks associated with using the VKS and the steps taken to mitigate them.

The initial intention was to develop and host the VKS using *'LifeGuide'*, open-source software that enables researchers with little/no programme experience to iteratively develop/refine digital behaviour change interventions (476). At the time of the VKS development, the LifeGuide software was in a period of transition and the available version of the software will not be supported in the future. The PAG therefore recommended that the VKS be developed/hosted on alternative software to ensure it has longevity. A tender for the VKS development/hosting was completed in April/May 2021. The contract was awarded to *'Frank'*, a web development/design company with extensive experience of developing digital health tools (477).

8.3.2 Prototype sections

To address regulatory/functional requirements and the Phase 1–3 findings, the VKS content was organised in five sections (Table 8.1). The main section covered all the pages/features that did not fit within the other sections, such as the homepage. The healthy lifestyle content was brief to meet VKS guiding principle six (VGP-6); therefore, it was included in the education section rather than as a separate section.

Table 8.1: Key sections included in the Virtual Knee School prototype

Section	Purpose	Key intervention planning findings used to inform the section			
		Phase 1a rapid review findings (Chapter 4)	Phase 1b modified Delphi study final recommendations (Chapter 5)	Phase 2 qualitative study/Phase 3 behavioural analysis findings (Chapters 6–7)	Phase 3 VGPs (Chapter 7)
Login	Enable users to sign up and log into the VKS to enable computer-tailoring and ensure that the VKS is only accessible to authorised users.	N/A	N/A	N/A	1
Main	Provide content required for regulatory purposes (e.g. privacy and cookies policy) and ensure that the VKS is accessible and simple to use.	N/A	N/A	Engage with pre-op TKR care in a web-based format	1
Introductory	Demonstrate that the VKS is credible and address users' potential concerns/ misconceptions about engaging with the VKS and its target behaviours.	N/A	N/A	Engage with pre-op TKR care in a web-based format Engage with pre-op TKR education Engage with a pre-op TKR exercise programme	1; 2; 4
Education	Provide and promote engagement with the VKS educational and healthy lifestyle content.	Education interventions Lifestyle interventions	Pre-op TKR education topics Pre-op TKR education delivery	Engage with pre-op TKR education Engage with healthy lifestyle changes	2; 3; 6
Exercise	Provide and promote engagement with the VKS exercise programme.	Exercise interventions	Pre-op TKR exercise types Pre-op TKR exercise programme delivery	Engage with a pre-op TKR exercise programme	4; 5

Pre-op; pre-operative; TKR, total knee replacement; VGP, Virtual Knee School guiding principle; VKS, Virtual Knee School

8.3.3 Intervention features selection

Key steps to take when deciding what features to include in a digital intervention include the following.

1. Collation of the findings of the intervention planning phases with all other relevant information, such as PPI representatives' suggestions (152, 478). During PBA intervention development, this is typically achieved by creating an intervention planning table (478). This table facilitates team discussions by providing a structured summary of potential features to include in the intervention along with their reasons for inclusion (478).
2. Prioritisation of the potential features to ensure that the most important features are included even if time and resources are limited (152). A simple and widely used tool for achieving this is the Must have, Should have, Could have, Would like (MoSCoW) model (152, 479).

In line with the above, VKS intervention planning tables were created for each section specified in Table 8.1. The features in each section were grouped into pages. Each feature was prioritised using the MoSCoW model (152, 479). Criteria to guide the prioritisation were specified to promote transparency and consistency. The researcher iteratively refined the prioritisation criteria and intervention planning tables based on discussions with her supervisors/advisors and PAG PPI members. The final intervention planning tables spanned 17 pages. Tables 8.2 and 8.3 provide the final prioritisation criteria and an excerpt from the education section intervention planning table respectively.

Table 8.2: Prioritisation criteria for including features in the Virtual Knee School prototype

Code	Reason for inclusion[a]	Importance level	Time-consuming to develop[b]	Priority[c]
FN	Important for the VKS functioning/navigation.	1	No	Must have
S	Required for safety purposes.		Yes	Must have
R	Required to meet relevant regulations/guidelines.			
VGP (VGP number)	Required to meet one or more VGPs developed in Phase 3 (Chapter 7).			
CGP (CGP number)	Required to meet one or more CGPs detailed in Phase 3 (Chapter 7).	2	No	Should have
PPI	Addresses PAG PPI member feedback.		Yes	Could have
PAS	Addresses BSI PAS 277:2015 quality criteria (472).			
NICE	Addresses the NICE primary joint replacement guideline (31).			
VIR (item number)	Addresses one or more items prioritised as *'Very important'* in the Phase 1b modified Delphi study final recommendations (Chapter 5).			
IR (item number)	Addresses one or more items prioritised as *'Important'* in the Phase 1b modified Delphi study recommendations (Chapter 5).	3	No	Could have
			Yes	Would like
BF (barrier/ facilitator set[d])	Addresses one or more barriers/facilitators identified in the Phase 3 behavioural analysis (Chapter 7)			

BSI, British Standards Institution; CGP, common guiding principle; NICE, National Institute for Health and Care Excellence; PAG, Project Advisory Group; PAS, Publicly Available Specification; PPI, Patient and Public Involvement; VGP, Virtual Knee School guiding principle; VKS, Virtual Knee School

[a] Key findings from the Phase 1a rapid review, Phase 1b modified Delphi study free-text comments and Phase 2 qualitative descriptive study were covered by the modified Delphi study recommendations and behavioural analysis; therefore, they were not listed as reasons for inclusion to help keep the length/complexity of the table manageable.

[b] Features were classed as time-consuming to develop if they would require substantial programming time or involve developing a video, photograph, infographic or PDF document.

[c] If a feature was supported by more than one reason, the priority was based on the reason with the highest importance level.

[d] The barrier/facilitator sets were labelled with the codes reported in the behavioural analysis table excerpts (Chapter 7, Table 7.6).

Table 8.3: Virtual Knee School education section intervention planning table excerpt

Page(s)	VKS feature	Importance level[a]			Time-consuming to develop	Priority	Include in prototype
		1	2	3			
Managing concerns during your recovery	Text covering how to lower the risks of having issues after TKR surgery, including wound care	–	NICE; VIR (1.14)	–	No	Should have	Yes
	Traffic light system checklist that: • includes complications of TKR surgery and common issues that do not need to cause alarm • explains how to organise help if complications occur	–	VIR (1.14, 1.15)	IR (1.33); BF (Ed3)	No	Should have	Yes
Getting up and about	Brief videos of patient models demonstrating how to use: • a walking stick • one and two crutches • a walking frame	VGP (3)	PPI	IR (1.8, 1.34); BF (W3, Ed2, Ed3)	Yes	Must have	Yes
	Text covering post-operative mobility, including: • the role of mobilising in rehabilitation following TKR surgery • the role of mobilising in lowering the risks of TKR surgery • key points about mobilising safely	–	VIR (1.14, 1.20)	IR (1.34)	No	Should have	Yes
	Accordion content covering: • returning to a normal walking pattern • how to stand up, sit down and perform bed transfers	–	–	IR (1.8, 1.34); BF (W3, Ed3)	No	Could have	Yes
	PDF booklets covering how to use walking aids	–	PPI	IR (1.8, 1.34, 2.5.3, 2.6)	Yes	Could have	No

	Photographs of a patient model getting up with one foot in front of the other and getting up with their feet in line	–	–	BF (Ed2)	Yes	Would like	No
	Photograph of a patient model getting on and off a bed	–	–	BF (Ed2)	Yes	Would like	No
	Brief video of a patient model getting up with one foot in front of the other and getting up with their feet in line	–	–	BF (W3, Ed2, Ed3)	Yes	Would like	No
	Brief video of a patient model getting on and off a bed	–	–	BF (W3, Ed2, Ed3)	Yes	Would like	No

PDF, Portable Document Format; TKR, total knee replacement; VKS, Virtual Knee School

[a] Table 8.2 provides the meaning of the codes.

8.3.4 Information architecture and navigation options

Definitive evidence on the optimal information architecture (content structure/display) for digital health interventions is lacking (480). Matrix, hierarchical and tunnel designs present different strengths and limitations (481). For example, tunnel designs are simple to navigate and ensure that users receive all the relevant content in the optimal order, but users may find the lack of flexibility frustrating (480, 481). A hybrid design was chosen for the VKS prototype to help mitigate the limitations of other designs (481, 482). The content was largely structured hierarchically with three page levels (Figure 8.1). The first time users logged in they were tunnelled to the introductory section menu to help ensure that they viewed a welcome video, which was designed to address key barriers to engagement with the VKS and its target behaviours. On all subsequent logins, users went straight to the homepage. To address VGP-1, the sections were accessible in any order (after the initial tunnelling) and the following navigation options were included:

- navigation buttons to provide a simple way for users to navigate the VKS;
- meganav (expandable menu) to enable users to view lists of the VKS pages and navigate quickly to specific pages;
- weighted search function to enable users to search for and navigate quickly to specific content;
- breadcrumb trail to show users their location in the VKS.

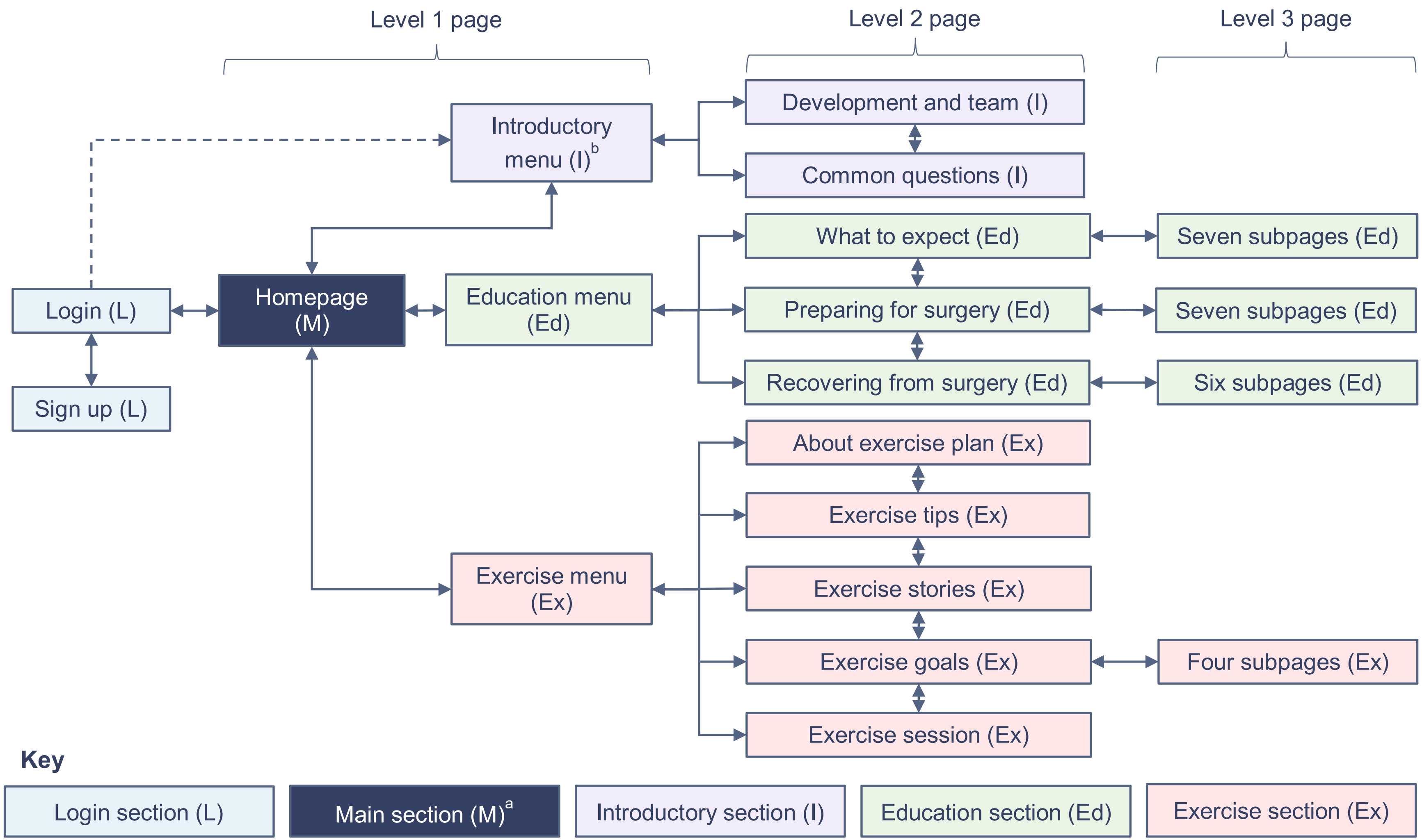


Figure 8.1: Virtual Knee School information architecture summary

[a] The main section also included the following pages accessible via the header, footer or meganav: Help; Accessibility statement; Privacy and cookies policy; Other helpful websites; Contact us

[b] Users were tunnelled to the introductory section menu on their first login but not subsequent logins

8.3.5 Content development

The researcher wrote content drafts corresponding with the intervention planning tables in Microsoft Word 2016. These included all *'Must have'* and *'Should have'* features, some *'Could have'* features and no *'Would like'* features. Decisions about which *'Could have'* features to include were primarily guided by the importance of the feature and the time required to develop it. The sources used to inform the content of each page were documented and included: the Phase 1–3 findings; additional relevant research; LifeGuide digital interventions; relevant guidelines; publicly available information from respected sources; and West Yorkshire Association of Acute Trusts (WYAAT) orthopaedic education resources. The WYAAT resources were developed by a multidisciplinary team of professionals, including the researcher, as part of a programme of work to standardise hip and knee replacement care across the six WYAAT trusts (483). A Caldicott letter was provided by the Leeds Teaching Hospitals NHS Trust (LTHT) Information Governance Team to permit use of the WYAAT resources in the VKS.

Key priorities during the content development were to address the common and VKS guiding principles (Chapter 7, Tables 7.3–7.4) and promote accessibility and inclusion. For example, patient stories were carefully crafted to model successfully overcoming barriers (in line with CGP-2) and ensure diversity in the patients' characteristics. Furthermore, the VKS prototype included an accessibility toolbar that enabled users to change the VKS language, text size and background colour. Development of the content was informed by discussions with the researcher's supervisors/advisors and PAG PPI member consultations. For example, the following actions were taken to address PPI members' views:

- the VKS email address was included on the *'Common questions'* page;
- extra details were added to the educational video transcripts e.g. about sleep difficulties and psychological well-being;
- a video on how to use one crutch was created (rather than advising users to use a crutch in a similar way to a walking stick).

In line with the VKS and common guiding principles, WCAG 2.1 (473) and PPI member consultations, content was developed in various formats to help ensure that the VKS prototype was accessible and engaging. These formats included static text, accordion content (boxes that the user can select to view additional content), static images, PDF documents and videos. To create the videos, the researcher recruited eight volunteer patient models of varied ages, genders, ethnicities and ability levels. The researcher scripted the videos, developed risk assessments, directed the filming and identified appropriate stock footage for the educational videos. A videographer from the University of Leeds Medical Teaching Centre undertook the filming and editing. The final videos comprised one welcome video and nine educational videos presented by the researcher, and 10 walking aids videos and 15 exercise videos of the patient models. To optimise page-loading speed and enable auto-translation of the video captions, all the videos were hosted on YouTube and embedded in the VKS prototype.

8.3.6 Exercise programme design

Ten target exercise types to include in the VKS exercise programme were identified from the final recommendations developed in the Phase 1b modified Delphi study (Chapter 5, section 5.3.6). Exercises that could be classified as each exercise type were identified from:

- outcomes studies included in the Phase 1a rapid review;
- free-text comments provided by PPI representatives during pilot testing of the Phase 1b Round 1 survey;
- free-text comments provided by panellists in the Phase 1b Round 1 survey.

The researcher created a table to document the target exercise types, associated exercises and considerations for deciding which exercise types/exercises to include in the VKS prototype. Key considerations included:

- areas of overlap between the exercise types;
- whether the exercise types/exercises were consistent with the VKS guiding principles;
- whether the exercise types/exercises would be addressed in other sections of the VKS prototype.

Table 8.4 provides an excerpt from the final four-page target exercise types table.

Table 8.4: Target exercise types table excerpt

Target exercise type (Phase 1b modified Delphi study item number)	Exercises classified as the exercise type in outcomes studies included in the Phase 1a rapid review (study citation)[ab]	Exercises identified from additional sources [source][a]	Considerations for including the exercise type/exercises in the VKS prototype
Balance exercises (3.6)	• Double leg stance on an unstable device (287, 288) • Single leg stance (on an unstable device, hard floor or balance mat, with or without support, with eyes open or closed) (287, 288, 292) • Slide step forward/backward on a hard floor or balance mat, with or without support, with eyes open or closed (292) • Step forward/backward on a hard floor or balance mat, with or without support, with eyes open or closed (292) • Squats on a hard floor or balance mat, with or without support, with eyes open or closed (292)	• *"Balancing on Bosu"* [DC] • *"Heel to toe walking"* [RR (292), PPI]	• Exercises that require a balance device/mat are inconsistent with VGP-5 due to requiring specific equipment. • *'Slide step forward/backward'* and *'Step forward/backward'* can also be classified as *'Leg strengthening exercises'* and *'Functional technique exercises'*. • *'Squats'* can also be classified as a *'Leg strengthening exercise'*.

DC, free-text comment provided by a panellist in the Phase 1b modified Delphi study; PPI, free-text comment provided by a Patient and Public Involvement representative during pilot testing of the Phase 1b Round 1 survey; RR, exercise identified from the warm-up or cool-down of an outcomes study included in the Phase 1a rapid review; VGP-5, Virtual Knee School guiding principle 5; VKS, Virtual Knee School

[a] Exercises were only identified from outcomes studies that were identified prior to the search updates and reported a statistically significant difference in favour of the intervention group for at least one outcome at one or more follow-up time points.

[b] The exercise classifications were based on the primary study authors' descriptions. Details in brackets were specified in at least one, but not all, of the outcomes studies listed.

Based on the target exercise types table and discussions with her supervisors/advisors, the researcher created a table specifying five proposed exercise categories to include in the VKS prototype and a prioritised list of candidate exercises for each category. An excerpt from this two-page table is provided in Table 8.5. The exercise categories/candidate exercises covered all the target exercise types except for *'Walking practice with walking aids'* because requiring specific equipment is inconsistent with VGP-5 and the VKS education section provides guidance on using walking aids. It was provisionally decided to include the top three candidate exercises from each category in the VKS exercise programme. Correspondingly, the prioritisation aimed to ensure that:

- the top three exercises in each category varied in difficulty and included at least one non-weight bearing exercise to address VGP-5;
- the top three exercises from all five categories combined covered all the target exercise types except for *'Walking practice with walking aids'*.

Table 8.5: Proposed Virtual Knee School exercise categories and candidate exercises table excerpt

Proposed exercise category	Candidate exercises[a]	Explanation
Knee strength and endurance	1. Chair stands *(sitting/standing)* 2. Knee straightening (knee extensions) *(sitting)* 3. Straight leg raise *(crook lying)* 4. Mini squats (squats) *(standing)* 5. Leg lifts with a rolled towel under the knee *(long sitting)*	• This exercise category focuses primarily on *'Leg strengthening exercises'* and *'Functional movement exercises'.* • Improving knee extensor muscle strength is a key target of TKR prehabilitation (118). Therefore, it was agreed that it was important to separate *'Leg strengthening exercises'* into two separate sections, one focusing solely on knee extensor exercises and one focusing on hip and ankle exercises. Correspondingly, it was decided not to include *the 'Hamstring flexion/leg curl'* in this category to help ensure that users perform at least one knee extensor strengthening exercise. • Given the exercises listed may improve both muscle strength and endurance, it was decided to name this category *'Knee strength and endurance'.*

TKR, total knee replacement

[a] Bracketed plain text indicates the original description of the exercise, which was amended for clarity for users. Bracketed text in italics indicates the exercise position(s).

The table of proposed exercise categories/candidate exercises was used to draft a provisional exercise programme. Consultations with two PAG PPI members led to two refinements: the title *'Leg stretching and flexibility'* was shortened to *'Leg flexibility'* and the *'Knee bending/straightening'* exercise was replaced with the *'Calf stretch'* exercise. Table 8.6 provides the finalised exercise categories and exercises.

Table 8.6: Finalised Virtual Knee School exercise categories and exercises

Exercise category	Exercises
1. Aerobic fitness	Seated marching Walking on the spot Step-ups
2. Knee strength and endurance	Straight leg raise Knee straightening Sit to stand
3. Hip and ankle strength and endurance	Sideways leg lifts Backwards leg lifts Heel raises
4. Balance and stability	Hip lifts Standing on one leg Step forwards and backwards
5. Leg flexibility	Thigh stretch Hamstring stretch Calf stretch

The researcher drafted the VKS exercise programme delivery approaches based on the Phase 1b final recommendations and discussions with her supervisors/advisors (Table 8.7). The delivery approaches were discussed with two PAG PPI members, who felt no changes were needed.

