

Informed consent for third molar extraction; a comparison of conventional verbal consent versus video-assisted consent

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Declaration

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Buíochas ó chroí libh

Abstract

Background: The goal of the informed consent process is to provide patients with the necessary educational information, defend their autonomy, and allow active involvement in treatment planning and decision-making. The informed consent process must not only describe the operation in full, but also provide information on the procedure's rationale, alternative therapies, associated benefits, risks, and complications. However, the process of acquiring informed consent is fraught with issues.

Objective: This research aims to assess if presenting information about third molar extraction via an informative, narrated, animated video changes a patient's perception of the consent process for third molar extraction when compared to conventional verbal/written consent. The outcomes that are evaluated include patient understanding, patient satisfaction and patient anxiety.

Methods: In this posttest-only control clinical trial patients scheduled for surgical removal of an impacted mandibular third molar that fulfilled the predetermined criteria were invited to participate in the study. The criterion variable was the presentation of an animated information consent video. Participants were randomly assigned into 2 equal groups receiving either verbal consent or video-assisted consent. After signing the consent form patients then filled out an electronic questionnaire rating their experience of the consent process. At the postoperative review, 7-14 days after the procedure, patients were asked to fill out a questionnaire rating their experience of the consent retrospectively. The outcome variables were patients' self-reported level of understanding, patient anxiety measured on the Dental Anxiety Scale and patient satisfaction. The data were analysed with Pearson's chi-squared tests, Fisher's Exact test, and linear regression analysis.

Results: Ninety patients fulfilled the inclusion criteria and were included in the study. The video-assisted group reported higher levels of understanding of the proposed procedure ($P < 0.001$) and the associated risks/complications ($P < 0.004$). Patients were more satisfied with information delivered to them via video. 98% of patients in the video consent group felt that the video-assisted consent was beneficial. There was no statistically significant change in the reported level of anxiety when video-assisted consent was used.

Conclusion: The present study suggests that video-assisted consent may improve patients' level of understanding of the potential postoperative risks and complications involved in surgical removal of an impacted mandibular third molar. This improved understanding did not increase patients' dental anxiety compared with conventional verbal/written consent but improved patients' level of satisfaction with the amount of information that they received.

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LIST OF ABBREVIATIONS

<i>AHRQ</i>	Agency for Healthcare Research and Quality
<i>ASA</i>	American Society of Anaesthesiologists
<i>DAS</i>	Dental Anxiety Scale
<i>GMC</i>	General Medical Council UK
<i>HBM</i>	Health Belief Model
<i>LLC</i>	Limited Liability Company
<i>NICE</i>	National Institute for Clinical Excellence
<i>OPG</i>	Orthopantomogram
<i>OR</i>	Odds Ratio
<i>PRISMA</i>	Preferred Reporting Items for Systematic Reviews and Meta-analyses
<i>SD</i>	Standard Deviation
<i>SPSS</i>	Statistical Package for Social Sciences
<i>STAI</i>	Spielberger State-Trait Anxiety Inventory
<i>WHO</i>	World Health Organisation

INTRODUCTION

Informed consent is the legal process where the two-way communication between the patient and physician enables a competent patient to make an educated decision about a proposed medical intervention or procedure (1). The goal of the informed consent process is to provide the patient with the necessary educational information, defend their autonomy, and allow active involvement in treatment planning and decision-making. Informed consent involves, among other things, explaining to the patient the nature and aim of the therapy, its potential consequences and related potential dangers, as well as any potential alternative treatments (2, 3). The following three requirements must be met in order to acquire valid informed consent from a patient for medical or dental treatment; the patient must have the capacity to make a rational decision, the patient must give consent voluntarily and the patient must be fully informed prior to the procedure (4). Patients should be given information regarding their disease, including diagnosis, prognosis, and alternative therapies, both verbally and in writing. It is the clinicians responsibility to ensure that the patient is sufficiently informed and understands the information about the recommended treatment (5). Patients should feel confident that they understand what will happen to them, the advantages of the therapy, what may go wrong, and that all of their questions have been answered before they give consent. The patient also needs to be aware of the repercussions of not receiving treatment. This process requires that the patient be given appropriate information and adequate time to evaluate it.

Informed consent is necessary for everyday clinical practice for legal, ethical, and administrative reasons (5). The legal necessity of informed consent is well established, and it is a doctor's responsibility to "make a reasonable disclosure to his patient of the nature, likely consequences, and dangers of the proposed treatment," and that "any surgical operation without the patient's consent could be considered assault (6)." It is one of the most crucial aspects of the preoperative consultation, where the patient is provided with information on the intervention as well as a detailed description of the potential complications. Informed consent is critical in providing a legal defence against potential complications and unanticipated events that may occur during medical treatment (5, 7). In the context of health services, emphasis is increasingly being placed on patient involvement and satisfaction, with the ultimate aim of being receptive to patients'

apprehensions and to enhance their understanding. Consent - what you have a right to expect: a handbook for adults, a paper from the Department of Health, describes how to obtain consent (8). It encourages a patient-centred approach; this emphasises the value of clinical judgment in determining how much information to provide to each patient (9). One of the milestones in a doctor-patient relationship is obtaining valid informed consent. In essence, this procedure safeguards the patient's decision-making autonomy (10). The necessity of informed consent has been re-emphasised in recent years as a result of greater patient engagement in their medical treatment and a rise in malpractice claims. Despite this, the process of acquiring informed consent is fraught with issues.