Table 8.7: Virtual Knee School exercise programme delivery approaches

Delivery category	Phase 1b modified Delphi study final recommendation (item number(s))	Addressed in the VKS	Explanation
Delivery mode	Be delivered using a combination of more than one format, including supervised exercise sessions, unsupervised exercise sessions and a booklet or other written format (4.1.2; 4.1.3; 4.1.5; 4.2)	Partly	The exercise programme was provided directly on the VKS prototype through text/videos with captions and as a PDF booklet that users could download.
	Provide an opportunity for peer support (4.11)	No	An online discussion forum would require moderation. This would be inconsistent with VGP-1.
	Include goal setting (4.12)	Yes	The VKS prototype included a goal-setting feature (details below).
Intensity	Include exercises which are low to moderate intensity (4.4.2)	Yes	The exercise instructions recommended starting at a low level and slowly building up to a medium level.
	Be progressive (4.6)	Yes	The exercise instructions encouraged users to progress by: • increasing the number of exercise sessions they perform per week; • increasing the intensity of the exercises; • increasing the number of exercises they perform per session.
Schedule	Involve exercise sessions which last a minimum of fifteen minutes each (4.7)	Yes	The exercise instructions recommended selecting at least one exercise from each category (five exercises in total) and performing three sets of 30 seconds of each exercise, with a 30-second rest after each set.
	Involve a minimum of two exercise sessions per week (4.8)	Yes	The exercise instructions encouraged users to perform at least two exercise sessions per week.
	Ideally be performed for a minimum of six weeks (4.9)	Partly	The exercise instructions encouraged users to start the programme as soon as possible. A specific timeframe was not provided because patients remain on the TKR waiting list for varying lengths of time.
Tailoring	Be tailored according to each patient's individual needs and ability (4.5; 4.10)	Yes	The content and delivery of the exercise programme were self-tailored because users could choose from a range of exercises and adapt the intensity and schedule to meet their individual needs and ability.

PDF, Portable Document Format; TKR, total knee replacement; VGP-1, Virtual Knee School guiding principle 1; VKS, Virtual Knee School

An exercise goal-setting feature was prioritised as *'Must have'* to address VGP-4. The goal-setting feature was designed to support users to set the following types of goals.

- Behavioural rather than outcome, as detailed in the behavioural analysis findings (Chapter 7, section 7.4.3).
- Specific and measurable, as goal-setting theory suggests that setting specific goals results in better performance than setting vague goals (484-486). In addition, ensuring that goals are specific and measurable is a key principle of SMART (specific, measurable, achievable, realistic, timed) goal setting, which is an established approach for setting rehabilitation goals (487, 488).
- Challenging but achievable, as goal-setting theory suggests that setting difficult goals leads to better performance than setting easier goals (484-486) and SMART goal setting specifies that goals should be achievable and realistic (487, 488).
- Short-term (weekly), as short-term goals are typically more specific than long-term goals and can provide an action plan (489, 490). In addition, SMART goal setting involves specifying a target timeframe for goal attainment (487, 488). A PAG PPI member suggested including both short- and long-term goals. However, another PAG member felt that including long-term goals was not necessary and the researcher and her supervisors/advisors agreed that including both short- and long-term goals would make the goal-setting feature too complex.

In line with the above, CGP-1, VGP-1 and the findings of the Phase 2 qualitative descriptive study (Chapter 6, section 6.3), the goal-setting feature enabled users to set the following goals for the week ahead:

- number of VKS exercise sessions they will perform (required);
- number of VKS exercises they will perform during each session (required);
- a personal exercise goal about a different type of physical activity such as walking (optional).

Providing feedback is a key component of goal setting for health behaviour change (491) and is consistent with the CGP-3 and the behavioural analysis findings (Chapter 7, section 7.4.3). In addition, a PAG PPI member felt that it is particularly important to provide tailored feedback. The goal-setting feature therefore encouraged users to review their goals each week and provided them with personalised encouraging feedback.

8.3.7 Prototype design, build and testing

The design, build and testing of the VKS prototype was a multistage process, informed by Frank's well-established approach for developing digital tools (Table 8.8).

Table 8.8: Virtual Knee School prototype design, build and testing process

Stage	Details	Activities	Contributors	Impact of feedback (key points)
Creation of a provisional VKS template and style guide	The researcher drafted six potential VKS design templates in Microsoft PowerPoint 2016, then used feedback on these to create a provisional VKS template and style guide.	Online Project Advisory Group meeting Online supervision meeting One additional online meeting Telephone call Email correspondence	Two PAG PPI members PAG key collaborator member Three supervisors One advisor	A turquoise/purple/blue colour scheme and a banner with three coloured triangles were chosen, as they were perceived to be the most aesthetically pleasing. A logo of a person demonstrating the knee straightening exercise was included without a motto, as the motto text would have been very small.
Creation of the VKS designs	The Frank team used the provisional VKS template, style guide and content documents/files to create VKS designs in a PDF document, and then iteratively refined them based on the feedback obtained.	Two online scoping coproduction sessions with a member of the Frank team Two additional online meetings Telephone call	Three PAG PPI members PAG independent chair Two supervisors One advisor	Instructions on how to use the accessibility toolbar were added to the *'About the Virtual Knee School'* and *'Help'* pages due to concerns that users may miss the toolbar and/or not know how to use it. The *'slider'* (rotating content in the website banner) proposed by the Frank team was removed due to concerns about its accessibility. *'Your most viewed pages'* hyperlinks were added to the footer to enable users to quickly navigate to their most frequently viewed pages.
Build of the VKS prototype	The Frank team used the refined designs and content documents/files to build the VKS prototype on their Content Management System, and then iteratively refined it based on the feedback obtained.	Two online show and tell coproduction sessions with two members of the Frank team	One PAG PPI member Three supervisors One advisor	The instructions on how to use the accessibility toolbar were moved from the bottom to the top of the *'About the Virtual Knee School'* page to make them more obvious. Extra colour was added to the goal-setting page and icons were added to the goal-review page to make them more visually appealing. The goal review time limit was removed to allow users to review their goals at any time rather than needing to wait a week to maximise flexibility.

User acceptance testing	The researcher provided each formal tester with individualised instructions for testing the VKS prototype. The instructions were designed to ensure that all key functions were tested using a range of devices, operating systems, browsers and accessibility software. Informal testers were invited to view the prototype and provide general comments. The researcher collated the feedback in a test log. The researcher addressed the feedback herself where possible and asked the Frank team to address it if not.	Two online testing sessions One face-to-face testing session Online supervision meeting Email correspondence	Formal testers: • Three PAG PPI members • Three supervisors • Two advisors Informal testers: • Two PPI representatives • PAG key collaborator • Four health professionals/ researchers	Navigation instructions were added to the *'About the Virtual Knee School'* and *'Help'* pages for clarity. The word *'surgery'* was changed to *'operation'* where appropriate to improve clarity and readability, particularly for people with English as an additional language. *'Video'* was added to the titles of the videos to make it clear they were videos not static images. Instructions on how to play the videos/change the video settings were added as accordion content to all videos for clarity. Captions were turned on by default on all videos to improve accessibility. The login process and goal-setting feature error messages were updated for clarity. Back and next buttons were labelled with the names of the pages they go to for clarity. Buttons were added to the final page in each section to allow users to return directly to the homepage to improve the ease of navigation.

PAG, Project Advisory Group; PDF, Portable Document Format; PPI, Patient and Public Involvement; VKS, Virtual Knee School

[a] The term *'coproduction'* refers to activities in which PAG PPI members played a direct role in making decisions (174).

8.3.8 Prototype summary

Completion of the user acceptance testing resulted in a version of the VKS prototype that was ready to be refined as described in section 8.4. Table 8.9 and Figures 8.2–8.5 provide a summary and example screenshots of this version of the prototype respectively.

Table 8.9: Virtual Knee School prototype summary

Section	Page(s)[a]	Level	Key features[b]
Login	*'Sign up to the Virtual Knee School'*	N/A	Sign up process that involved entering an email address, password and participant ID number and completing a CAPTCHA verification.
	'Login'	N/A	Login process that involved entering an email address and password. Reset password option.
Main	*'Welcome'* (homepage)	1	Brief text summarising the VKS purpose. Picture buttons to the other three level 1 pages.
	'Help'	N/A	Text and accordion content explaining how to use the VKS/overcome problems users may encounter when using the VKS.
	'Contact us'	N/A	Text providing the VKS email address.
	Footer pages	N/A	Privacy and cookies policy, accessibility statement, links to other helpful websites.
	All pages	N/A	Header with *'Help'* and *'Log out'* buttons. Footer containing links to the footer pages, University of Leeds terms of use and the user's most viewed pages. Meganav and search box. Breadcrumb trail (not shown on the homepage). *'Print this page'* button (not shown on the homepage). Accessibility toolbar that allows users to change the VKS language, text size and contrast (automatically open but can be opened and closed by selecting the toolbar header).
Introductory	*'About the Virtual Knee School'* (introductory menu)	1	Picture buttons to both level 2 introductory pages. Text and an image explaining how to use the accessibility toolbar. Welcome video designed to address key barriers to engagement with the VKS and its target behaviours. Text navigation instructions.

	'Virtual Knee School development and team'	2	Text providing a brief overview of the VKS development. PDF of the Phase 1b modified Delphi study final recommendations (371). Names, photographs and brief biographies of the researcher and her supervisors from the University of Leeds. Names of the researcher's additional supervisor and advisors, and the PAG PPI members.
	'Common questions'	2	Accordion content with answers to questions about the VKS and how to use it.
Education	*'Information for your operation'* (education menu)	1	Picture buttons to all three level 2 education pages.
	'What to expect'	2	Picture buttons to all seven level 3 expectations subpages.
	Seven expectations subpages	3	Text/accordion content covering TKR surgery; what to expect before, during and after the hospital stay; risks of TKR surgery; a brief list of medical terms; and patients' knee replacement stories. Knee joint anatomy image, PDF list of medical terms and five educational videos.
	'Preparing for your operation'	2	Picture buttons to all seven level 3 preparing subpages.
	Seven preparing subpages	3	Text/accordion content covering managing knee pain; healthy lifestyle changes; goal setting; walking aids and other equipment; making practical preparations; return to work planning; and patients' preparation stories. PDF exercise goal-setting/recording sheet, two educational videos and 10 walking aid videos.
	'Recovering from your operation'	2	Picture buttons to all six level 3 recovering subpages.
	Six recovering subpages	3	Text/accordion content covering strategies for improving post-operative recovery; managing concerns (including a traffic light checklist); post-operative mobilisation, returning to usual activities and travelling; and patients' recovery stories. Three educational videos and 10 walking aid videos.
Exercise	*'Your exercise plan'* (exercise menu)	1	Picture buttons to all five level 2 exercise pages. Text covering benefits of exercising pre-operatively, guidance about the VKS exercise programme and essential safety information.
	'About the Virtual Knee School exercise plan'	2	Text covering key questions and answers about the VKS exercise programme, including potential concerns and safety considerations.
	'Tips for sticking to your exercise plan'	2	Text covering goal setting, self-monitoring exercise completion, habit formation, identifying reasons for wanting to exercise and setting exercise reminders. PDF exercise goal-setting/recording sheet and PDF exercise diary.

	'Patients' exercise stories'	2	Two patient stories modelling how patients have successfully overcome barriers to and benefited from exercising pre-operatively.
	'Your exercise goals'	2	Text explaining the benefits of goal setting. PDF exercise goal-setting/recording sheet and PDF exercise diary. Buttons to set new goals and view current goals. Dated list of goals with options to edit goals and review goals/edit review.
	Four exercise goal subpages	3	Goal setting form that includes two VKS exercise goals (required) and a personal exercise goal (optional). Text summarising the goals set. Goal review form with *'Yes'*, *'Partly'* and *'No'* options for each goal set. Goal feedback that is personalised based on the goal review form responses, with tips on how the user could adapt/progress their goals.
	'Carry out an exercise session'	2	Text advising users to view the *'Your exercise plan'* and *'About the Virtual Knee School' exercise plan'* pages before performing an exercise session, with hyperlinks to both pages. Text providing guidance on how to perform an exercise session. Fifteen exercise videos organised in five categories, with text explaining the benefits of each exercise category. PDF exercise booklet.

CAPTCHA, Completely Automated Public Turing test to tell Computers and Humans Apart; PAG, Project Advisory Group; PDF, Portable Document Format; PPI, Patient and Public Involvement; TKR, total knee replacement; VKS, Virtual Knee School

[a] Text in italics in single quotation marks is the page name displayed in the website banner.

[b] All static images were accompanied by PDF documents and all videos were accompanied by transcripts/a booklet for accessibility.

A

B

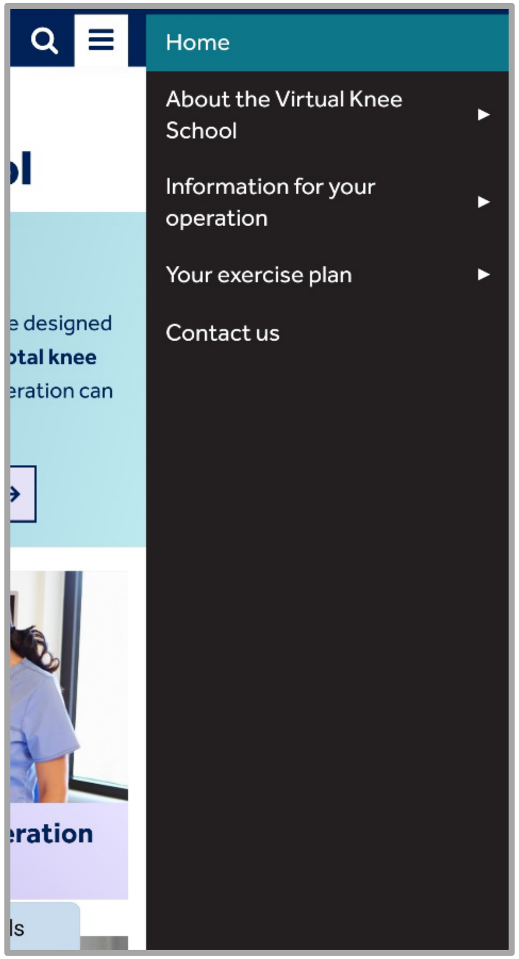
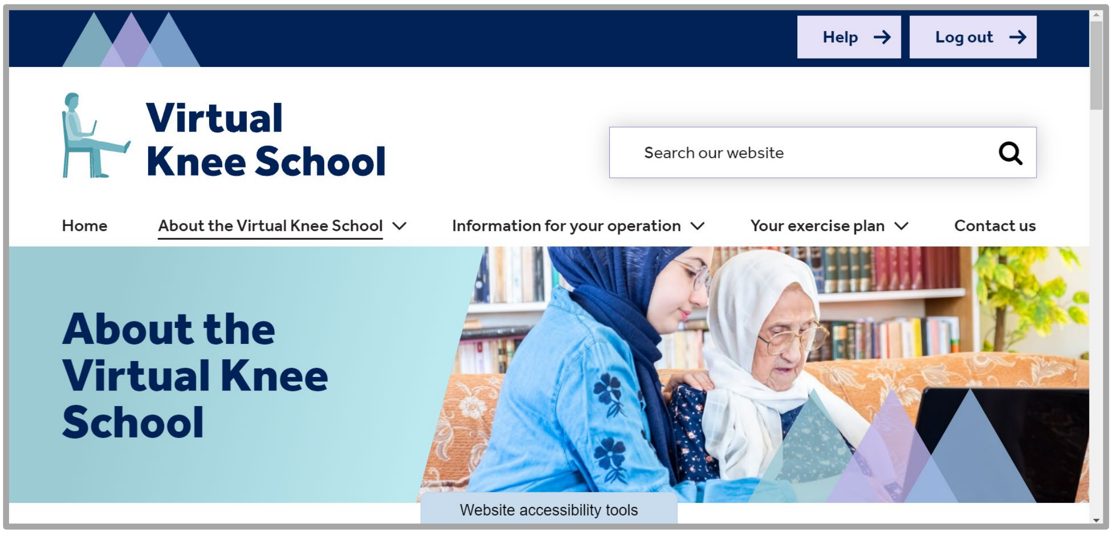


Figure 8.2: Virtual Knee School prototype homepage (mobile phone display)

A: Meganav closed

B: Meganav open

A



B

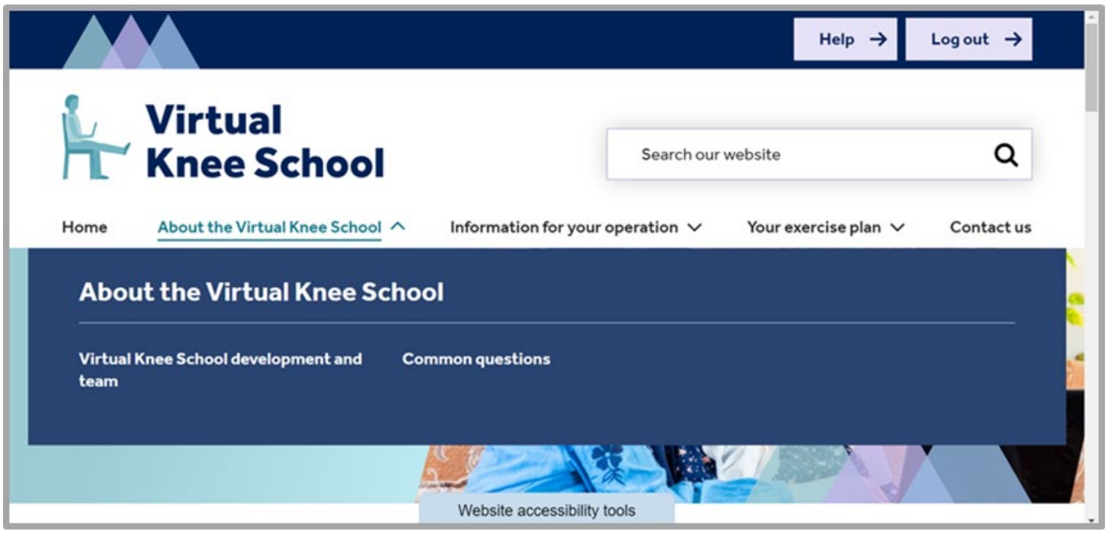


Figure 8.3: Virtual Knee School prototype introductory menu (laptop display)

A: Meganav closed

B: Meganav open

A

B

C

D

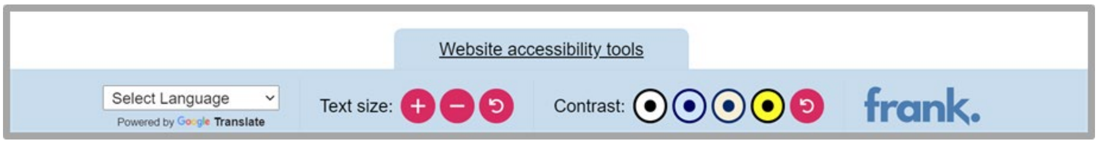


Figure 8.4: Virtual Knee School prototype features (education and main sections, laptop display)

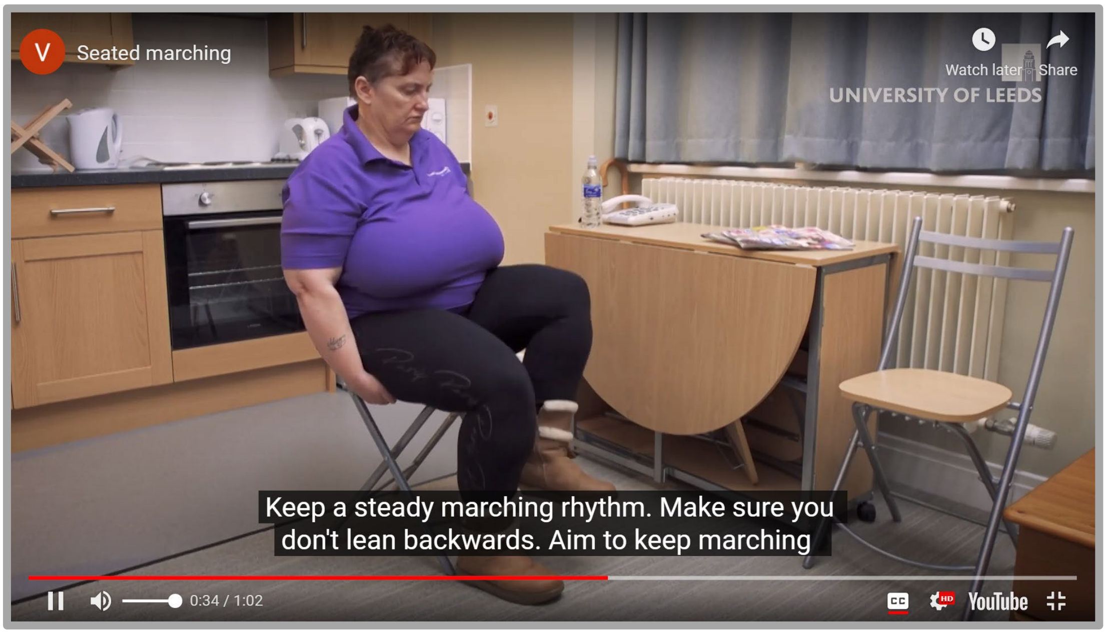
A: Breadcrumb trail and *'Print this page'* button (all pages except the homepage)

B: Accordion content (preparing subpage, *'Making practical preparations'*)

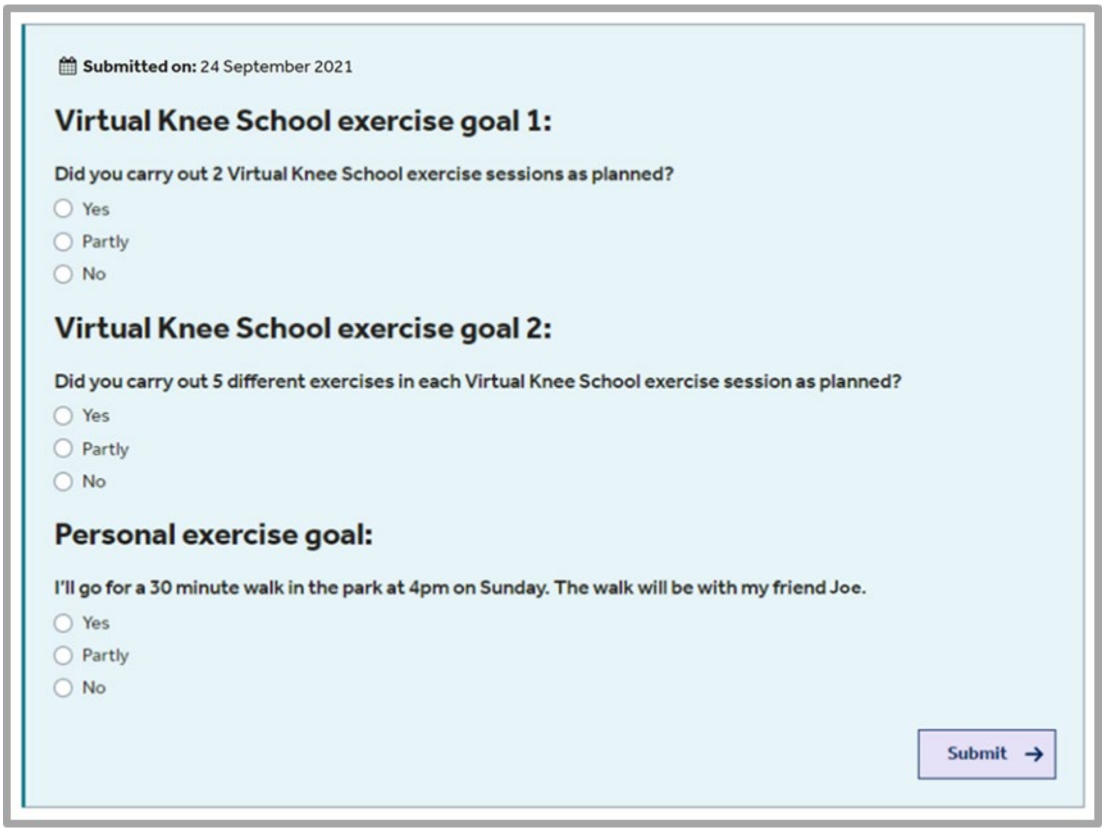
C: Patient story (expectations subpage, *'Patients' knee replacement stories'*)

D: Accessibility toolbar (all pages)

A



B



Submitted on: 24 September 2021

Virtual Knee School exercise goal 1:

Did you carry out 2 Virtual Knee School exercise sessions as planned?

- Yes
- Partly
- No

Virtual Knee School exercise goal 2:

Did you carry out 5 different exercises in each Virtual Knee School exercise session as planned?

- Yes
- Partly
- No

Personal exercise goal:

I'll go for a 30 minute walk in the park at 4pm on Sunday. The walk will be with my friend Joe.

- Yes
- Partly
- No

Submit

Figure 8.5: Virtual Knee School prototype features (exercise section, laptop display)

A: Video (exercise page, *'Carry out an exercise session'*)

B: Goal review form (exercise goal subpage, *'Review your exercise goals'*)

8.4 Prototype refinement methods

8.4.1 Overview and rationale

As discussed in section 8.1.1, the PBA involves using in-depth qualitative research to iteratively refine intervention prototypes (178). This is typically achieved through two key approaches (178, 492).

- Think-aloud method: this involves participants using the prototype and verbalising their thoughts in the presence of a researcher (152, 493, 494). This enables the researcher to observe how participants use and respond to all aspects of the prototype (178). The think-aloud method is therefore particularly useful for highlighting navigational problems and can identify both major and subtle content issues (152, 228). Correspondingly, Michie et al. (38) explicitly highlight the think-aloud interview method as an option for evaluating digital behaviour change interventions. Key disadvantages of the think-aloud method are that the researcher's presence may influence participants' use of the prototype and participants do not have the opportunity to try implementing the desired behaviour changes (152).
- Process evaluation: this involves participants using the prototype independently in real-life contexts (178, 495). Qualitative and/or quantitative data may be collected using various methods such as diaries, retrospective semi-structured interviews and automatically collected intervention usage data (178, 495). This approach overcomes the disadvantages highlighted above for the think-aloud method (152, 228). However, relying on participant recall may limit the depth of information obtained (152, 228). In addition, conducting a process evaluation is likely to require more time than conducting a think-aloud study and the risk of participant attrition is higher (152).

The above methods provide complementary insights; therefore, both should ideally be used during the refinement process (152, 178). The think-aloud method is typically employed first to enable any substantial content and navigational issues to be addressed before participants use the prototype independently (152, 178). Given this study was the first step in refining the VKS prototype, the think-aloud method was chosen. As discussed in Chapter 3 (section 3.3.4), the initial intention had been to conduct a process evaluation after this study but that was not possible due to a combination of factors, including delays associated with the COVID-19 pandemic. As explained in Chapter 9 (section 9.6.2), a process evaluation will be included in a future feasibility study of the VKS if appropriate.

This study incorporated multiple strategies to address the trustworthiness criteria proposed by Lincoln and Guba (398). These were largely the same as the strategies used during the Phase 2 qualitative descriptive study (Chapter 6, Table 6.2) except that:

- the methods chosen for the data collection (section 8.4.3) and analysis (section 8.4.4) were different due to the think-aloud method employed;
- integration of this study's findings with other data sources was undertaken during the analysis (section 8.4.4) and overall discussion (Chapter 9, section 9.3).

8.4.2 Participants

8.4.2.1 Eligibility criteria

Individuals who met the following inclusion criteria were eligible:

- adult (aged ≥18 years old);
- able to communicate in English;
- listed for primary TKR at a hospital in the UK and/or have undergone primary TKR at a hospital in the UK within the past two years;
- able to use and have access to the Internet and email and/or be willing and able to be interviewed in person[4].

Individuals who were unable to give informed consent were excluded to ensure that all participants could engage in the interview process.

8.4.2.2 Sample size

As in Phase 2, the sample size was guided by the aim of achieving data saturation. During intervention refinement studies, data saturation can be considered as the point at which additional qualitative data collection does not lead to the identification of further substantial changes that should be made to the intervention (228). Nielsen (496) suggests that conducting around five think-aloud interviews is sufficient for identifying most usability problems. Based on this and previous relevant studies (412, 497), it was estimated that ~8–10 participants would be required. The eighth and ninth participants' interviews did not lead to the identification of any substantial changes that

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[4] Potential participants were considered able to be interviewed in person if they lived in West Yorkshire and the government and University of Leeds COVID-19 guidance at the time of the study permitted meeting in person.

should be made to the VKS prototype. Data saturation was therefore considered to have been achieved and no additional participants were recruited.

8.4.2.3 Sampling

Maximum variation purposive sampling was employed to ensure that the perspectives of a diverse range of intended users were considered, as detailed for Phase 2 (Chapter 6, section 6.2.2.3). The purposive selection criteria included those used in Phase 2 (age, gender, experience of TKR and varying confidence in using the Internet) plus two additional criteria – ethnicity and highest educational qualification completed. The additional criteria were included because all the patient participants in the previous project phases were White British and ensuring that the VKS is accessible for people with low literacy was a priority. Furthermore, both ethnicity and educational attainment may affect engagement with digital interventions (413).

8.4.2.4 Recruitment

The researcher recruited most participants from a large NHS teaching hospital in northern England by posting patients recruitment packs and discussing the study in person with patients at orthopaedic and pre-assessment clinics. In line with a PAG PPI member's suggestions, the PAG PPI member shared a WhatsApp message with contacts in her communities to facilitate recruitment of participants from minority ethnic groups. Twitter and Facebook adverts were also shared with the aim of facilitating recruitment of individuals from minority ethnic and other under-served groups. The WhatsApp message and Twitter and Facebook adverts included details of specific purposive selection criteria (example provided in Supplementary File 3). Additionally, the researcher contacted two local community networks that work with individuals from under-served groups, but neither were willing to share the recruitment adverts. Participants were not actively encouraged to share the study details. However, individuals who heard about the study via word-of-mouth were included. Participants from the previous project phases were not invited to participate to maximise the diversity of perspectives obtained.

8.4.3 Data collection

Table 8.10 summarises the main types of think-aloud data collection methods.

Table 8.10: Main types of think-aloud data collection methods

Method	Participant verbalisation	
	Whilst performing the task[a]	**Whilst watching a recording of their task performance**
Concurrent	Yes	No
Retrospective	No	Yes
Hybrid	Yes	Yes

[a] In the context of this study, the task was using the VKS prototype.
Table based on Ericsson and Simon (494) and Alhadreti and Mayhew (498).

The concurrent think-aloud method was employed in this study because it is at least as effective at identifying usability problems as the other two methods and is less time-consuming to conduct (493, 499). Furthermore, concurrent think-aloud interviews are typically used during PBA intervention development studies (177, 228, 500). The initial intention was to ask each participant to complete a single interview. However, due to the large volume of content included in the VKS prototype, an amendment was made so that each participant was asked to complete two interviews. This helped to ensure that participants viewed all key parts of the prototype and the length of each interview remained manageable. Participants opted to complete their two interviews on the same day or one or two days apart. Data collection and analysis were conducted iteratively so that the impact of changes made based on earlier interviews could be explored in subsequent interviews (178).

In line with the University of Leeds COVID-19 guidance at the time of the study, interviews were conducted remotely if possible but in-person interviews with appropriate safety precautions in place were permitted if necessary e.g. if a participant lacked internet access. Remote interviews were conducted via Microsoft Teams (237), a secure online videoconferencing tool provided by the University of Leeds. This tool was selected to enable automatic transcription. In-person interviews were conducted in the participants' own homes. Being interviewed remotely via telephone or in person at the recruitment site were also available options but were not chosen by any participants.

The researcher conducted all interviews independently between 13th October 2021 and 20th January 2022. Prior to their first interview, all participants received the study PIS, discussed the study with the researcher and were required to complete the study eConsent Form and Questionnaire. At the beginning of each interview, the researcher briefly reviewed key details from the PIS, explained the interview procedures and offered the participant a further opportunity to ask questions. During the interviews, participants accessed the VKS prototype via a secure login process. The researcher provided participants with login details so that they did not need to enter any personally identifiable data into the VKS prototype.

Participants interviewed remotely (n=5) were required to access the VKS prototype via their own digital device and shared their screen using Microsoft Teams (237). Videoconferencing uses substantial bandwidth, potentially disrupting internet access, and seeing faces on-screen may distract participants (501). To address these issues, the researcher and participants turned off their cameras during the interviews. Participants interviewed in person (n=4) were offered the opportunity to access the VKS prototype via their own digital device or via a University-owned laptop or smartphone. All chose a University-owned device. Due to health problems, one participant was unable to use a mouse or keyboard and found it difficult and painful to use a touchscreen. The researcher performed the manual actions required to navigate the VKS prototype for this participant as per the participant’s directions. A mobile WiFi hotspot was used to provide internet access for all the in-person interviews. Across all participants, a variety of devices, operating systems and browsers were used. To the researcher’s knowledge, all participants were alone throughout their interviews.

The researcher instructed each participant to work through the VKS prototype and say everything they were thinking out loud. In the classic think-aloud method, further interactions with the interviewer are limited to simple reminders to continue talking (494). This avoids the participant’s performance being affected by the additional cognitive demand of having to describe or explain their thoughts (502). An alternative is the *‘interactive’* think-aloud style, in which the interviewer actively intervenes to explore the participant’s perspectives and experiences (503: p.582). The interactive style can lead to participants feeling more relaxed and expressing more comments of value for usability analysis (503). Correspondingly, Tamler (504) proposed that the degree of interaction during a usability test should be guided by its purpose, with interactions such as asking probing questions being essential in certain circumstances. Given this study aimed to gain in-depth information about the usability of the VKS prototype and explore participants’ perspectives of it more broadly, an interactive style was chosen. The researcher therefore asked the participants probing questions as they worked through the VKS. This approach is consistent with previous PBA intervention development studies (497, 505), Other than one participant who withdrew, all participants were asked to complete the VKS prototype sign-up process during their first interview or independently beforehand. Early in their interviews, the participant could access any of the VKS prototype pages/aspects they wished. Later in their interviews, the researcher guided the participant to specific pages/aspects to ensure that sufficient feedback about each page/aspect was obtained. In line with other PBA intervention development studies (211, 228), the researcher asked brief semi-structured interview questions after completion of the main think-aloud interview component. This provided an insight into participants' perspectives of the VKS prototype as a whole.

All steps in the interview process were guided by a topic guide (Appendix G). This was developed based on the study objectives and an example think-aloud topic guide for PBA intervention development studies (506). Two PAG PPI members were invited to review the topic guide but did not suggest any changes. The researcher pilot tested the topic guide during a practice interview with one of her advisors (JJ), who has extensive experience of think-aloud interviews. The topic guide remained unmodified throughout the study. Interviews were audio-recorded using an encrypted University-owned laptop or smartphone and video-recorded using Microsoft Teams (237). One in-person interview was not video-recorded due to the recording accidentally being turned off shortly after commencement. Field notes were documented during and/or shortly after each interview. Interviews lasted between 23 and 87 minutes (median 63 minutes; IRQ 17 minutes).

8.4.4 Data analysis

Refining an intervention based on qualitative data requires quick and efficient analysis of the data as soon as it is obtained (228). This enables changes to the intervention to be implemented prior to further data collection. Traditional qualitative analysis approaches such as thematic analysis are time-consuming and can delay the refinement process (228). Another challenge during the refinement process is deciding which changes to implement, as users' opinions may differ and potentially contradict priorities identified during the intervention planning (228). To address these challenges, Bradbury et al. (228) developed a novel analysis approach for the refinement phase of PBA intervention development studies. This approach was chosen for the present study because it enables efficient systematic analysis of qualitative data and provides criteria to guide decisions about which intervention changes to implement. The key steps involved were as follows.

1. Intelligent verbatim transcription of the interview data. This was initially undertaken using the built-in transcription functionality of Microsoft Teams (237) for the first participant's interviews. Due to significant inaccuracies in the Microsoft Teams' transcripts, subsequent interviews were transcribed by 1st Class Secretarial services as described in Chapter 3 (section 3.4.4). The researcher verified all transcripts and corrected inaccuracies.
2. Familiarisation with the data by reading and re-reading the transcripts.
3. Working through each transcript line-by-line to identify positive and negative comments about the VKS prototype. Field notes were used to facilitate this process where appropriate. Negative comments included explicit negative feedback and comments indicating a potential barrier to engagement with the VKS and/or its target behaviours, such as a navigation difficulty or misunderstanding.
4. Identifying and prioritising changes that could be made to the VKS prototype to address each negative comment.
5. Agreeing what changes to implement through discussions with the researcher's supervisors/advisors.
6. Implementing the agreed changes.

In relation to step 4, Bradbury et al. (228) proposed five *'Reason for change'* criteria for deciding whether to make a change and separate MoSCoW criteria for prioritising the change (228: Tables 3–4). These two sets of criteria partially overlap. For example, the reason for change criteria include *'Important for behaviour change'* (228: Tables 3–4) and the definition of *'Must have'* in the prioritisation criteria is:

> 'This modification must be made in order for the intervention to be effective in changing a participant's behaviour (given what we know about the evidence base).' (228: Table 3)

In addition, the criteria proposed by Bradbury et al. (228) do not account for the time required to implement potential changes and differ slightly from the criteria proposed in other PBA resources (506, 507). To account for these issues and ensure consistency with the criteria used when developing the VKS prototype (Table 8.2), the criteria proposed by Bradbury et al. (228) and the other PBA resources (506, 507) were adapted. The resulting criteria provided a transparent approach for prioritising each change based on the reason for the change and how time-consuming it would be to implement (Table 8.11).

Table 8.11: Criteria for implementing changes to the Virtual Knee School prototype

Code	Reason for change[a]	Importance level	Time consuming to implement[b]	Priority[c]
FSR	Important for the VKS functioning/navigation, safety or compliance with relevant regulations/guidelines.	1	No	Must have
			Yes	Must have
VGP (VGP number)	Consistent with the VGPs developed in Phase 3 (Chapter 7).			
CGP (CGP number)	Consistent with the CGPs detailed in Phase 3 (Chapter 7).	2	No	Should have
EEQ (type)	Consistent with experience, evidence and/or the BSI PAS 277:2015 quality criteria (472). This includes changes supported by PAG member feedback, the NICE primary joint replacement guideline (31), the Phase 1b modified Delphi study recommendations (Chapter 5) and/or the expertise of the researcher's supervisors/advisors.		Yes	Could have
BEH (target behaviour)	Likely to impact engagement with any of the following: • pre-op TKR care in a web-based format; • pre-op TKR education; • a pre-op TKR exercise programme; • healthy lifestyle changes. This includes, but is not limited to, changes that address barriers/facilitators identified in the Phase 3 behavioural analysis (Chapter 7) and changes that impact precursors to the desired behaviours e.g. acceptability, accessibility, persuasiveness etc.			
REP	Addresses a point repeated by more than one participant.			
EAS	Easy and uncontroversial as it does not require any substantial design changes e.g. amending a sentence for clarity.	3	No	Could have
			Yes	Would like
NTC	Does not contradict any of the criteria listed above. (Only listed in the table of changes if none of the criteria above applied).			
NTA (reason)	Not appropriate, for example due to contradicting one of the criteria listed above.	N/A	N/A	N/A

BSI, British Standards Institution; CGP, common guiding principle; N/A, not applicable; NICE, National Institute for Health and Care Excellence; PAG, Project Advisory Group; PAS, Publicly Available Specification; PPI, Patient and Public Involvement; pre-op, pre-operative; TKR, total knee replacement; VGP, Virtual Knee School guiding principle; VKS, Virtual Knee School

[a] Reasons for change criteria adapted from Bradbury et al. (228) and additional PBA resources (506, 507).

[b] Changes were classed as time-consuming to implement if they required substantial programming time, involved amending multiple pages, amending a static image or video and/or developing a new page, video, photograph, infographic or PDF document.

[c] If a change was supported by more than one reason, the priority was based on the reason with the highest importance level. Changes considered *'Not appropriate'* were not prioritised.

Microsoft Excel 2016 was used to record the findings of steps 3–6 in a *'Table of changes'* (441: p.5), which was based on a template from the PBA website (506). Due to its large size, the table was split into 11 sheets with up to 90 rows each. Each sheet included the columns shown in the table of changes excerpt (Table 8.12). To ensure that verbatim comments were readily accessible, all comments were also coded using QSR International NVivo software[5]. The codes were organised to correspond with the table of changes. Appendix H provides an example of the coding structure in the final NVivo file.

5 Most of the analysis was undertaken using NVivo 12. Further analysis was undertaken using NVivo Release 1 due to a software upgrade.

Table 8.12: Table of changes main section excerpt

Page/ aspect	Positive comment [participant pseudonym]	Negative comment [participant pseudonym]	Suggested change	Reason for change[a]	Time-consuming to implement	Priority MoSCoW	Change agreed	Date change implemented[b]
Homepage		Does not feel it is clear from the homepage that the website has three key sections. [Glen]	Add text to the homepage to explain that the website has three key sections.	VGP (1) BEH (web-based) EAS	No	Must have	Agreed 28/10/2021	28/10/2021
			Change the *'About the Virtual Knee School'* text button to a picture button next to the buttons to the other key sections (so that there are three picture buttons corresponding with the three key sections).	VGP (1) BEH (web-based)	No	Must have	Agreed 28/10/2021	28/10/2021
	Likes colour, layout and "*less writing"* (compared to the *'About the Virtual Knee School'* page). Feels it is *"very clear but not overwhelming".* [Ella]							

	Feels the page layout is clear. [Arthur] Feels the page layout is *“easy to use, clear, and not confusing.”* [Haaniya] Feels the page layout *“works, and it’s nice, ‘cause it’s very visual, so it makes it more appealing doesn’t it? It’s not just all text.”* [Naomi] Feels the homepage layout is *“helpful”.* [Zuri]							

MoSCoW, Must have, Should have, Could have, Would like

[a] Table 8.11 provides the meanings of the codes.

[b] An additional column called *‘Notes’* was included in each Excel sheet but is not shown due to space limitations. The *‘Notes’* column was used to document any key points related to the potential change, such as comments from the researcher’s discussions with her supervisors/advisors and the time requirements for changes that would have to be made by the Frank team rather than the researcher.

The researcher undertook all steps of the data analysis. Different people evaluating the same system may identify different usability problems, the so-called *'evaluator effect'* (508: p.421). In line with suggested strategies for addressing this issue (509), the researcher employed a detailed systematic analysis approach (steps 1–6) and organised four meetings with her supervisors/advisors to discuss the table of changes and agree which changes to implement (step 5). Member checking was not undertaken due to the rapid iterative nature of the analysis process.

8.4.5 Reflexivity

The researcher's only previous experience of conducting think-aloud interviews was the practice interview held with one of her advisors (JJ). In addition, the researcher had shadowed think-aloud interviews conducted by NHS Digital and participated in a think-aloud interview for an external piece of work. Chapter 6 (section 6.2.5) provides further details of the researcher's characteristics and experience. The researcher discussed the study via telephone and/or in person with all participants prior to their first interview to build rapport. Seven participants were patients at the site where the researcher is based, but none had received clinical care from the researcher prior to the study. All the participants were aware that the researcher was a physiotherapist undertaking a PhD focused on developing/refining the VKS. Knowing that an interviewer has been involved in an intervention's development may encourage participants to provide socially desirable feedback (228). To minimise this risk, the researcher emphasised that negative comments would be particularly valuable for refining the VKS prototype during each pre-interview introduction. As detailed for Phase 2 (Chapter 6, section 6.2.5), the researcher documented her reflections on factors that may have influenced the study in a reflexive journal. The researcher also used her journal to reflect on and identify pages/aspects of the VKS prototype that required further exploration in subsequent interviews.

8.5 Prototype refinement findings

8.5.1 Participants

Figure 8.6 presents the flow of individuals through the study. Of the nine participants, seven were recruited through the NHS (recruitment pack n=4; orthopaedic clinic n=1; pre-assessment clinic n=2) and two were recruited via word-of-mouth. Tables 8.13–8.14 present the participants' characteristics.

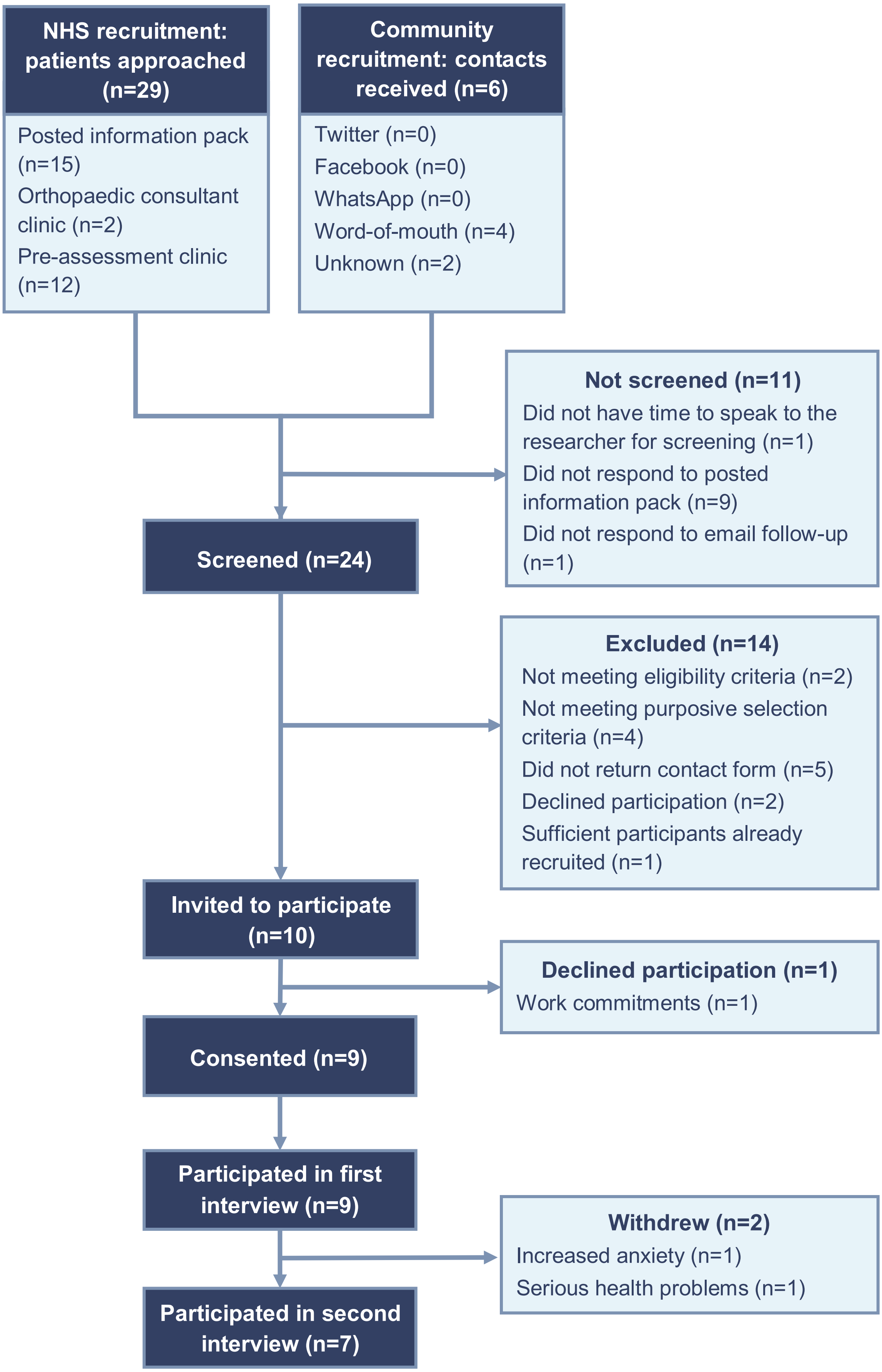

Figure 8.6: Think-aloud interview participant flow chart

NHS, National Health Service

Table 8.13: Think-aloud interview participants' key characteristics

Pseudonym[a]	Age (years)	Gender	Experience of TKR	Confidence in using the Internet
Ella	40–49	Female	Pre	Confident
Jessica	50–59	Female	Pre	Neither confident nor unconfident
Glen	70–79	Male	Post	Confident
Arthur	80–89	Male	Post	Very confident
Vera	70–79	Female	Post	Unconfident
Haaniya	60–69	Female	Pre, post	Neither confident nor unconfident
Laurence	60–69	Male	Pre	Confident
Naomi	60–69	Female	Post	Very confident
Zuri	70–79	Female	Pre, post	Unconfident

Post, previously undergone TKR; pre, listed for TKR; TKR, total knee replacement
[a] Participants are listed in the order in which they were interviewed.

Table 8.14: Think-aloud interview participants' additional characteristics

	Number of participants (%) (n=9)
Indication for TKR[a]	
Osteoarthritis	9 (82)
Rheumatoid arthritis and osteoarthritis	2 (18)
Location of TKR[a]	
NHS hospital	10 (91)
Private hospital	1 (9)
Months since previous TKR[b]	
<3	3 (50)
3–5.6	2 (33)
6–11.9	1 (17)
Body mass index (kg/m²)	
18.5–24.9	2 (22)
25–29.9	1 (11)
30–39.9	3 (33)
≥40	3 (33)
Ethnicity	
White British	7 (78)
Indian	1 (11)
African Caribbean	1 (11)
Disability or health condition that could affect ability to use a website or carry out gentle exercises[c]	
Dyslexia and dyspraxia	1 (11)
Visual impairment	2 (22)
Hand pain/swelling	1 (11)
Living location	
Yorkshire and the Humber	8 (89)

Scotland	1 (11)
Highest educational qualification	
None	2 (22)
Apprenticeship	1 (11)
Vocational qualification (or equivalent)	3 (33)
Undergraduate degree	3 (33)
Current employment status	
Employed full-time	1 (11)
Employed part-time	1 (11)
Retired	6 (67)
Medically disabled	1 (11)

NHS, National Health Service; TKR, total knee replacement

[a] Participants who were both awaiting and had undergone TKR were counted twice (11 TKRs in total).

[b] Only includes participants who had previously undergone TKR (n=6).

[c] Participants could report more than one option.

8.5.2 Interview findings overview

The majority of participants were very positive about the VKS prototype, making comments such as *"it's all been excellent"* (Jessica) and *"I think it is going to be very beneficial"* (Haanyia). Key perceived benefits were that it is comprehensive, realistic and reassuring, and would provide a constantly available resource to refer back to. Two participants highlighted that the VKS could potentially prevent patients from searching for information on less reliable websites. For example, Glen commented:

> "I think it's an absolutely invaluable tool, and I think it's so useful what you're doing. Because it'll stop people googling sites that probably aren't doing them any favours." (Glen)

In contrast, Laurence was largely unimpressed with the VKS prototype. He felt that a lot of the content was *"irrelevant"* because he knew most of the information already and the exercise programme failed to meet his individual needs. Furthermore, Vera highlighted that the online format can be anxiety provoking and is not appropriate for all patients:

> "[...] to me a website is alright if you can use these, but if you can't use them, it's just not helpful at all." (Vera)

Similarly, although Zuri thought the prototype was *"very good and very helpful"*, she commented that she would not have tried using it independently. Other participants also emphasised the importance of providing the website content in alternative formats. Suggested options included leaflets, face-to-face care and a video.

Three participants commented on the optimal timing for accessing the VKS, all of whom highlighted that they would have accessed it both pre- and post-operatively. Their perspectives about when to first access the VKS varied. Naomi felt that viewing the VKS before being listed for TKR would have facilitated her decision-making and helped her identify questions to ask her consultant. Glen suggested that patients would want to access the VKS *"from the minute that you know you're going to have your operation"*. Conversely, Arthur indicated that he would have preferred to first access the VKS once he had been given an approximate surgical date:

> "As soon as…if I had the first inclination that I'd be going roughly in, say, two months, I would love to have that available." (Arthur)

Multiple potential changes to the VKS prototype were identified, prioritised and implemented when appropriate. Sections 8.5.3–8.5.9 below summarise the main changes and the usability and participants' perspectives of the VKS prototype more broadly. Unless specifically indicated, the changes implemented appeared to be successful. The refined version of the VKS prototype, which includes all the changes implemented, is accessible using the details in Supplementary File 4.

8.5.3 Design and overall content

Participants generally felt that the VKS prototype was aesthetically pleasing, commenting on aspects such as the professional appearance, calming colours and helpful imagery. A few participants also emphasised that they liked the *"simple language"* (Haaniya). The accordions were considered particularly useful for breaking up the text and providing optional extra detail, but not all participants realised that it was possible to select them. To help address this, the accordions' background colour was changed to blue to distinguish them from the other website features. In addition, text was added to highlight that users could select the accordions.

In contrast to most participants, Laurence did not like the layout. This appeared to be at least partly related to his perception that there was too much text. To help address this, some of the text was restructured into accordions. Laurence also disliked the instructions on aspects such as how to use the website, play videos etc. as he felt they were *“a bit babyish”* and unnecessary:

> “[…] but it’s just a bit, making me feel like, ooh, blooming heck, more load of rubbish, you know, I don’t need all this.” (Laurence)

Conversely, the instructions were positively received by most other participants. The majority of participants also felt that the accessibility toolbar was useful. However, some had difficulty locating and/or using it. The accessibility toolbar instructions were therefore updated for clarity. Additionally, the toolbar header was amended to display *‘Hide website accessibility tools’* when it was open and *‘Show website accessibility tools’* when it was closed. Despite these changes, Zuri felt that the accessibility toolbar was only appropriate for people with higher levels of digital literacy:

> “Well, it [accessibility toolbar] is good for people who are very literate, fluent in computer and anything it’s alright, but I'm at the creeping stage. […] I’m still bottle fed.” (Zuri)

Participants were highly positive about the content and clarity of the videos. Haaniya valued the auto-translate function, although she required some guidance on how to use it. The embedded YouTube format also created other usability problems. Two participants using a mobile device did not initially realise that they needed to select the play button twice. The unrelated YouTube video links caused confusion, with a couple of participants selecting them by accident. These problems could not be addressed because using an alternative video hosting approach would have compromised the page loading speed and/or prevented auto-translation of the video captions.

The duration of each video was added to its title to address concerns about whether there was enough time to watch the videos. This was viewed positively for the educational videos. However, the durations in the exercise video titles were misunderstood as referring to the durations of the exercises themselves. The durations were therefore removed from the exercise video titles.

The majority of participants felt that the patient stories were helpful, particularly because they provided varied perspectives and were constructive. Participants’ comments during the earlier interviews implied that they believed the stories were from real-life patients. To clarify this, text was added above the stories to explain that they were based on other patients' experiences. Naomi subsequently thought that the stories were from real-life patients. She explained this was initially because she had not read the text above the stories due to being *"a bit of a skim reader"*. However, even after reading the text, she felt that further clarification was required:

> "I think that just needs clarity because I think it's misleading because I'm quite in the know about this stuff and I thought, oh, that's good because Felicity's got diabetes and back pain." (Naomi)

Naomi emphasised that the ideal option would be to include testimonials from real-life patients. Obtaining sufficiently diverse and constructive testimonials would be very time-consuming, so was not prioritised highly enough to address in this study.

8.5.4 Information architecture and navigation options

The VKS prototype information architecture and navigation options were generally perceived as simple and clear, even for people with lower levels of digital literacy:

> "I liked the website, how it was organised. And it was very visual. Then if you're not very computer literate it's very practical." (Jessica)

A couple of participants also commented that being able to access the sections in any order was useful. Despite this, some specific usability problems and broader concerns were identified, particularly during the earlier interviews.

The first four participants were tunnelled to the introductory section menu on their first login. Two participants valued the tunnelling because it provided an overview of the website. The other two found the tunnelling confusing and unhelpful. Ella related this to the larger volume of text on the introductory menu compared to the homepage, which she felt could be *"off-putting"*. Glen believed that all websites should open at the homepage:

> "Because that's the starting point, the homepage is the starting point, the homepage tells you what the website's, what the content of the website is." (Glen)

Another potential issue with the tunnelling was that it relied on users logging in. As discussed below (section 8.5.5), this could present a substantial barrier for some intended users. In light of these concerns, the tunnelling was removed so that users went straight to the homepage on their first login. Text was added to advise users to select the introductory section menu picture button if it was their first visit to the website. However, two participants did not appear to notice the text and viewed other pages first.

Participants' use and perspectives of the navigation options varied. The majority of participants mainly used a combination of the navigation buttons and meganav. However, there was a tendency for participants using a laptop rather than a mobile device to use the meganav more than the navigation buttons and vice versa. This appeared to be at least partly because the meganav was immediately obvious on the laptop display, whereas it was necessary to scroll down to access the navigation buttons. The location of the meganav meant a couple of participants opened/closed it by accident. Furthermore, not all participants realised that they could access level 1 pages via the meganav. The only way to fully address these issues would have been to remove the meganav. That was not considered appropriate because some participants preferred using the meganav. This appeared to be because they were accustomed to navigating websites via a meganav and felt it facilitated rapid navigation.

Another issue with the meganav was that the education dropdown menu displayed the titles of all 24 education pages/subpages. This appeared to make the volume of content seem overwhelming, even though the content on each page was generally considered appropriate:

> "When you see all these sections, you think it's going to be a mammoth, but I like the fact that it's short, it's straight to the point." (Ella)

To address this, the education menu page was removed and the education subsections were promoted to full sections (i.e. the level 2 and 3 education pages were converted to level 1 and 2 pages respectively). This meant that the prototype's three key sections (introductory, education and exercise) were replaced with five key sections (introductory, expectations, preparing, recovering and exercise). Each resulting education section had a separate dropdown menu, limiting the number of page titles displayed at any one time to a maximum of eight. The main disadvantage of this approach was that the titles displayed in the meganav had to be shortened in order to fit, making them less explanatory.

A couple of additional changes to the navigation options were made to address specific usability issues. Firstly, the triangles in the meganav displayed on a mobile device in portrait orientation were made larger to make it clearer that it was possible to select them. Secondly, the next buttons were removed from the final page in each section. This change was made to avoid confusion about the next and back buttons going to the same page if the user accessed the last page in the section from the section menu.

Few participants used the breadcrumb trail or *'Your most viewed pages'* and opinions were divided about whether they added any value. All three participants who commented on the search function felt it was important for navigating rapidly to specific content. Of the two participants who trialled the search function, Laurence did not find the content he wanted, whereas Naomi was impressed by it:

> "I particularly thought the search facility was good in that just entering one word gave me a whole load of access to different bits I could go back and find which, as I say, some search functions aren't as effective as that." (Naomi)

Initially the VKS prototype included minimal hyperlinks to other VKS pages to help ensure that users viewed the pages in a logical order. However, participants reported that they liked hyperlinks to enable them to quickly check other pages. In addition, although the inclusion of certain words/phrases in bold was considered useful for emphasis, there was some confusion over whether they were hyperlinks. To help account for these factors, extra hyperlinks were added. This change was partly successful, but Naomi still thought that words/phrases in bold might be hyperlinks and commented that selecting a hyperlink had interrupted the logical way she was working through the content.

8.5.5 Login section

Many participants described the sign-up/login process using terms such as *"very easy"* (Ella) and *"pretty standard really"* (Glen). However, a few found the process difficult and/or required assistance to complete it. A key challenge was the level of manual dexterity required to accurately type characters, particularly on a mobile device. Mistyped characters led to problems such as participants' passwords not matching. To help address this *'Show password'* options were added to the sign-up and login pages, enabling participants to easily identify any mistyped characters. A couple of participants also found the Completely Automated Public Turing test to tell Computers and Humans Apart (CAPTCHA) verification process difficult to understand or complete. Correspondingly, Haaniya felt that the VKS should be accessible without the requirement to sign-up due to the demographics of the intended users:

> "Most of the people will be older people who are not very computer literate and having to put passwords in, understanding lowercase and uppercase and with their stubbly arthritic fingers, like myself, they seem to go everywhere." (Haaniya)

Participants also expressed broader concerns about the need to sign-up. These included a fear of being sent lots of messages, the need to remember a password and uncertainty about whether signing-up would be worth it. Jessica highlighted that she would like to view some of the website before deciding whether to sign-up:

> "But if I could look at it and then see, and then if I wanted to and carry on I could give my email address, I think that might be better." (Jessica)

In contrast, a few participants were quite happy with idea of signing-up or even preferred it. Reasons for this included being willing to sign-up for *"anything for the NHS"* (Ella) and a desire to receive personalised content.

8.5.6 Main section

Feedback on the main section was generally positive. However, Glen felt it was not clear from the homepage that the VKS prototype had three key sections. To help address this, the location and formatting of the button to the introductory section menu was amended so that homepage included three picture buttons, corresponding with the three key sections. In addition, text was added to explicitly state *'This website has **three main sections.**'* Glen also felt that the text in the banner was not fully accurate:

> "I keep coming back to the fact that you're selling it as a pre-operation thing and yet you've got information on what you do afterwards. I find that a little bit contradictory." (Glen)

In line with Glen’s suggestions, the banner text was updated to highlight that the VKS prototype provides information related to before, during and after TKR surgery. Most subsequent participants’ comments suggested that the layout was clear and the banner text was helpful. In contrast, Laurence felt that the three homepage buttons did not indicate where he could find the information he wanted, such as a picture of a knee implant. This was addressed by restructuring the education section as discussed above (section 8.5.4). This meant that the homepage included five buttons, corresponding with the five website sections; hence providing a greater level of detail about the information available. In addition, the title of the expectations section was changed from *‘What to expect’* to *‘About your operation’* for clarity.

The other main section pages were considered useful. The only issues identified related to the *‘Contact us’* page. In response to feedback from Ella, a link to the *‘Contact us’* page was added to the footer for consistency with other websites. When viewing the *‘Contact us’* page, Arthur commented that he might use the VKS email address for the following:

> “I’m thinking I might ask something about my knee operation, possibly. Or if there was anything I couldn’t quite understand on the School, you know, on the actual pages.” (Arthur)

Text was therefore added to clarify that users should contact their own care team for questions about their operation and the VKS email address was only for questions about the VKS website itself. Laurence later indicated that he might use the VKS email address for operation-related queries, as he had not noticed the extra text that had been added.

8.5.7 Introductory section

Ella and Jessica both stated that the introductory section menu contained *“a lot of information”* and appeared slightly confused by the navigation instructions. To address this, the instructions on how to use the accessibility toolbar and website were moved into accordions. In addition, separate instructions on using the website were provided for computers and mobile devices and labelled screenshots were added. As highlighted in section 8.5.3, the accessibility toolbar instructions were also amended for clarity. Most additional feedback on the introductory section menu was positive. Participants particularly liked the welcome video because its content was considered informative. Additionally, a couple of participants related to the clip of someone climbing steps:

> "You know, they don't give you that information to do exercises before and, as I said, that were useful and how to walk up steps, I mean I walk up steps, I always have a stick anyway so I always walked up steps with my stick anyway but how he were walking up that's how I do it." (Vera)

Participants were also very positive about the photographs and biographies on the *'Virtual Knee School development and team'* page. These were felt to make the website *"more human"* (Glen). In addition, details of the team members' qualifications reassured participants that the content was credible. Some participants also felt that brief information about the VKS prototype development was useful. Haaniya valued the additional details available in the PDF document of the Phase 1b final recommendations, but Ella felt that the document was too detailed and *"very confusing"*. The document was therefore deleted and a link to the Phase 1b journal publication was added to the *'Other helpful websites'* page instead. Participants' feedback also led to a few changes to the *'Common questions'* page. These comprised minor wording amendments and the addition of an accordion to explain that the VKS exercise programme is appropriate for people with bilateral knee problems.

8.5.8 Education section

Participants were generally impressed with the education section content, perceiving it as relevant, informative and appropriately detailed. Many commented on new things they had learned, such as the practicalities and benefits of using cold for pain management. Some also highlighted that information on topics such as how to manage recovery concerns was a useful reminder. The specific content that participants considered new versus familiar varied between participants. This appeared to be related to factors such as whether they had previously undergone TKR and/or had personal connections with health professionals.

As discussed in section 8.5.2, Laurence felt that most of the information was *"irrelevant"* to him because he knew it already. However, Laurence liked a few aspects, particularly the *'What happens during knee replacement surgery'* video. The other three participants who watched this video also felt it was particularly helpful:

> "I like the diagram of the knee on there. Rather than actual seeing a person's knee, I think it's the best way to actually show a video. Very clear of what would happen." (Ella)

Feedback on the knee joint anatomy image and additional educational videos was similarly positive. Viewing the videos and other educational content occasionally prompted participants to ask queries or highlight that they would like more information about a specific topic. These points were mostly addressed through adding hyperlinks to other VKS prototype pages or minor text amendments. For example, text was added to the *'Planning your return to work'* page to explain why users may want to keep their original fit note. Certain information was not considered appropriate or a priority to add, such as information about different types of TKR implants due to its complexity.

Overall, the educational content was perceived as reassuring and encouraging. For example, Jessica made the following comment about the healthy lifestyle information:

> "I think it's very good, it's not pushing you to do it, but it's just encouraging you. And I think that's better. Because if someone pushes you to do it you're not going to do it, are you?" (Jessica)

However, there were a couple of notable exceptions. Naomi highlighted that some patients may not have sufficient time to make healthy lifestyle changes pre-operatively, so the information may risk *"setting you up to fail"*. Fully addressing this would have required removal of the healthy lifestyle information. This change was not made as it would have been inconsistent with VGP-6. The other exception was that Haaniya felt the *'Goal setting'* page should provide more encouragement for people who do not meet their goals; therefore, the text was amended accordingly. The *'Goal setting'* page was also updated to include examples of post-operative goals and a photograph of a beach to address feedback about wanting goals to look forward to and *"something visual"* (Ella).

A couple of participants queried the ordering of specific content/pages, but this did not lead to any changes. For example, Laurence queried the location of the anaesthetics video:

> "I don't know if I'm reading this right, but I'm looking at a page here, before my hospital stay and then I'm suddenly having an anaesthetic, I would have thought that would have come on a different page." (Laurence)

The anaesthetic video was left in its original location to correspond with the text explaining that patients may be able to discuss their anaesthetic choices during one of their pre-operative appointments. This was considered important because it could potentially empower patients to ask about their anaesthetic choices if their health professionals do not mention them.

8.5.9 Exercise section

A couple of the participants in the earlier interviews were initially confused about whether the exercise section was for the pre- or post-operative phase. This was addressed by adding *'pre-op'* to the section title and amending the introductory text on the exercise section menu. As for the healthy lifestyle information, Naomi highlighted that the focus on pre-operative exercise might concern patients who do not have much time before their surgery. Despite this, Naomi and other participants emphasised that the VKS exercise programme was valuable because they had not received pre-operative exercise guidance from their own care team.

The text explaining aspects such as how to perform the VKS exercise programme was generally considered clear and informative. Many participants particularly liked the questions and answers on the *'About the Virtual Knee School exercise plan'* page as they felt they were relevant and reassuring:

> "Because it's questions that, that I would ask. And it's nice having an answer without having to contact somebody. Yeah, I really do like the question and answers section." (Ella)

In contrast, Laurence was unimpressed with the volume and content of the text, which he felt was mostly *"flowery"* and unnecessary. Other participants also had queries or concerns about specific aspects of the text. These were addressed with minor amendments where appropriate. The most notable amendments both related to the exercise instructions. Firstly, to address the concern that five exercises might be too many for some people, the text was updated to emphasise that performing any number of exercises will have benefits and users can start with fewer exercises and build up to five if they need to. Secondly, the text was amended to advise users to build up to exercising every day if they feel able to. This addressed participants' concern that performing two exercise sessions per week may not be frequent enough and a request for more specific guidance on increasing the session frequency.

Laurence perceived the VKS exercises as *"too easy"* for him personally. This appeared to be at least partly because he had ready access to a swimming pool so was used to doing all his exercises in water. In contrast, most other participants were very positive about the variety of exercises provided, with many identifying exercises that were familiar to them and others that were new. Participants were especially impressed with the exercise videos, which they considered very clear and easy to follow. Ella also highlighted that she liked how they showed *“everyday people”* in homely settings. Conversely, Zuri did not appear to relate to the patient models:

> “But they all have sticks, but I still have to have my Zimmer.” (Zuri)

Given only one of the videos showed walking sticks, Zuri’s comment appeared to be due to her perceptions of the patient models’ ability levels. Addressing this would have been very time-consuming due to requiring further filming, so was not considered a high enough priority to address in this study.

A couple of participants particularly liked how the exercises were grouped into categories, with explanations of the benefits of each category. However, Jessica initially thought that the exercise category titles related to the videos above them rather than below them. This was addressed by adding a horizontal line above and below each exercise category and labelling the exercises to correspond with their category. For example, *‘Category 1’* exercises were labelled as *‘1a Seated Marching’*, *‘1b Walking on the spot’* etc. Jessica also commented that she found the layout of the PDF exercise booklet *“easier”.* Due to not having a printer, Jessica suggested providing the option to ring someone to request a printed booklet. The other three participants who commented on the booklet also felt it was useful. Glen highlighted that he would mainly use the printed booklet for exercising because it would be *“handy”.* In contrast, although Arthur felt that the booklet would be useful for specific circumstances such as going on holiday, he indicated that he would use the website most of the time:

> “Mostly yes, because I think it’s excellent to be able to see moving pictures and the reasons why you do it, telling you how it’s going to help during the operation and afterwards, excellent.” (Arthur)

Feedback on the exercise tips and goal-setting feature was slightly mixed. Some participants particularly liked the PDF goal-setting/recording sheet and exercise diary because they felt that documenting their exercises/goals would make them more likely to adhere to them. Similarly, the goal-setting feature was considered useful to provide a focus and many participants liked how the feedback was encouraging, constructive and specific:

> "It's good to have a concrete feedback rather than just assuming yourself that you've met your goals or not met your goals. So, if this is in writing, it's there to help you; I think it is good to get a concrete reply." (Haaniya)

A few participants felt they would not find specific tips or the goal-setting feature useful. This was mainly because they were already confident in their ability to adhere to their exercises. For example, Laurence commented that recording his exercises would be *"pointless for me because I know where I am".* Glen also suggested that people's personalities would influence whether they used the goal-setting feature, as certain people might think, *"well, I can't be bothered"*.

A few usability problems with the goal-setting feature were identified and addressed. Text was added to the goal-setting and review forms to help prevent users forgetting to select the *'Submit'* button. Similarly, text was added to the goal-setting form to advise users to enter numbers as numerals, as a couple of participants experienced problems due to entering numbers as words. A few participants found it challenging to set appropriate goals because they were not familiar with the VKS exercise programme. To address this, the pages were reordered so that the exercise session page was before the goal-setting pages. Additionally, text was added to advise users to try carrying out a VKS exercise session before setting their goals.

8.6 Discussion

8.6.1 Main findings

This study employed systematic and transparent methods to develop and iteratively refine a prototype version of the VKS. The initial development process involved integrating the findings of Phases 1–3 (Chapter 4–7); conducting multiple PPI consultations and coproduction activities; and drawing on relevant guidelines/regulations. This aimed to ensure that the VKS prototype was usable, accessible and engaging for its intended users. By evaluating how patients used the VKS prototype and exploring their perspectives of it, important usability problems and broader concerns about the prototype were identified. Most of these were successfully addressed. The feedback obtained suggested that many patients would find the refined version of the VKS a highly valuable resource. However, a minority felt its content or the digital delivery format did not meet their individual needs.

As discussed in section 8.1.1, usability encompasses the effectiveness, efficiency and satisfaction with which users can achieve their objectives when using a website (471). Some of the usability problems identified with the VKS prototype were relatively minor issues linked to efficiency and satisfaction. For example, the initial information architecture did not prevent users navigating the prototype, but it reduced users' satisfaction as the number of titles displayed in the meganav appeared overwhelming. There were also occasions where participants appeared unable to achieve their objectives effectively. Most notably, a minority of participants were not able to complete the sign-up/login process independently. This finding builds on the study by Sharif et al. (107) included in the Phase 1a rapid review, in which health professionals suggested that some patients may have difficulty logging into mobile health tools. The problems with the sign-up/login process in this study occurred despite the process being what one participant described as *"pretty standard really"*. In addition, participants highlighted broader concerns about the need to sign-up, such as whether it would be worth it. This aligns with previous research, which has shown users are generally reluctant to sign-up to health websites and their decision about whether to sign-up is typically dependent on the perceived benefits of doing so (510).

Removing the VKS sign-up/login process would address the above issues. However, it would prevent the inclusion of certain features that involve computer-tailoring, such as the goal-setting feature. An alternative option suggested by one participant would be to enable users to view some of the VKS before deciding whether to sign-up. Those that wished could then sign-up to access tailored features. This approach would be particularly appropriate for the VKS, as the majority of the content does not rely on computer-tailoring. Furthermore, research suggests that users' trust in and perspectives of health websites are shaped over time as they engage with the content (510, 511). Correspondingly, allowing users to freely access some of the VKS would be likely to build their trust in the website and increase its perceived value; hence making them more willing to sign-up.

The majority of changes implemented appeared to be successful. Those with lower success mainly involved adding extra text, for example about the purpose of the VKS email address. The extra text did not always achieve its intended purpose due to some participants not reading it. This was at least partly related to participants skim reading the pages. Accounting for skim reading is a recognised challenge for website design

(512). A useful strategy for addressing this is to create visual hierarchies, for example by locating key text at the top of a page and making it a larger type size and different colour compared to the rest of the text (512). Visual hierarchies were used where possible in the VKS prototype. However, the ability to change the text formatting was slightly limited by Frank's Content Management System to ensure that the text met accessibility guidelines. Formatting key words/phrases in bold is another established strategy for accounting for skim reading (512). This was employed in the VKS prototype and appeared to be valued, but also caused some confusion due to participants thinking that words/phrases in bold were hyperlinks. These findings highlight that alternative strategies may be needed to ensure that participants read key text, such as putting the text in boxes or alert banners.

In addition to assessing the usability of the VKS prototype, this study explored participants' perspectives of the prototype more broadly. A key finding was that most participants felt the VKS would support them to engage with its target behaviours. Participants' main concerns related to the recommended numbers of VKS exercises to perform per session and sessions to perform per week. These concerns appeared to be successfully addressed by minor wording changes. However, as discussed in Chapter 5 (section 5.4.1), there is ongoing uncertainty about the optimal pre-operative TKR exercise session duration and frequency. The VKS recommendations on these aspects may therefore need to be reconsidered as further evidence becomes available.

Another key finding was that participants' perspectives of the acceptability of the VKS prototype varied widely. Perski and Short (513) suggest that acceptability of digital health interventions is a multifaceted concept that incorporates usability and other interacting components, such as an intervention's perceived effectiveness and burden. This corresponds with the theoretical framework of acceptability developed by Sekhon et al. (514), which proposes that the component constructs of acceptability are affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy. Most participants appeared to perceive the VKS prototype as highly acceptable because they valued the support it offered and were confident in their ability to use it effectively with relatively little effort. In contrast, a minority of participants felt that the acceptability of the VKS prototype was low in their specific context.

One participant's negative perceptions of the VKS prototype appeared to be largely related to its perceived effectiveness, as he felt that he knew most of the information already and the exercise programme was too easy for him. This is arguably not a major concern in terms of the potential value of the VKS as this individual appeared to have high health literacy. Ensuring that the VKS meets the needs of patients with low health literacy is the main priority because such patients are less likely to obtain and act on health information from other sources and are at higher risk of poor TKR outcomes (92, 515). The other two participants who perceived the VKS as less acceptable related this to the digital delivery format, which they felt was anxiety provoking and required a lot of effort to engage with. Furthermore, these two participants were unconfident in their ability to use the prototype effectively. They both highlighted that they would value pre-operative support delivered through an alternative format. Some participants who considered the VKS prototype acceptable also expressed a desire to receive its content in another format, such as a booklet for increased convenience. This highlights the importance of ensuring that pre-operative TKR care is available in a variety of delivery formats, as discussed further in Chapter 9 (section 9.3.2).

8.6.2 Comparison with previous similar studies

Similarly to the theoretical modelling study (Chapter 7), this study expands the growing body of evidence supporting the value of using an evidence-, theory- and person-based approach to develop digital interventions (211, 439-441). In particular, the findings build on previous studies that have demonstrated how think-aloud interviews are particularly useful for iteratively refining digital behaviour change interventions (211, 228, 439-441). Whilst the feedback obtained in previous studies was specific to the particular intervention being refined, there are parallels with this study's findings. For example, Bradbury et al. (211) reported that participants trusted their digital intervention for cancer survivors because it was developed by experts. This aligns with participants' feedback on the *'Virtual Knee School development and team'* page and wider research suggesting that the expertise of a health website's owner(s) has a strong influence on users' trust in the website (511). In addition, one of the changes implemented by Bradbury et al. (211) was making the names of buttons to the intervention sections more descriptive to help avoid confusion. Similarly, amending the title of the VKS exercise section to include *'pre-op'* was an important change in this study. This emphasises the importance of ensuring that digital content is self-evident or at least self-explanatory, which is an established principle of website design (512).

To the researcher's knowledge, no previous studies have developed and iteratively refined a digital pre-operative TKR intervention using a similar approach to this study. However, the studies by Clarkson et al. (462) and Pearson et al. (412) discussed in Chapter 7 (section 7.6.2) both used think-aloud interviews to obtain feedback on prototypes of their web-based interventions. In the study by Clarkson et al. (462), one think-aloud participant queried whether goal setting was necessary and only one of the six participants in the subsequent evaluation phase used the intervention's goal-setting feature. The present study expands this finding by highlighting that some users' reluctance to use a goal-setting feature may be because they already have high self-efficacy for engaging in the target behaviour and/or because they do not feel that goal setting is worth the effort. A notable finding reported by Pearson et al. (412) was that video testimonials from people who had participated in ESCAPE-pain appeared to be a facilitator to engagement with the website. Similarly, participants in this study valued the patient stories. An additional point highlighted by this study is that it is important to clearly explain whether testimonials/stories are from real-life or fictional patients.

The study by Reid et al. (384) discussed in Chapter 6 (sections 6.1.1 and 6.4.2) explored patients' and caregivers' perspectives of the optimal timing for accessing a pre-operative TKR/THR education and prehabilitation digital intervention. As in this study, participants' preferences varied, although most stated that they would like to access the intervention as soon as they found out they required surgery. In contrast, nurses in the study by Causey-Upton et al. (109, 314), which was included in the Phase 1a rapid review (Chapter 4, section 4.3), suggested that pre-operative TKR education should ideally be provided two to four weeks pre-operatively. Their main rationale for not providing education further in advance was to minimise the risk of patients forgetting the information. As highlighted by this study, digital delivery of education would overcome that issue by providing a constantly available resource for patients to refer back to. A key additional consideration identified in this study is that delivering prehabilitation advice too close to surgery might concern patients due to the limited time available to implement the advice. Another important finding was that enabling patients to access the VKS prior to listing for surgery could facilitate their decision-making.

8.6.3 Limitations

Although employing an interactive think-aloud interview style was appropriate for this study's aim, it may have affected how participants used the VKS prototype. For example, participating in an interactive think-aloud interview has been shown to increase participants' mouse clicks, scrolling instances and perceived mental workload (516). Participants' use of the VKS prototype may also have been affected by the researcher's presence (152, 517). Furthermore, participants did not have the opportunity to try making any of the desired behaviour changes, such as undertaking the exercise programme. Due to the VKS prototype's large volume of content, no participants accessed all the pages, watched all the videos etc. Participants' overall judgements about the VKS prototype were therefore based on a limited sample of its content. As discussed in section 8.4.5, knowing that the researcher led the development of the VKS prototype may have encouraged participants to provide socially desirable feedback. However, that did not appear to be a major issue, as most participants appeared willing to make negative comments.

During remote interviews, the researcher observed how the participants used the VKS prototype via screen sharing. However, she may have missed valuable non-verbal cues due to being unable to see the participants' faces (501). Despite this, the depth of feedback obtained did not appear to be limited by the remote format. Similarly, Morton et al. (518) reported that they successfully completed telephone think-aloud interviews *'without any apparent loss of depth or rapport'* (p.9). A more substantial problem in this study was that the researcher performed the manual actions required to navigate the VKS prototype for one participant. This limited the ability to explore how the participant would have navigated the prototype independently and may have influenced the participant's perspectives of it. As described in section 8.4.4, the researcher took steps to account for the evaluator effect. Full analysis of the interview data by multiple people would have addressed this issue further (509). A key challenge related to the analysis process was deciding when saturation was achieved, as this relied on the subjective assessment of whether potential changes were substantial.

Diversity in this study's sample was obtained in key characteristics such as age, ethnicity and confidence in using the Internet. However, most of the participants were recruited from a single hospital and only participants who could communicate in English were eligible. In addition, few participants had a disability or health condition that could affect their ability to use a website or carry out gentle exercises. Correspondingly, although the VKS prototype appeared to be accessible, future work will be necessary to evaluate its accessibility for people with a wider range of impairments. Another limitation was that all participants were required to be willing to use the VKS prototype during their interviews. A useful addition would have been to conduct semi-structured interviews with patients who were unwilling to use the VKS prototype, as that approach can provide unique insights into factors that may affect a digital intervention's uptake (228).

8.6.4 Implications for practice and future research

This study's findings suggest that the refined version of VKS would be a valuable resource for many patients undergoing TKR, although the digital delivery format is unlikely to meet all patients' needs. Future research of the VKS is therefore warranted. As discussed in Chapter 9 (section 9.6.2), the logical next step would be to conduct a randomised feasibility study with embedded process and economic evaluations. This would help determine whether it is appropriate to progress to an RCT evaluating the clinical- and cost-effectiveness of the VKS. Conducting a feasibility study could also help inform a potential future RCT by addressing key uncertainties, such as the optimal timing for delivering the VKS. Whilst most of the usability problems and broader concerns about the VKS prototype identified in this study were successfully accounted for, a minority were not resolved. For example, one participant did not relate to the patient models in the exercise videos because none of them appeared to require a walking frame. Addressing these issues prior to a feasibility study would be beneficial.

This study's findings also have implications for clinical practice and wider research. As discussed above, the findings highlight the importance of ensuring that pre-operative TKR care is available in a variety of delivery formats and at least some sections of digital interventions are freely accessible without the requirement to sign-up. The findings also emphasise that navigation options and digital features should be clear and intuitive, and suggest that strategies such as putting key text in boxes may be necessary to account for skim reading. Additional learning points that could apply to other digital interventions include: adding the duration of educational videos to their titles may encourage users to watch them; tunnelling users to other pages before the homepage may cause confusion; and including large numbers of options in dropdown menus may be overwhelming for users.

The diversity of participants' overall views about the VKS prototype demonstrates the challenges of accounting for patients' differing needs and preferences. Strategies such as providing accordion content and optional features may address these challenges to some degree. It may also be necessary to prioritise the needs of certain groups of patients, such as those with low health literacy. This study also highlights specific areas that warrant further research, such as how to encourage users to engage with goal-setting features.

8.7 Conclusion

This chapter achieved its aim of developing a prototype version of the VKS and iteratively refining it by evaluating how patients use it and exploring their perspectives of it. Integrating the findings of Phases 1–3 (Chapter 4–7) throughout the development process ensured that the VKS prototype was based on evidence, theory and patients' perspectives. Numerous PPI consultations/coproduction activities and relevant guidelines were also employed with the aim of making the VKS prototype usable, accessible and engaging. Conducting think-aloud interviews with diverse patients enabled numerous potential changes to the VKS prototype to be identified and prioritised. Most of the important changes were successfully implemented. Participants' in-depth feedback suggested that the refined version of the VKS would be a usable, acceptable and valued resource for many patients both pre- and post-TKR. The feedback also indicated that the VKS is unlikely to fully cater for all patients' individual needs and emphasised the importance of ensuring that non-digital alternatives are available. This study's findings highlight that future research of the VKS is warranted. As discussed in Chapter 9 (section 9.6.2), undertaking a feasibility study of the VKS would be a logical next step to help determine whether/how to progress to an RCT evaluating the clinical- and cost-effectiveness of the VKS. This study provides a valuable original contribution to the literature by identifying novel learning points that have implications for clinical practice and wider research. For example, the findings suggest that a key strategy for promoting engagement with pre-operative TKR digital interventions is to make at least some of the interventions' content freely accessible without the requirement to sign-up.

Chapter 9 Discussion and conclusion

9.1 Introduction

This chapter discusses the overall project, including its key original contributions to the literature. Firstly, a summary of each project phase is provided and meta-inferences generated by integrating the findings of all the phases are outlined. Strengths and limitations, assessment of the project success and implications for practice and future research are then discussed. Finally, the overall conclusion is presented.

9.2 Project summary

9.2.1 Overview

The overall aim of this project was to develop a pre-operative TKR education and prehabilitation digital intervention, the VKS. This was achieved by employing a rigorous evidence-, theory- and person-based intervention development approach and complex mixed methods design. Each project objective was successfully addressed through separate phases, which built on the findings of the preceding phase(s). The findings of all the phases were integrated to generate meta-inferences. Sections 9.2.2–9.2.6 summarise the key findings of each phase. Section 9.3 describes the meta-inferences and their relationships with existing literature.

9.2.2 Rapid review of the content and delivery of pre-operative TKR interventions (Phase 1a, Chapter 4)

This study aimed to identify and synthesise recent literature on the content and delivery of pre-operative TKR interventions (project objective 1a). This was achieved through a rapid review with a convergent segregated mixed methods design. The 52 included studies covered a broad range of intervention types, the most common of which were education and exercise. The findings demonstrated that definitive evidence on the optimal content and delivery of pre-operative TKR interventions is lacking. Digital delivery formats were identified as potentially useful for providing education and/or exercise interventions. However, no studies evaluating a digital intervention delivered without health professional support were identified. This demonstrates that the VKS could address an important gap in the evidence base. The review's findings highlighted various considerations for designing pre-operative TKR interventions, providing a valuable original contribution to the literature. Key findings were that personal tailoring and employing more than one delivery format appear to be important design elements for most pre-operative TKR intervention types. Preliminary evidence was identified that indicates including balance training and hospital versus home delivery do not affect the effectiveness of pre-operative TKR exercise interventions. The findings also suggested that pre-operative TKR education should cover a comprehensive range of topics, including rehabilitation and recovery expectations.

9.2.3 Modified Delphi study to develop recommendations on pre-operative TKR interventions (Phase 1b, Chapter 5)

This study aimed to develop evidence- and consensus-based recommendations on the content and delivery of pre-operative TKR interventions (project objective 1b). This was achieved through a UK-based, three-round, online modified Delphi study with equal numbers of patients and professionals. The Phase 1a findings were used to develop an initial set of recommendations for Round 1. Sixty, 57 and 55 panellists completed Rounds 1, 2 and 3 respectively. The final recommendations cover 34 education topics, 18 education delivery approaches, 10 exercise types, 13 exercise delivery approaches and two other pre-operative treatments. The final recommendations provide an important original contribution to the literature, as they are more detailed than other sources of guidance in this area. The recommendations were developed in concise and prioritised versions to ensure that they were appropriate for informing the VKS development and provide a resource for guiding UK health professionals' decision-making on pre-operative TKR service provision until more robust evidence becomes available. A notable recommendation is that pre-operative TKR education should be delivered using a combination of formats, including a website or other electronic format. This supports the rationale for the VKS project.

9.2.4 Qualitative exploration of potential barriers and facilitators to engagement with the Virtual Knee School (Phase 2, Chapter 6)

This study aimed to explore patients' perspectives of potential barriers and facilitators to engagement with the VKS (project objective 2). This was achieved through a qualitative descriptive study involving online focus groups with 14 patients who were awaiting/had undergone TKR. The focus group discussions were facilitated using digital trigger materials (example digital features) developed from the Phase 1 findings. Reflexive thematic analysis led to the development of two intersecting themes, each with three subthemes. Theme 1 indicated that the VKS should account for the impact of individual differences on engagement with digital technologies, pre-operative education and prehabilitation. Theme 2 emphasised the importance of tailoring the VKS to the pre-operative context. Key pre-operative contextual features identified included physiological/psychological factors, social/occupational factors and limitations in pre-operative TKR care provision. By highlighting principles, barriers/facilitators and design features to consider when developing pre-operative TKR digital interventions, the study's findings provide a valuable original contribution to the literature.

9.2.5 Theoretical modelling to guide the Virtual Knee School design, description and evaluation (Phase 3, Chapter 7)

This study aimed to use theoretical modelling to guide the design, description and evaluation of the VKS (project objective 3). This was achieved using three theoretical modelling approaches, each of which provided inter-related and complementary insights. All three approaches were informed by the Phase 1–2 findings and PPI consultations. In line with the person-based approach (PBA), six VKS guiding principles were created to concisely summarise the key design objectives and features of the VKS. Through a behavioural analysis using the BCW and BCTTv1, an in-depth understanding of the behaviours targeted by the VKS was gained. This enabled a detailed list of potential VKS features to be compiled and characterised using standardised terminology. A diagrammatic representation of the VKS was developed by integrating the guiding principles and behavioural analysis findings in a logic model. This transparently summarises the proposed causal mechanisms and intended outcomes of the VKS. Demonstrating how three theoretical modelling approaches can be integrated when developing a novel pre-operative TKR digital intervention provides a useful original contribution to the literature.

9.2.6 Virtual Knee School prototype development and iterative refinement using the think-aloud method (Phase 4, Chapter 8)

This study aimed to develop a prototype version of the VKS and iteratively refine it by evaluating how patients use it and exploring their perspectives of it (project objective 4). This was achieved using systematic and transparent methods. Firstly, a prototype version of the VKS was developed by integrating the Phase 1–3 findings, conducting multiple PPI consultations/coproduction activities and drawing on relevant guidelines. This ensured that the VKS prototype was based on evidence, theory and patients' perspectives, with the aim of making it as usable, accessible and engaging as possible. The VKS prototype was then iteratively refined based on the findings of concurrent think-aloud interviews with nine patients who were awaiting/had undergone TKR. Multiple potential changes to the VKS were identified and prioritised. Most of the important changes were successfully implemented. The findings suggested that many patients would find the refined version of the VKS a usable, acceptable and valued resource both pre- and post-TKR. They also highlighted that the VKS is unlikely to fully cater for all patients' individual needs and offering non-digital alternatives is essential. Many of the novel learning points identified in the study could be applied to clinical practice and wider research; hence the findings provide a valuable original contribution to the literature.

9.3 Meta-inferences

9.3.1 Overview

The researcher generated meta-inferences by integrating the findings of all the project phases. This involved linking inferences from the different phases; assessing potential similarities and differences; developing credible explanations of the similarities/differences and identifying implications of the findings (519). This process generated two intersecting meta-inferences (Figure 9.1), which both make original contributions to the literature. Each meta-inference is underpinned by three principles and provides a recommendation that applies to clinical practice and future research. Sections 9.3.2–9.3.3 summarise the meta-inferences, their underpinning principles and their relationships with existing literature.

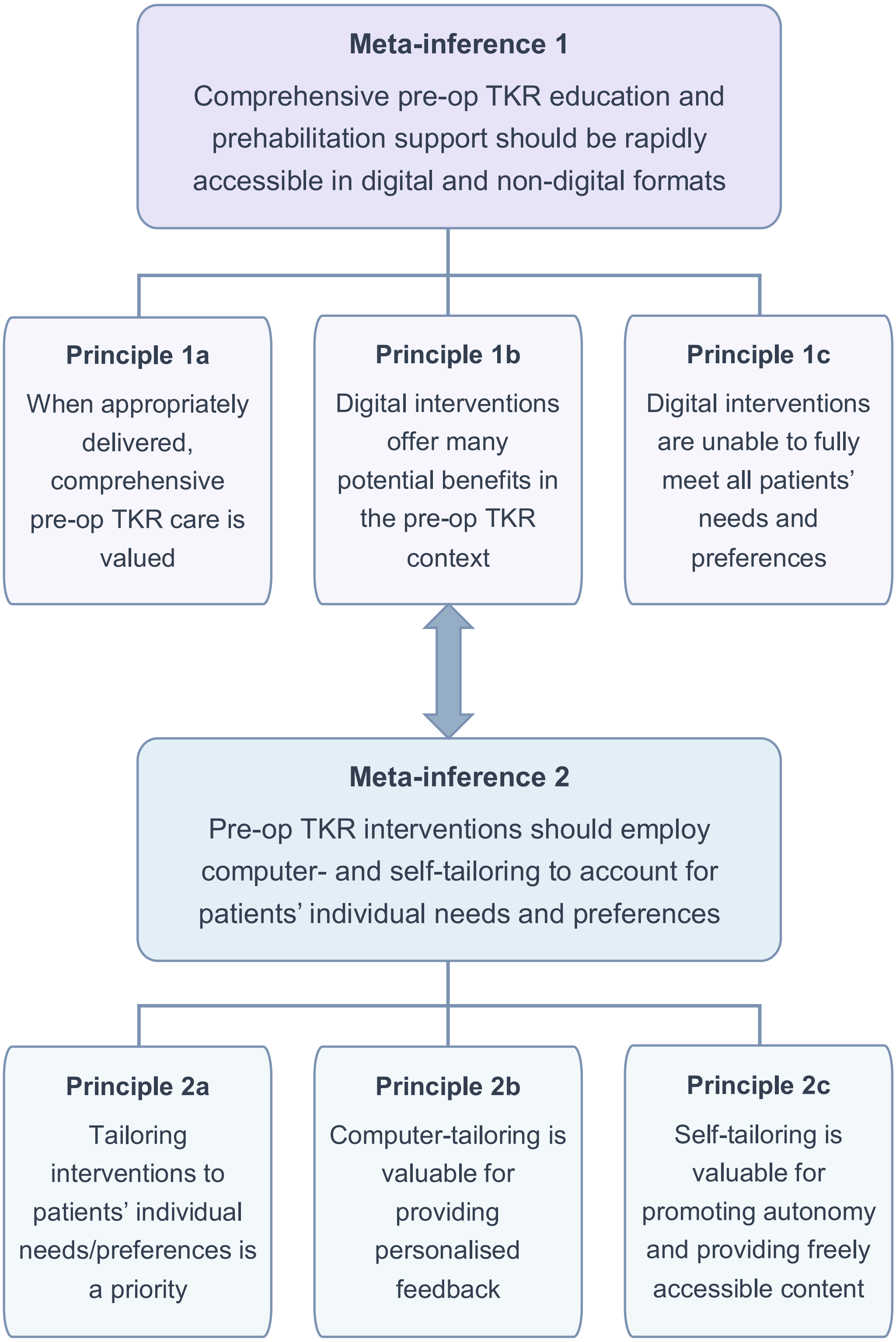

Figure 9.1: Meta-inferences schematic diagram

Pre-op, pre-operative; TKR, total knee replacement

9.3.2 Meta-inference 1: Comprehensive pre-operative TKR education and prehabilitation support should be rapidly accessible in digital and non-digital formats

This meta-inference highlights the importance of ensuring that patients can rapidly access comprehensive pre-operative TKR education and prehabilitation support in formats that meet their individual needs and preferences. Offering both digital and non-digital formats is recommended as digital interventions offer unique benefits but are unable to fully cater for all patients' needs and preferences.

9.3.2.1 Principle 1a: When appropriately delivered, comprehensive pre-operative TKR education and prehabilitation support is valued

The perceived value of comprehensive pre-operative TKR education and prehabilitation support was demonstrated in all the project phases. Patients and health professionals appeared to value comprehensiveness in terms of intervention types and intervention content. This was particularly evident in Phase 1b. The final recommendations covered education (including 34 education topics), exercise (including 10 exercise types) and other pre-operative treatments (weight management and CBT-based therapy). Similarly, participants from studies included in the Phase 1a review and participants from the Phase 2 focus groups perceived multiple intervention types and intervention components as valuable. This was reflected in the Phase 3 theoretical modelling approaches. For example, the behavioural analysis identified an extensive array of potential intervention features related to education, exercise and healthy lifestyle changes. In Phase 4, participants highlighted the comprehensiveness of the VKS prototype as one of its strengths and appeared impressed by the range of exercises provided.

Although most of the project findings suggested that comprehensive pre-operative TKR education and prehabilitation support is valued, the Phase 1a findings highlighted that there is a risk of overwhelming patients with too much information. In addition, one Phase 2 participant indicated that he did not want to receive detailed information pre-operatively, whilst another reported finding a large volume of simple information frustrating. The Phase 4 findings demonstrated that delivering information appropriately is key to addressing these challenges. For example, participants found the initial education dropdown menu overwhelming due to the large number of options provided and felt the accordions were useful for reducing the volume of text displayed.

9.3.2.2 Principle 1b: Digital interventions offer many potential benefits in the pre-operative TKR context

Potential benefits of digital interventions in the pre-operative TKR context were highlighted in all the project phases. Benefits identified in Phase 1a included enhancing patient engagement, providing more personalised care and increasing service efficiency. The Phase 1b free-text comments indicated that digital interventions could provide a useful information resource. Correspondingly, education delivery via a website or other electronic format was included in the Phase 1b final recommendations. The final recommendations also state that pre-operative TKR exercise programmes should be delivered using unsupervised sessions, which digital interventions could support.

A key finding from Phase 2 was that digital interventions could help overcome limitations in current pre-operative TKR care provision. For example, two participants highlighted issues with the timing of pre-operative TKR care delivery. They felt a digital intervention could help address these issues by providing a rapidly accessible information source. Limitations in pre-operative TKR care provision were also highlighted in the other project phases. Problems identified included insufficient information on specific topics, lack of exercise guidance and inadequate tailoring to patients' individual needs. The Phase 3 theoretical modelling approaches demonstrated how a digital intervention could help overcome these problems by providing comprehensive education and prehabilitation support, which is tailored to patients' individual needs and preferences.

The Phase 4 findings confirmed that pre-operative TKR digital interventions such as the VKS offer many potential benefits. As in Phase 2, participants identified specific features that they would find helpful, such as exercise videos. Some participants particularly liked the tailored feedback provided by the goal-setting feature. Functions such as the accessibility toolbar and video auto-translation option were also valued. Phase 4 participants highlighted an important benefit of the VKS is that it would provide a constantly available resource to refer back to. In addition, participants commented that they would like to start accessing the VKS at different time points in the TKR pathway. Accounting for these differing preferences would be feasible due to the flexible nature of the digital delivery format.

9.3.2.3 Principle 1c: Digital interventions are unable to fully meet all patients' needs and preferences

The inability of digital interventions to fully meet all patients' needs and preferences was particularly evident from Phases 2 and 4. One Phase 2 participant highlighted that some patients have limited experience of using digital tools such as apps, which she related to the older demographic of patients undergoing TKR. Two additional Phase 2 participants were reluctant to use digital technologies in general due to their personal preferences. To help address this, participants suggested that a digital intervention should include printable documents, so PDF documents were included in the VKS prototype. Some Phase 4 participants particularly liked the PDF documents, which they felt would be easy and convenient to use. However, one participant highlighted that she does not have access to a printer, so simply providing the PDF documents on the website would not fully meet her needs. The Phase 4 findings demonstrated that some patients find digital delivery formats anxiety-provoking. In addition, the VKS prototype's web-based format was not fully accessible for one participant due to her health problems.

The inability of digital interventions to meet all patients' needs was also briefly addressed in the other project phases. The Phase 1a findings highlighted potential problems related to using digital technologies to deliver pre-operative care, such as patients lacking access to technologies and/or having low digital literacy. The Phase 1b free-text comments also indicated that some patients lack internet access. Correspondingly, the Phase 1b final recommendations state that pre-operative TKR education and exercise programmes should be delivered through a combination of formats. The recommended formats include non-digital options such as booklets. Due to some patients not being able to access or effectively engage with websites, the Phase 3 logic model states that the key unintended consequence the VKS needs to avoid is increasing health inequities.

9.3.2.4 Relationship with existing literature

The finding that comprehensive pre-operative TKR education and prehabilitation support should be accessible in formats that meet patients' needs and preferences aligns with the NICE guideline on primary joint replacement (31). This guideline states that patients should be given information in an easily understandable format at their first appointment and as needed during the rest of their care. It also lists specific information topics to address and recommends providing advice on pre-operative rehabilitation, including exercise and healthy lifestyle changes. These recommendations are reflected in the recently published NICE quality standard on joint replacement (328). Quality statement 1 of this standard is:

> ‘Adults who will have hip or knee replacement are given advice on preoperative rehabilitation when they are listed for surgery.’ (328: p.5)

This project’s findings build on the NICE guideline and quality standard by recommending that pre-operative TKR education and prehabilitation should be rapidly accessible in both digital and non-digital formats. By justifying this recommendation and highlighting strategies for optimising the use of digital delivery formats, this project provides an important original contribution to the literature.

As discussed in Chapter 2 (section 2.4.1), digital delivery of pre-operative TKR care is consistent with the NHS Long Term Plan (35). Many of the benefits of digital interventions identified in this project correspond with general literature on digital interventions. For example, the potential for digital interventions to enhance patient engagement and increase service efficiency is widely recognised (38, 151). A key finding of this project is that digital interventions have the potential to address specific limitations in pre-operative TKR care, including problems with the timing of care delivery, gaps in the support provided and inadequate tailoring to patients’ individual needs. Ensuring that pre-operative TKR digital interventions address these limitations is likely to optimise their effectiveness. This project highlights strategies that can help achieve this, such as enabling all sections of digital interventions to be accessed rapidly, providing a flexible exercise programme and employing the tailoring strategies discussed below (section 9.3.3).

Ensuring that pre-operative TKR care is available in non-digital delivery formats aligns with literature on actions needed to minimise the risk of the digital inverse care law discussed in Chapter 2 (section 2.4.2) (520, 521). As well as offering care in non-digital formats, it is essential to understand the drivers of digital exclusion (37). This can help identify strategies for ensuring that digital interventions counter rather than compound health inequities (37). This project identified multiple factors that can contribute to patients not being able to access pre-operative TKR digital interventions or engage with them effectively. These include lack of access to the Internet/an appropriate device, low digital literacy and anxiety about using digital interventions. This suggests that a combination of strategies is likely to be important for promoting digital inclusion amongst patients undergoing TKR. Potential strategies include providing free devices and digital skills training programmes, as offered by various third-sector organisations (165, 521). Another key strategy is ensuring that digital interventions are developed collaboratively with intended users at risk of digital exclusion (37, 521), as undertaken in this project.

9.3.3 Meta-inference 2: Pre-operative TKR digital interventions should employ computer- and self-tailoring to account for patients' individual needs and preferences

This meta-inference highlights the importance of tailoring pre-operative TKR interventions to patients' individual needs and preferences. Employing both self- and computer-tailoring in digital interventions is recommended due to the complementary benefits they may offer. This meta-inference intersects with Meta-inference 2 through Principle 1b (section 9.3.2.2), which highlights that a key benefit of digital interventions is the potential to provide tailored support.

9.3.3.1 Principle 2a: Tailoring interventions to patients' individual needs and preferences is a priority

The importance of tailoring pre-operative TKR interventions to patients' individual needs and preferences was emphasised in all the project phases. In Phase 1a, personal tailoring was associated with improved outcomes and/or perceived as valuable for education, exercise, psychological and lifestyle interventions. The Phase 1b free-text comments highlighted multiple factors to consider in relation to tailoring such as age, comorbidities, language needs and personal preferences. Correspondingly, the Phase 1b final recommendations state that pre-operative TKR education and exercise programmes should be tailored according to each patient's individual needs.

One of the themes developed in Phase 2 was *'Accounting for individual differences'*. This theme demonstrates how participants' differing circumstances and preferences affected their perspectives of potential barriers and facilitators to engagement with digital technologies, pre-operative education and prehabilitation. The findings suggested that accounting for patients' individual differences would help to optimise their engagement with the VKS. All three Phase 3 theoretical modelling approaches reflected the importance of tailoring. For example, VKS guiding principle 3 (VGP-3) states that a key intervention design objective of the VKS is:

> ‘To account for users’ varying pre-operative TKR education preferences and needs.’ (Table 7.4)

The VKS prototype developed in Phase 4 employed computer- and self-tailoring to account for patients’ individual needs and preferences, as discussed in sections 9.3.3.2–9.3.3.4 below. The tailoring strategies were largely successful, with most participants appearing to perceive the VKS prototype as highly acceptable. Participants who considered the VKS prototype less acceptable highlighted that its content or digital delivery format did not meet their individual needs and preferences.

9.3.3.2 Principle 2b: Computer-tailoring is valuable for providing personalised feedback

Computer-tailoring involves using computer algorithms to adapt an intervention’s content/delivery to a specific user based on an assessment of their individual characteristics (428, 429). Phases 2–4 demonstrated the value of using computer-tailoring to provide personalised feedback. Although Phase 2 participants’ perspectives of goal setting varied, many liked the idea of receiving personalised feedback via a goal-setting feature. Proposed benefits included increasing patients’ motivation and prompting reflections. Correspondingly, a goal-setting feature was included in all the Phase 3 theoretical modelling approaches and in the VKS prototype developed in Phase 4. The Phase 3 behavioural analysis tables also included healthy lifestyle screening/feedback features. These were not considered a high enough priority to include in the VKS prototype. Phase 4 participants’ perspectives of the VKS prototype goal-setting feature were mixed but mostly positive. Participants particularly liked the personalised feedback because it was encouraging, constructive and specific.

Whilst Phases 1a and 1b did not directly address computer-tailoring, their findings support the use of features that involve computer-tailoring. For example, the Phase 1a findings demonstrated that some patients experience problems attaining their sedentary behaviour reduction goals. This highlights the potential value of providing personalised feedback with tips on how patients can adapt their goals. In addition, goal setting was included as an education topic and exercise delivery approach in the Phase 1b final recommendations.

9.3.3.3 Principle 2c: Self-tailoring is valuable for promoting autonomy and providing freely accessible content

Self-tailoring involves offering users choices so that they can adapt the intervention content/delivery independently. According to Self-Determination Theory (SDT), offering choices enhances intrinsic motivation by promoting autonomy (203). This is reflected in the PBA common guiding principles incorporated in Phases 3–4. Common guiding principle 1 (CGP-1) states a key design objective is *'To promote user autonomy'* (178: Table 3). The key intervention feature designed to meet this objective is:

> 'Offering users choice where possible (e.g. of goals, tools, timing, method of implementation).' (178: Table 3)

Due to Phase 2 participants' differing needs and preferences, they felt a pre-operative TKR digital intervention should include a choice of features and implementation options. For example, they suggested that users should be able to self-select times to receive exercise email reminders. The findings of all three Phase 3 theoretical modelling approaches reflect the importance of offering choices. For example, VGP-3 states that key information should be kept brief and more detailed information should be available for users who wish to access it. Phase 4 participants' feedback suggested that participants valued the choices offered by features such as the accordion content and accessibility toolbar. They also liked the option to download some of the content in PDF documents and appreciated the flexibility of the VKS exercise programme.

The Phase 4 findings demonstrate that a key benefit of self-tailoring strategies is that they enable tailoring without relying on users logging in, as some participants found the VKS prototype sign-up/login process challenging and/or expressed additional concerns about the process. In contrast, many computer-tailoring strategies, such as those used in the goal-setting feature, require users to login.

Phases 1a and 1b did not address self-tailoring directly. However, the Phase 1a findings suggested that some patients might have difficulty logging into digital interventions and remembering their passwords. This supports the use of self-tailoring for delivering freely accessible content.

9.3.3.4 Relationship with existing literature

As discussed in Chapter 4 (section 4.4.1), the importance of tailoring interventions to patients' individual needs and preferences highlighted in this project is consistent with the NICE quality standard on primary joint replacement (328). Furthermore, Versus Arthritis recommends that patients awaiting TKR should receive personalised self-management support (100) and the NHS Long Term Plan sets out the ambition of providing people with *'more personalised care when they need it'* (35: p.12). The importance of accounting for patients' individual needs and preferences has also been highlighted for digital interventions specifically. The recommendations on digital behaviour change interventions discussed in Chapter 2 (section 2.4.3) emphasise digital interventions should be *'responsive to users' needs and preferences'* to optimise user engagement (38: 'Understanding and Promoting Engagement'). This project's findings make an original contribution related to this by providing specific recommendations on how and why to tailor pre-operative TKR digital interventions.

The recommendation to employ computer-tailoring aligns with the meta-analysis by Lustria et al. (430) discussed in Chapter 6 (section 6.4.1). This suggested that computer-tailored web-based interventions are more effective at improving health outcomes than non-tailored web-based interventions. Computer-tailoring aims to optimise the personal relevance and salience of messages (522). This is proposed to increase recipients' motivation to engage with the messages; hence supporting the desired behaviour changes (522). Web-based interventions can employ diverse computer-tailoring strategies (523). These range from provision of immediate feedback in response to a single assessment to delivery of sophisticated personalised programmes based on iterative assessments of multiple criteria (523). The content of messages can be tailored using various mechanisms including personalisation (including specific information obtained during the assessment), feedback (providing individualised recommendations) and adaptation (providing content based on determinants of the behaviour such as demographic characteristics) (523). In addition, the message frame and delivery mode can be tailored to the user's information processing style and learning style respectively (429).

This project demonstrates how computer-tailoring can be successfully incorporated into pre-operative TKR digital interventions. The VKS prototype goal-setting feature asked users to review their weekly exercise goals and provided messages that incorporated personalisation (encouragement that acknowledged whether the user had met their goals) and feedback (individualised tips on how the user could adapt their goals). The findings suggested that both aspects of the messages were valued, supporting the use of computer-tailoring to provide personalised feedback. This project also highlights strategies for incorporating self-tailoring in pre-operative TKR digital interventions by offering users choices. For example, the VKS prototype provided accordion content and a flexible exercise programme. The findings indicated that users value being offered choices. This aligns with the PBA (178) and SDT (203), which suggest that offering choices promotes autonomy and enhances intrinsic motivation.

The VKS goal-setting feature demonstrated how self- and computer-tailoring can be combined as users were offered a choice of goals (enabling self-tailoring) and provided with personalised feedback (though computer-tailoring). van Strien-Knippenberg et al. (524) demonstrated how self- and computer-tailoring can be combined using a more complex approach involving message-frame tailoring. van Strien-Knippenberg et al. (524) redesigned a web-based smoking cessation intervention so that users with a high need for autonomy received feedback messages with autonomy-supportive language and choice, whilst users with a low need for autonomy received messages with controlling language and no choice. An RCT of the intervention found message-frame tailoring did not affect smoking abstinence, although there was some evidence that message-frame tailoring might be useful for people with a high need for autonomy (525). These findings should be interpreted cautiously as the dropout rate was over 50% at the one-month follow-up.

Whilst combining computer- and self-tailoring may be valuable, this project's findings emphasise that employing self-tailoring in isolation is also beneficial, as it facilitates tailoring of freely accessible content. This enables digital interventions to offer a degree of tailoring to users who are unwilling or unable to sign-up/login. This project therefore adds to existing literature by suggesting that the optimal approach for combining computer- and self-tailoring within a pre-operative TKR digital intervention is to:

- employ self-tailoring in isolation to deliver freely accessible content;
- employ computer-tailoring, combined with self-tailoring where appropriate, to deliver features that provide personalised feedback.

9.4 Strengths and limitations

Chapters 4–8 detail limitations of each project phase. Sections 9.4.1–9.4.3 summarise key strengths and limitations of the overall project.

9.4.1 Intervention development approach

The use of an evidence-, theory- and person-based approach to develop the VKS was a major strength of this project. This enabled the best available evidence, relevant theory and stakeholders' perspectives to be integrated systematically and transparently. The development process comprehensively addressed most of the actions highlighted as important by the INDEX guidance (174) discussed in Chapter 2 (section 2.4.3). For example, primary data were collected and the VKS programme theory was articulated. The only action addressed to a limited degree was:

> 'Pay attention to future implementation of the intervention in the real world' (174: p.7)

Implementation at an individual level was addressed by analysing and targeting specific patient behaviours, such as engagement with pre-operative TKR care in a web-based format. However, this project did not assess how patients used the VKS in real-life contexts. Implementation at other levels was considered to a lesser degree. For example, VGP-1 states that a key intervention design objective of the VKS is to provide a cost-effective source of pre-operative TKR education and prehabilitation support. Conducting a process evaluation, as initially planned, would have enabled implementation of the VKS to be addressed more thoroughly. Another useful addition would have been to conduct in-depth qualitative research with a broader range of stakeholders, including health professionals and policy makers. The qualitative findings could then have been incorporated into a behavioural analysis using a theory such as Normalisation Process Theory (NPT) (447) discussed in Chapter 7 (section 7.4.1).

Another alternative would have been to use an implementation-based intervention development approach such as RE-AIM (526, 527). The RE-AIM framework addresses five dimensions: reach, effectiveness, adoption, implementation and maintenance. Benefits of RE-AIM include its flexibility and applicability to multiple levels, including individual, staff delivery and setting levels (527). An important disadvantage of RE-AIM is that guidance on how to apply it during intervention development is limited (171).

9.4.2 Research design and methods

This project's complex exploratory sequential mixed methods design enabled the overall project aim and multiple objectives to be addressed rigorously and transparently. Building each phase on the findings of the previous phase(s) aligned with the evidence-, theory- and person-based intervention development approach and optimised the VKS development process. For example, integrating the findings of Phases 1–2 in the Phase 3 behavioural analysis enabled many potential barriers and facilitators to engagement with the VKS target behaviours to be identified. Generating meta-inferences provided greater insights than would have been gained by considering each phase in isolation. As discussed in Chapter 3 (section 3.3.6), two approaches recommended by Creswell and Plano Clark (213) were employed to address validity concerns specific to exploratory sequential mixed methods designs:

- the building process used to develop the VKS prototype was reported in detail;
- the VKS prototype was designed systematically.

As highlighted in Chapters 4–8, various designs and methods were considered for each project phase to ensure that those selected were the most appropriate. The designs and methods were rigorously implemented and transparently reported. This helped to ensure that all the inferences and meta-inferences generated were high quality (519).

As with all research, the methods also presented limitations. Many of these were unique to the project phase. For example, using the Mixed Methods Appraisal Tool (MMAT) (279) rather than a combination of design-specific critical appraisal tools/frameworks was a specific limitation of Phase 1a. The main limitation present in all the phases was reliance on subjective judgements for aspects such as the data extraction, data analysis and sampling decisions. This risks limiting the confirmability/objectivity of the research findings (398). The researcher took multiple steps to minimise this risk. For example, she maintained transparent audit trails and organised verification of documents such as the Phase 1b categorisation matrix by her supervisors/advisors. Greater input from the researcher's supervisors/advisors, for example by directly coding data, could have addressed this further. This was not feasible because the research was a doctoral project.

Another recurring limitation was inadequate diversity in the study samples. For example, all the patient participants in Phases 1b–2 were White British and most Phase 4 participants were recruited from a single hospital. This limits the transferability/external validity of the research findings (398). Specifying additional purposive selection criteria and using a more diverse range of recruitment sites/approaches could have helped address this. However, the recruitment options available during this project were limited by COVID-19-related restrictions. As discussed in Chapter 3 (section 3.3.4), delays associated with the COVID-19 pandemic also affected this project. These delays, combined with other factors such as the large volume of content included in the VKS, meant it was not possible to evaluate the VKS through a process evaluation. The Phase 4 think-aloud interviews ensured that evaluation of the VKS was still embedded in this project.

9.4.3 Patient and Public Involvement

The central role of PPI throughout this project was another key strength. Multiple inclusive PPI activities were conducted. As summarised in Chapter 3 (section 3.5), these had a meaningful impact on the research procedures, VKS prototype content/design and dissemination activities. Input from the PAG PPI members was particularly valuable as they provided oversight of the project and were actively involved in many other activities, such as the VKS prototype development. Their involvement in these activities was complementary to the qualitative research. For example, two PAG PPI members helped decide what exercises to include in the VKS exercise programme. Selecting appropriate exercises at an early stage in the VKS development was essential because filming the exercise videos required substantial time and resources. Most think-aloud interview participants appeared impressed with the exercises. Their unfamiliarity with the VKS exercise programme also enabled them to provide novel insights. For example, one participant thought that the exercise category titles related to the videos above them rather than below them. This aligns with previous research demonstrating that PPI and qualitative research can offer important complementary benefits during intervention development (200).

Recruiting a larger number of more diverse PAG PPI members at the start of the project would have enabled a wider range of perspectives to be considered and may have facilitated the recruitment of diverse participants. To help achieve this, it would have been valuable to employ more strategic and innovative PPI recruitment approaches. Examples of these approaches include providing talks on selected radio stations and building long-term, reciprocal relationships with communities who are often underserved by health research, such as minority ethnic groups and people experiencing socioeconomic disadvantage (528, 529).

Whilst most of the PPI representatives' suggestions were addressed, this was not always possible due to various factors. These included contradictory views between PPI representatives (e.g. about what photographs to include in recruitment adverts), incompatibility with the research design or regulatory requirements (e.g. removing the funder acknowledgement text from participant documents would not have been appropriate) and time/resource constraints (e.g. developing an easy read version of the VKS would have been too time-consuming). Maintaining a PPI log throughout this project was appropriate for providing a basic summary of the PPI activities and their impact (242). Using a more in-depth evaluation approach may have provided additional valuable insights (242). For example, the Public Involvement Impact Assessment Framework (PiiAF) (530) could have been used to develop a comprehensive impact assessment plan.

9.5 Assessment of the project success

This section assesses the success of the project in relation to the project aim and objectives; the success criteria defined and agreed by the multi-stakeholder PAG (Appendix A); and the definition of successful intervention development proposed by Turner et al. (175) during the INDEX study.

As highlighted in section 9.2.1 and Chapters 4–8, the project aim and objectives were all successfully addressed. During the final PAG meeting, the PAG members agreed that the project success criteria they had defined and agreed had all been met. One success criterion was only partly met because it relates to dissemination of the project findings, which is still ongoing. All the other criteria were fully met. Decisions about whether the criteria had been met were largely uncontroversial. However, differing opinions were expressed regarding the criterion *‘Decide whether or not it is appropriate to feasibility test the VKS’*. PAG members were unanimous that it is worth investing in the VKS further and agreed that conducting a feasibility study of the VKS would be appropriate in principle. However, they were concerned about the length of time a feasibility study would require, particularly if followed by an RCT. Most PAG members felt that implementing the VKS as soon as possible is a priority due to its potential to improve care for large numbers of patients undergoing TKR. PAG members also acknowledged that successful implementation of the VKS would require substantial resources and it is essential to evaluate the VKS further, as discussed in section 9.6.2.

As part of the INDEX study, Turner et al. (175) conducted an international qualitative study that explored how intervention developers and wider stakeholders define successful intervention development. Participants’ definitions encompassed various factors linked to short-, medium- and long-term goals. The VKS development has met all the short-term goals (Table 9.1). Determining whether it has met the medium- and long-term goals will require future work addressing factors such as the effectiveness of the VKS and its implementation in the real world.

Table 9.1: Virtual Knee School development short-term goal achievement

<table>
<tr><th rowspan="2">Definition/ measure</th><th rowspan="2">Short-term definitions relating to processes and outcomes</th><th colspan="2">Achievement in the VKS development</th></tr>
<tr><th>Yes/no</th><th>Justification</th></tr>
<tr><td>Intervention</td><td>Acceptable to stakeholders
Feasible to deliver
Meets the needs of end users
Relevant to health contexts, practices and policies</td><td>Yes</td><td>The Phase 4 findings and feedback from PAG members suggest that the VKS is acceptable to stakeholders and is likely to meet the needs of most end users.
The VKS is fully automated to help ensure that it is feasible to deliver.
The VKS directly addresses limitations in current pre-operative TKR service provision, NICE recommendations (31) and a NICE quality standard (328).</td></tr>
<tr><td>Development process</td><td>Uses research evidence
Incorporates stakeholders' views
Demonstrates methodological expertise
Scientifically robust</td><td>Yes</td><td>The VKS was developed using a rigorous evidence-, theory- and person-based intervention development approach (178).
PPI was central throughout the project.
The research design and methods were clearly justified, rigorously implemented and transparently reported.</td></tr>
<tr><td>Academic impact</td><td>Journal publications
Professional credibility, particularly with funders</td><td>Yes</td><td>The Phase 1b modified Delphi study has been published in BMC Musculoskeletal Disorders (371).
The Phase 1a rapid review manuscript has been submitted for publication.
The researcher was invited to provide a presentation on the VKS project at the ATOCP Annual Conference 2021 and subsequently delivered the presentation.</td></tr>
</table>

ATOCP, Association of Trauma and Orthopaedic Chartered Physiotherapists Annual Conference; PAG, Project Advisory Group; PPI, Patient and Public Involvement; VKS, Virtual Knee School

Columns 1–2 reproduced from the left half of Figure 1 in Turner et al. (175) (https://doi.org/10.1136/bmjopen-2018-028756) under the terms of the Creative Commons Attribution 4.0 International License (194) with minor formatting amendments only.

9.6 Implications for practice and future research

Implications for practice and future research from each project phase are summarised in Chapters 4–8. Sections 9.6.1 and 9.6.2 highlight broadly applicable and VKS-specific implications of the overall project respectively.

9.6.1 Broadly applicable implications for practice and future research

As discussed in section 9.3, the meta-inferences generated in this project provide recommendations that apply to clinical practice and future research. Meta-inference 1 states that comprehensive pre-operative TKR education and prehabilitation support should be rapidly accessible in digital and non-digital formats. This highlights the importance of addressing limitations in pre-operative TKR service provision. This is a major priority due to the large number of patients facing long waiting times for TKR (5, 6). Improvements are needed in multiple aspects of pre-operative support, including its comprehensiveness, timing of delivery and potential to be tailored to patients' individual needs. Offering support in both digital and non-digital formats is a key area to address. The benefits of digital interventions and barriers to digital inclusion identified in this project suggest that strategies are needed to encourage and enable patients to access digital interventions where appropriate. For example, patients could be simultaneously signposted to a pre-operative TKR digital intervention and a third-sector organisation that provides free devices and digital skills training programmes. Research evaluating this type of approach would be valuable. It is also essential that any future studies of pre-operative TKR digital interventions consider their interventions' potential effects on existing health inequities. Furthermore, research is required to identify optimal approaches for delivering pre-operative TKR education and prehabilitation in non-digital formats.

The strategies for optimising pre-operative TKR digital interventions identified in this project could be applied in clinical practice and research. These include strategies highlighted in Meta-inference 1, such as ensuring that all the intervention sections can be accessed rapidly, and the tailoring strategies described in Meta-inference 2. Meta-inference 2 suggests that computer-tailoring of pre-operative TKR digital interventions is valuable for providing personalised feedback, particularly in the context of goal-setting. However, this project did not robustly evaluate the impact of personalised feedback or investigate other computer-tailoring strategies. Future research focused on identifying optimal computer-tailoring strategies would be useful for guiding intervention development and ensuring that resources are not wasted through unnecessarily complex tailoring strategies. Meta-inference 2 also suggests that self-tailoring should be employed in isolation to deliver freely accessible content. That approach could feasibly be implemented in clinical practice. However, it would be problematic in an RCT as control group participants could potentially access the intervention content. That would increase the risk of contamination bias, which can lead to underestimation of intervention effects (531). In addition, if intervention group participants did not log into the digital intervention, it would not be possible to obtain individual usage data. That would limit the potential to gain an in-depth understanding of how different subgroups of participants use the intervention and whether certain usage patterns are associated with the desired behaviour changes and improved outcomes (532). These issues highlight the tension between developing interventions that are optimised for implementation in practice versus interventions that are appropriate for evaluating in RCTs. This problem was noted by Turner et al. (175), who suggested that funders should consider adapting their processes to facilitate long-term planning.

This project demonstrates that developing a pre-operative TKR digital intervention using a rigorous evidence-, theory- and person-based approach can be achieved successfully in a three-year doctoral project. A similar approach could be used to develop pre-operative interventions for other elective surgical procedures. Whilst this project’s findings are primarily applicable to pre-operative TKR digital interventions, they could also help inform other types of digital interventions. The findings are likely to be most applicable to interventions that focus on other phases of the TKR pathway (e.g. the post-operative phase) or related orthopaedic procedures (e.g. UKR and THR). Some of the findings arguably have broad applicability. For example, employing self-tailoring in isolation to deliver freely accessible content is likely to be valuable for many digital health interventions.

9.6.2 Implications for future evaluation of the Virtual Knee School

This project’s findings and feedback from the PAG members demonstrate that the VKS is a promising resource that warrants further research. PAG members identified a tension between wanting to implement the VKS as soon as possible and needing to robustly evaluate it as a clinical intervention. The time required for traditional evaluation approaches is a recognised challenge for digital interventions due to the rapid pace of technological advancements (38, 149). Evaluating digital interventions is also challenging for other reasons, such as the interventions’ context-sensitivity and data security issues (38, 533). To help address these challenges, NICE published an evidence standards framework for digital health technologies (533). This framework includes standards for effectiveness and economic impact. The effectiveness standards comprise minimum and best practice standards grouped into three tiers. The Tier C best practice standards apply to the VKS because it is a self-management intervention and presents a relatively high risk due to being fully automated. The Tier C standards address multiple evidence categories. The rigorous VKS development process has already provided evidence related to some of these categories such as *'Use of appropriate behaviour change techniques'* (533: p.26) and *'Acceptability with users'* (533: p.28). Future work will be required to address all the applicable categories, including *'Demonstrating effectiveness for preventative behaviour change or self-manage functions'* (533: p.24).

The best practice standard for the above effectiveness category states that a high quality intervention study is required. Correspondingly, a paper by Murray et al. (149), which was informed by the international consensus-building workshop discussed in Chapter 2 (Table 2.2), emphasises that RCTs are essential for providing definitive evidence on the effectiveness of digital health interventions. The paper also highlights that RCTs should ideally only be undertaken once the following criteria are met:

> 'the DHI [digital health intervention] and its delivery package are stable, can be implemented with high fidelity, and are highly likely to lead to clinically meaningful benefits.' (149: p.14)

Future research is required to assess whether the VKS meets these criteria. Furthermore, the MRC/NIHR complex intervention framework emphasises the importance of completing a feasibility testing phase prior to a full evaluation (170). Conducting a feasibility study of the VKS would be a logical next step following this project because it would enable further refinement of the VKS, help determine whether it is appropriate to progress to a RCT and, if so, provide valuable information for informing the RCT. This would maximise the chances of a future RCT being successful. Planning a feasibility study of the VKS would require collaboration with a range of stakeholders, such as PPI representatives and health professionals, and researchers with varied methodological expertise. Table 9.2 summarises key considerations for the planning process. These highlight that conducting a pragmatic randomised feasibility study with embedded process and economic evaluations would be likely to be optimal. This would involve replicating most parts of a potential RCT on a smaller scale; therefore, the study could also be described as a randomised pilot study (534). Given that there are substantial uncertainties to address, an external pilot study would be more appropriate than an internal pilot study (535).

Table 9.2: Key considerations for a feasibility study of the Virtual Knee School

Consideration	Details	Key resources
VKS refinements	As discussed in Chapter 8 (section 8.6.4), the Phase 4 findings suggest that making a few further refinements to the VKS prior to a feasibility study would be beneficial. It will also be important to ensure that the VKS meets the DTAC (536). This provides minimum criteria that digital technologies must meet to be commissioned by UK NHS and social care organisations. The DTAC was not used in this project because it was launched in 2021. The feasibility study findings could subsequently be used to refine the VKS further if appropriate.	Phase 4 findings (Chapter 8, section 8.5) DTAC (536)
EDI	Addressing EDI considerations will be essential to ensure that the feasibility study findings are meaningful for informing decisions about a future RCT and the risk that the VKS may exacerbate health inequities is adequately explored. A key consideration will be how to recruit a diverse sample. In line with Meta-inference 1 (section 9.3.2), another important consideration will be deciding if and how to offer a non-digital alternative to the VKS.	NIHR INCLUDE guidance (537) and associated frameworks (538, 539) NIHR RDS EDI toolkit (529)
Design	The feasibility study design will need to be guided by the key uncertainties that the study aims to address (540). Considering areas of uncertainty for pragmatic trials will be important because a future RCT would aim to provide results that are directly applicable to clinical practice. Areas of uncertainties are likely to include whether it is possible to recruit, randomise and retain sufficient participants; what outcomes measures to employ and when to administer them; when and how to deliver the VKS; what constitutes effective engagement with the VKS; and the potential impact of the VKS on existing health inequities (38, 170, 540). A randomised design will be necessary to assess participants' willingness to be randomised. The VKS logic model will be useful for informing the choice of outcome measures. Decisions about when to provide access to the VKS and administer the outcome measures will need to account for PAG members' concerns about a feasibility study being time-consuming.	VKS logic model (Chapter 7, section 7.5.3) MRC/NIHR complex intervention framework (170) Domains of uncertainty for pragmatic trials identified by Chan et al. (540) Recommendations on developing and evaluating digital behaviour change interventions developed by Michie et al. (38)
Embedded process evaluation	Process evaluations are valuable for gaining an in-depth understanding of how an intervention functions through assessing its implementation, mechanisms of impact and contextual features (227). Including an embedded process evaluation will be particularly useful for overcoming the implementation-related limitations of this project and refining the VKS guiding principles, behavioural analysis and logic model.	Phase 3 findings (Chapter 7, sections 7.3–7.5) MRC process evaluation guidance (227)
Embedded economic evaluation	Evaluating the economic impact of digital interventions is essential to ensure that limited resources are allocated appropriately (38). Including an embedded economic evaluation will enable exploration of aspects such as whether the necessary economic data can be collected (170).	NICE evidence standards framework for digital health technologies (533) MRC/NIHR complex intervention framework (170)

Progression criteria	Pre-specifying progression criteria is an important element of feasibility studies to help guide decisions about whether to progress to a full evaluation (170).	MRC/NIHR complex intervention framework (170)
Reporting	Appropriate reporting of the VKS and feasibility study will be important to promote transparency and comparability of the findings; ensure that the findings are useful for researchers planning other similar feasibility studies/RCTs; and optimise the retrievability of any resulting publications on online databases (541, 542).	CONSORT extension for pilot and feasibility studies (541) CONSORT-EHEALTH (542) TIDierR checklist and guide (272)

CONSORT, Consolidated Standards of Reporting Trials; EHEALTH, Electronic and Mobile HEalth Applications and onLine TeleHealth; DTAC, Digital Technology Assessment Criteria; EDI, equality, diversity and inclusion; MRC, Medical Research Council; NHS, National Health Service; NIHR, National Institute for Health and Care Research; NICE, National Institute for Health and Care Excellence; RCT, randomised controlled trial; RDS, Research Design Service; TIDieR, Template for Intervention Description and Replication; UK, United Kingdom; VKS, Virtual Knee School

Although conducting a feasibility study and subsequent RCT of the VKS would be appropriate in certain respects, there is growing recognition that alternative methodological options may be particularly valuable for evaluating digital interventions (38, 543). Similarly, the MRC/NIHR complex intervention framework highlights the importance of selecting an evaluation approach based on how useful the resulting evidence is likely to be for informing decision-making, instead of focusing on minimising bias (170). Many alternative options to traditional RCTs are available, such as the Continuous Evaluation of Evolving Behavioral Intervention Technologies (CEEBIT) framework (544), adaptive trial designs (545), n-of-1 trials (546) and realist evaluation (547). This project's findings demonstrate that the effectiveness of the VKS is likely to be highly context-dependent and vary between patients. Correspondingly, realist evaluation may be a particularly useful approach for evaluating the VKS because it seeks to explain *'what works for whom in what circumstances … and why'* (548: p.15).

In light of the challenges with evaluating digital interventions and potential methodological options discussed above, consulting with diverse stakeholders will be essential to identify the most appropriate evaluation approach for the VKS. Selecting an approach that enables assessment of the impact of the VKS on health inequities and facilitates timely implementation of the VKS will be a priority.

9.7 Conclusion

This project achieved its aim of developing a novel pre-operative TKR education and prehabilitation digital intervention, the *'Virtual Knee School'* (VKS). A rigorous evidence-, theory- and person-based intervention development approach and complex mixed methods design were employed. This enabled the project's multiple objectives to be addressed successfully. The central role of PPI in this project helped to ensure that the research procedures and VKS development prioritised patients' needs. Key outputs of the project include a set of recommendations on pre-operative TKR interventions and the refined VKS prototype. A prioritised version of the recommendations was particularly useful for informing the VKS development. A concise version of the recommendations was also developed to provide a resource for guiding UK health professionals' decision-making on pre-operative TKR service provision until more robust evidence emerges. The project findings and feedback from PAG members suggest that the VKS is a potentially valuable resource that warrants further research. A possible next step would be to conduct a pragmatic randomised feasibility study with embedded process and economic evaluations. This project's findings provide numerous original contributions to the literature and have broadly applicable implications for clinical practice and future research. Key recommendations developed by integrating the findings of all the project phases include:

- comprehensive pre-operative TKR education and prehabilitation support should be rapidly accessible in digital and non-digital formats;
- pre-operative TKR digital interventions should employ computer- and self-tailoring to account for patients' individual needs and preferences.

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Appendices

Appendix A: Project success criteria

Phase	Success criterion[a]
Phase 1	Produce a prioritised list of recommendations on pre-operative TKR care
	Obtain ethical approval for Phases 2–5
Phase 2	Identify potential barriers and facilitators to engagement with the VKS
Phase 3	Conduct a behavioural analysis and develop guiding principles and a logic model to help guide the design, description and evaluation of the VKS
Phase 4	Identify key components to include in the VKS
	Develop a prototype version of the VKS
	Identify and prioritise changes that could be made to refine the VKS
	Develop a refined version of the VKS
	Establish whether the VKS is usable and acceptable
Overall project	Develop a version of the VKS that could be feasibility tested if appropriate
	Decide whether or not it is appropriate to feasibility test the VKS
	Disseminate the project findings to health professionals, researchers, patients and the public

TKR, total knee replacement; VKS, Virtual Knee School

[a] The success criteria were defined and agreed by the Project Advisory Group.

Appendix B: Rapid review Medline (Ovid) search strategy

The search strategy below was used during the initial database searches on 11th September 2019. The searches were subsequently updated to 31st December 2020. The search strategies for additional databases are not provided due to word limit restrictions.

1 Arthroplasty, Replacement, Knee/ (22063)

2 Knee Prosthesis/ (11206)

3 (TKA or TKR).tw,kw. (11739)

4 1 or 2 or 3 (30266)

5 Knee/ (13711)

6 Knee Joint/ (52242)

7 Osteoarthritis, Knee/ (18298)

8 knee?.tw,kw. (139011)

9 5 or 6 or 7 or 8 (154624)

10 Arthroplasty, Replacement/ (5872)

11 (arthroplast* or replace*).tw,kw. (425753)

12 10 or 11 (427000)

13 9 and 12 (34513)

14 4 or 13 (39999)

15 Preoperative Care/ (60281)

16 Preoperative Period/ (6405)

17 (preop* or pre-op* or presurg* or pre-surg* or ?prehab* or ?pre-hab* or teleprehab* or tele-prehab* or prepar*).tw,kw. (1184603)

18 15 or 16 or 17 (1211482)

19 Patient Education as Topic/ (82785)

20 Health Education/ (59265)

21 exp Consumer Health Information/ (8221)

22 Teach-Back Communication/ (28)

23 exp Educational Technology/ (107154)

24 Patient Education Handout/ (5007)

25 ((health* or educat* or inform* or knowledge or teach*) adj3 (class* or group? or program* or school? or booklet? or leaflet? or DVD? or YouTube or video? or website?

or "web platform" or "web platforms" or "web page" or "web pages" or web-page? or microsite? or app? or application? or multimedia)).tw,kw. (255384)

26 ((patient? adj2 educat*) or psychoeducat* or psycho-educat*).tw,kw. (33748)

27 exp Exercise/ (182510)

28 exp Exercise Therapy/ (47249)

29 exp Exercise Movement Techniques/ (7683)

30 Rehabilitation/ (17926)

31 Hospitals, Rehabilitation/ (34)

32 Rehabilitation Centers/ (8017)

33 Rehabilitation Nursing/ (1397)

34 Rehabilitation Research/ (129)

35 Recreation Therapy/ (114)

36 Telerehabilitation/ (277)

37 "Physical and Rehabilitation Medicine"/ (3122)

38 Physical Therapy Modalities/ (35459)

39 Occupational Therapy/ (12741)

40 Hydrotherapy/ (2511)

41 ((joint? or knee? or motor or physical* or cardio* or strength* or propriocept* or balance or neuromuscular or aerobic or weight or stretch* or resistance or endurance or aqua*) adj2 (school* or train* or activit* or fit* or program* or class* or therap*)).tw,kw. (243474)

42 (?rehab* or ?prehab* or ?pre-hab* or telerehab* or tele-rehab* or teleprehab* or tele-prehab or ?exercis* or ?physiotherap* or hydrotherap* or "occupational therapy" or swim* or cycl* or bik* or self-management or "self management").tw,kw. (1572703)

43 exp Psychotherapy/ (189129)

44 exp Mind-Body Therapies/ (48979)

45 Counseling/ (34516)

46 Distance Counseling/ (36)

47 exp Directive Counseling/ (3807)

48 (psychotherap* or "guided imagery" or CBT or relax* or hypnosis or "motivational interviewing" or mindfulness or counsel* or "pain coping skills training").tw,kw. (328178)

49 ((psychologic* or behavio?r* or cognitive or emotion* or mind) adj2 (intervention* or technique* or therap* or treat* or prepar* or restructur* or reframe* or distract*)).tw,kw. (73859)

50 exp Health Promotion/ (73339)

51 exp Diet Therapy/ (52287)

52 exp Life Style/ (88041)

53 Alcohol Abstinence/ (557)

54 Smoking Cessation/ (27171)

55 Smoking Reduction/ (28)

56 "Tobacco Use Cessation"/ (1094)

57 ("physical activity" or "weight loss" or "weight reduction" or diet*).tw,kw. (688013)

58 ((behavio?r* or lifestyle* or health*) adj2 (chang* or modif* or motivat* or promot* or educat* or inform* or teach*)).tw,kw. (232005)

59 ((smoking or tobacco or alcohol) adj2 (cessat* or reduc* or stop* or quit*)).tw,kw. (42910)

60 Nutrition Therapy/ (2086)

61 exp Dietary Supplements/ (70536)

62 Functional Food/ (1668)

63 exp Micronutrients/ (636727)

64 exp Minerals/ (159185)

65 ((nutrition* adj2 supplement*) or probiotic* or prebiotic* or synbiotic* or "functional food" or nutraceutical* or nutrient* or glucosamine or chondroitin or curcumin or "fish oil" or "fish oils" or "omega 3" or vitamin* or mineral* or "trace element" or "trace elements" or flavonoid* or (hydroly* adj2 collagen)).tw,kw. (623531)

66 Transcutaneous Electric Nerve Stimulation/ (4486)

67 (electrotherap* or "transcutaneous electrical nerve stimulation" or TENS).tw,kw. (17392)

68 exp Therapy, Soft Tissue/ (6707)

69 Trigger Points/ (474)

70 (massag* or "soft tissue therapy" or "trigger point" or "trigger points").tw,kw. (12297)

71 exp Orthotic Devices/ (12585)

72 (orthotic* or orthos* or insole* or "arch support" or (knee adj2 brace*)).tw,kw. (24743)

73 Acupuncture/ (1626)

74 exp Acupuncture Therapy/ (23292)

75 (acupuncture or acupressure or "dry needling").tw,kw. (21980)

76 Rehabilitation, Vocational/ (9329)

77 ((occupation* or vocation*) adj2 rehab*).tw,kw. (3749)

78 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 (4522618)

79 14 and 18 and 78 (1629)

80 exp Animals/ (22584094)

81 Humans/ (17966945)

82 80 not 81 (4617149)

83 79 not 82 (1616)

84 limit 83 to (english language and yr="2009 -Current") (1092)

Appendix C: Changes made to Round 1 following pilot testing

Type of change	Item
'More info' explanation added	2.2.1 Orthopaedic surgery team
	2.2.2 Nursing team
	2.2.3 Physiotherapy team
	2.2.4 Occupational therapy team
	2.2.5 Social work team
	2.5.7 PowerPoint presentation
New item added	1.7 Using heat and cold
	1.23 Returning to driving and other types of travel
	1.15 Common issues that may occur following TKR surgery which do not need to cause alarm
	3.12 Cardiovascular exercises
	4.3.3 A community setting, such as a sports centre
Original item amended[a]	1.2 Health conditions that may contribute to needing TKR surgery (Osteoarthritis)
	1.29 Avoiding alcohol misuse (Alcohol cessation)
	4.7 Each session in a pre-operative TKR exercise programme should last a minimum of fifteen minutes (Each session in a pre-operative TKR exercise programme should last between 45 and 75 minutes)
	4.9 A pre-operative TKR exercise programme should ideally be performed for a minimum of six weeks (A pre-operative exercise TKR programme should ideally be performed for a minimum of eight weeks)
	5.2 Patients waiting for TKR surgery who have been formally diagnosed anxiety or depression should be offered cognitive behavioural therapy (CBT)-based therapy (Patients waiting for TKR surgery who have anxiety or depression should be offered cognitive behavioural therapy (CBT)-based therapy)

TKR, total knee replacement

[a] Original item provided in brackets.

Appendix D: Focus group topic guide

IRAS 262809; version 2.0, dated 07 Apr 2020

The following topic guide may be modified during the data collection phase so that themes identified in earlier interviews or focus groups can be explored in later interviews or focus groups. Example prompts are provided; however the specific prompts used may vary. Consent will have been obtained online prior to the interview or focus group.

Interview or Focus Group Introduction

The facilitator(s) should complete all the following actions prior to commencing the interview or focus group

1. Welcome everyone and complete introductions

2. Review the information provided in the Participant Information Sheet, including:

    - Aim of the study
    - Participants can withdraw at any time
    - Interview or focus group will be recorded with a digital voice recording device
    - Confidentiality

3. Explain the process for the interview or focus group, including:

    - Facilitator(s) will ask prompt questions
    - Facilitator(s) may show digital trigger materials (these will also have been provided in advance via email)
    - Interview or focus group is not a test and there are no right or wrong answers
    - Importance of respecting others' views

4. Offer the participant(s) an opportunity to ask questions

Preparing for Surgery Questions

1. Can you tell me about your experiences of receiving information about total knee replacement surgery?

   Prompts may include: Can you tell me about whether you feel you have received enough information? Can you tell me about any additional information you would like to receive? Etc.

2. Can you tell me about any experiences you have had of doing exercises to help prepare for your total knee replacement surgery?

   Prompts may include: Can you tell me about anything that has prevented you from doing exercises? Can you tell me about anything that has helped you to do exercises? Etc.

3. Can you tell me about any experiences you have had of making healthy lifestyle changes to help prepare for your total knee replacement surgery?

   Prompts may include: Can you tell me about whether you have tried to lose weight? Can you tell me about anything that has helped you lose weight? Etc.

4. Can you tell me about anything else that you think is helpful when preparing for total knee replacement surgery?

   Prompts may include: Can you tell me about whether you have spoken to anyone else who has had TKR surgery? Can you tell me about whether you have made, or are planning to make, any changes to your home, such as moving furniture, to help you prepare for your TKR surgery? Etc.

Website Questions

1. Can you tell me about any experiences you have had of using websites to help you prepare for your total knee replacement surgery?

    Prompts may include: Can you tell me about any experiences you have had of looking for information about TKR surgery on websites? Have you found any websites particularly helpful and, if so, why? Etc.

2. Can you tell me about any experiences you have had of using websites for anything else related to your health?

    Prompts may include: Can you tell me about any experiences you have had of using websites to help you carry out exercises? Can you tell me about any experiences you have had of using websites to help you increase your physical activity levels? Etc.

3. Can you tell me about whether you think there might be any issues with using websites to help prepare for your TKR surgery?

    Prompts may include: Do you have any concerns related to privacy when using websites and, if so, what are your concerns? Can you tell me about whether you think there might be any issues with carrying out an exercise programme that is provided through a website? Etc.

Trigger Materials Questions

More than one set of trigger materials may be used during each interview or focus group.

1. Can you tell me what you think about using a website to provide <<insert website content>>?

    Prompts may include: Can you tell me what you think about the advice on weight management? Can you tell me whether you would have any problems following the advice? Etc.

2. Can you tell me what you think about <<insert digital feature/activity/tool>>?

   Prompts may include: Can you tell me about whether you think you would use an activity tracker? Can you tell me about how you would use it? Etc.

3. Can you tell me about anything that might encourage you to use <<insert website content/digital feature/activity/tool>>?

   Prompts may include: Are there any aspects of the exercise videos you would find particularly helpful? Can you tell me about how you think the exercise instructions could be improved? Etc.

4. Can you tell me about anything that might prevent you from using <<insert website content/digital feature/activity/tool>>?

   Prompts may include: Do you have any concerns about using an online discussion forum and, if so, what are your concerns? Do you think you would have time to use it? Etc.

Final Questions

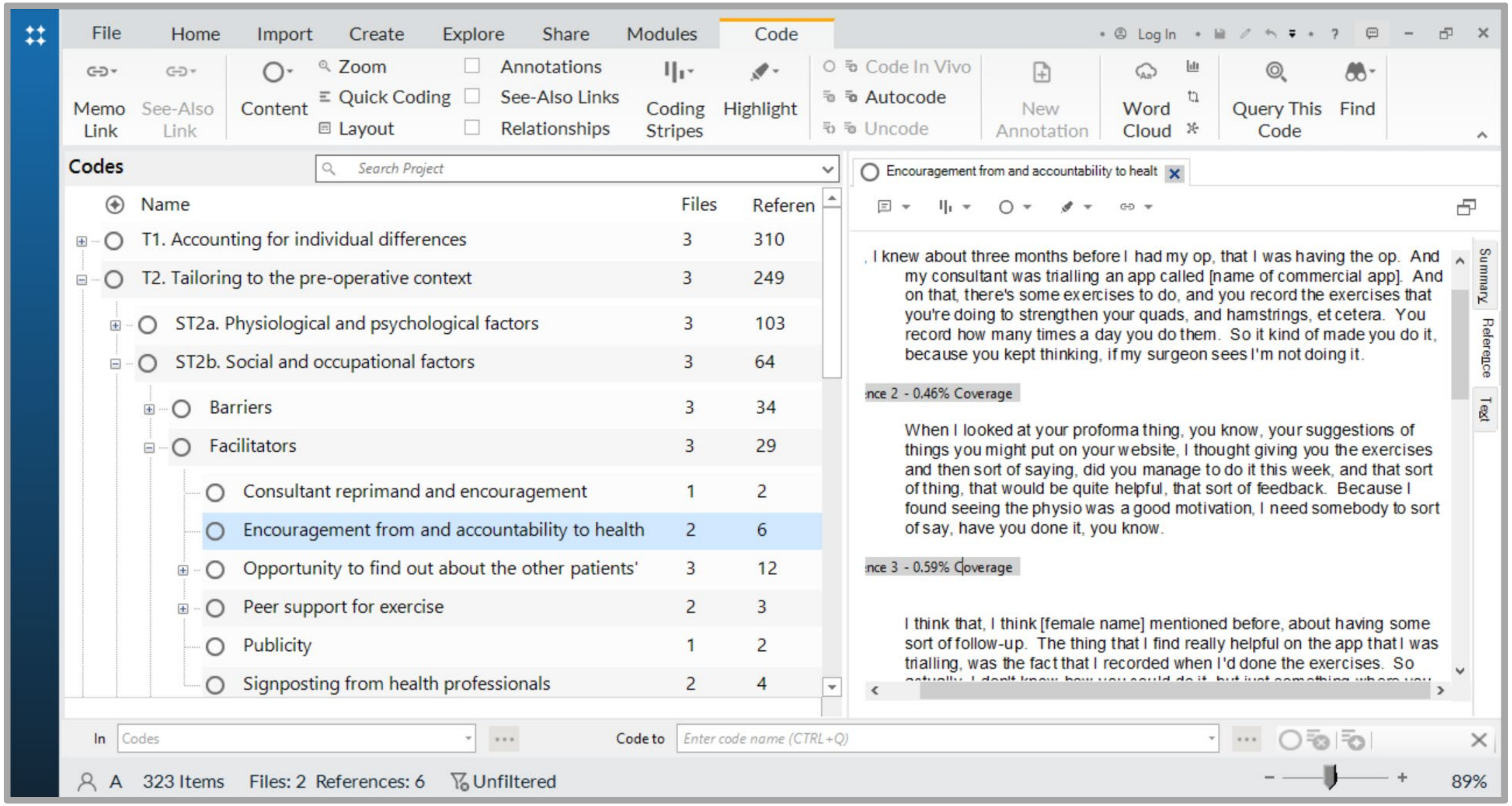
1. Is there anything else you would like to add?
2. What is your key take-home message from today?

Interview or Focus Group Closure

The facilitator(s) should complete all the following actions after the interview or focus group is completed

1. Thank the participant(s) for taking part in the interview or focus group
2. Remind the participant(s) about confidentiality
3. Ask the participant(s) to complete a travel expenses form if the interview or focus group took place at [recruitment site]

Appendix E: Example of the coding structure in the final Phase 2 NVivo file



Appendix F: Additional behaviour change techniques identified in the review by Safari et al. (2020)

Cluster[a]	Behaviour change technique[a]
1. Goals and planning	1.7 Review outcome goals
2. Feedback and monitoring	2.4 Self-monitoring of outcome(s) of behaviour
	2.6 Biofeedback
3. Social support	3.2 Social support (practical)
	3.3 Social support (emotional)
4. Shaping knowledge	4.2 Information about antecedents
5. Natural consequences	5.4 Monitoring of emotional consequences
	5.5 Anticipated regret
9. Comparison of outcomes	9.2 Pros and cons
11. Regulation	11.2 Reduce negative emotions
12. Antecedents	12.4 Distraction
15. Self-belief	15.4 Self-talk
16. Covert learning	16.2 Imaginary reward
	16.3 Vicarious consequences

[a] Clusters and behaviour change techniques are from the Behaviour Change Technique Taxonomy (v1) (226: Supplementary Table 3). The behaviour change techniques were identified in the systematic review of digital-based structured OA self-management programmes by Safari et al. (450) but were not employed in any of the potential VKS features.

Appendix G: Think-aloud interview topic guide

IRAS 262809; version 3.0, dated 04 Aug 2021

The following topic guide may be modified during the data collection phase so that themes identified in earlier interviews can be explored in later interviews. Each participant will complete two interviews. This topic guide will be used for both interviews. Consent will have been obtained online prior to the participant's first interview.

Interview Introduction

The interviewer should complete all the following actions prior to commencing the interview

1. Review the information provided in the Participant Information Sheet, including:
    - Aim of the study
    - Participant can withdraw at any time
    - Interview will be recorded with an encrypted mobile phone, laptop and/or secure video conferencing tool
    - Confidentiality
2. Explain the process for the interview, including:
    - Participant should say what they are thinking out loud as they work through the Virtual Knee School
    - Interviewer may ask prompt questions
    - Interview is not a test and there are no right or wrong answers
    - Interviewer cannot answer questions during the interview, but can discuss them at the end
    - Interviewer may ask the participant to access specific information/sections/pages of the Virtual Knee School
    - Once the participant has finished working through the Virtual Knee School, the interviewer will ask questions about the participant's overall views of the Virtual Knee School
3. Reiterate the Virtual Knee School is still in development and is not fully ready to be used
4. Offer the participant an opportunity to ask questions

Think-aloud Prompts

The interviewer may ask the participant any of the following prompt questions as the participant works through the Virtual Knee School. Each prompt may be used multiple times, if appropriate. The prompts may be adapted/expanded for clarity.

1. Can you tell me what you think about the <<insert website content>> on this page?
2. Can you tell me how you feel about using <<insert digital feature/activity/tool>>?
3. Can you tell me what you like about <<insert website content/digital feature/activity/tool>>?
4. Can you tell me what you DON'T like about <<insert website content/digital feature/activity/tool>>?
5. Can you tell me why you selected that?
6. Can you tell me about your overall views of this page?
7. Can you tell me what you are thinking at the moment?
8. Can you explain that a bit more?

Post-Think-aloud Prompts

1. What are your overall views of the Virtual Knee School?
2. Can you tell me about anything you particularly liked about the Virtual Knee School?
3. Can you tell me about anything you particularly DIDN'T like about the Virtual Knee School?
4. How do you think the Virtual Knee School could be improved?
5. Is there anything else you would like to add?

Interview closure

The interviewer should complete all the following actions after the interview is completed

1. Thank the participant for taking part in the interview
2. If the interview was the participant's first interview, confirm the plan for their second interview

3. Offer the participant an opportunity to ask questions
4. Complete the travel expenses form if the interview took place at [recruitment site]

Appendix H: Example of the coding structure in the final Phase 4 NVivo file