The discipline of oral surgery is struggling to keep up with the ever-changing legal minefield that encompasses informed consent. Since 1957, clinicians have been legally obligated to obtain consent for a procedure (11). Since then, the guidelines have been incrementally tightened, with a focus on patient autonomy and shared decision-making. The ruling in *Montgomery v Lanarkshire Health Board* (12) created a shift from the standard of the reasonable professional (the Bolam test (13)), to that of the reasonable patient. It was alleged that in this case (12), a health professional had not disclosed sufficient information to meet the criteria of valid consent. This generated concern and confusion within the dental profession and there has not been sufficient subsequent cases to facilitate an examination of the changes that this case may bring to the way dentistry is provided. The lack of recent studies in this area highlights the need for further research to provide clarification on the “reasonable patient.”

Furthermore, in the benchmark case *Geoghegan v Harris* 2000 IEHC (14) where the plaintiff suffered chronic neuropathic pain after damage caused to a nerve supplying his chin area following a bone graft taken to facilitate the placement of a dental implant, it was concluded that in an elective procedure all known risks however remote, of grave consequences, or severe pain must be disclosed to the patient. In *Fitzpatrick v Eye and Ear Hospital* 2007 IESC (15), the Reasonable Patient Test (12) was employed stating the patient has a right to know and the practitioner has a duty to advise of all material risks associated with the proposed treatment. A risk is material if in the circumstances of the particular case, *“a reasonable person in the patient’s position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably*

be aware that the particular patient if warned of the risk, would be likely to attach significance to it (12).”

Further judicial guidance was issued in 2017 in the case of *Thefaut v Johnston* (16). While this case is about elective surgery, it could be relevant to other consent instances. The court's decision was based on substantial dangers, which were split into objective and subjective categories. The decision cautioned against using jargon or overly technical terminology when discussing the procedure's objective dangers. The judgement also emphasised that objective hazards cannot be reduced to a surgical consent form or a brochure with information on their condition.

Conversely, courts of law have held that medical physicians have a "therapeutic privilege" not to warn patients who may be damaged by the given information (17). This therapeutic privilege, however, should be utilised with caution in order to avoid undermining the concept of informed consent and patient autonomy. The information given to patients concerning the potential risks should not make them feel unnerved or excessively anxious.

The National Institute for Clinical Excellence (NICE) patient information booklet on third molars recommends that all patients having their mandibular third molars removed should be informed of the following sequelae and complications: pain, swelling, trismus, bleeding, infection, damage to other teeth and numbness of the lip, chin or tongue caused by temporary or permanent nerve injury (18). Although certain adverse effects (such as swelling and minor pain) occur in virtually every patient, problems such as a mandibular fracture or allergic reactions to the local anaesthetic are uncommon and are not included in the aforementioned list. As there is no gold standard, each physician must choose which side effects and problems to inform the patient about from a list of all known side effects and consequences (17).

According to the World Health Organisation (WHO), patients are increasingly being pushed to make health-care decisions for themselves or their family members (19). The prerequisite to provide an array of treatment options prior to the delivery of care has contributed to a shift in the role of the clinician from “doctor knows best” to a more reciprocal role. This leads to dilemmas for the practitioner about the parameters of informed consent and ethical concerns regarding how treatment options and risks are

presented. Guidance from the General Medical Council (GMC), the medical royal colleges, and medical defence bodies all now stipulate that consent should not only be informed but also personalised (20). Individual patients should be told what they want to know, not what professional opinion deems “appropriate and sufficient” for patients in general. This begs the question; how much information is enough? While there is no absolute guideline for how much information to disclose as part of the consent process, current Irish law states that the doctor must provide what a reasonable patient would want to know, as well as what that specific patient would want to know in light of their own values and interests (21). Resultantly, there is ambiguity about which risks a patient would like to be informed of and would attach significance to. As D'Cruz and Kaney (22) expressed: *“The requirement is that a dentist, in respect of consent, should tell the patient everything they want to know as well as everything the dentist thinks they might need to know. You might be forgiven for thinking that this has a mystic clairvoyant feel about it and you may not be far wrong”*. Therefore, there is a need for an appreciation of a patients' preferences for treatment, and to provide appropriate, valid and reliable methods of eliciting these through informed consent.

Obtaining valid informed consent is a critical, yet challenging, aspect of oral surgery, especially in the context of more complex procedures and multistage treatment plans. Although, much has been written on the process of informed consent and the frequency of individual complications (23), little is known about how much information the patient truly wishes to receive. There is no gold standard on the information that a patient should be informed about in order for their consent to be valid: there is also no legal prerequisite dictating the amount and quality of information that must be provided to a patient prior to third molar removal specifically. The Medical Council of Ireland recommends that for elective procedures *“comprehensive warning must be given in relation to a risk, however remote, of grave consequences involving severe pain into the future. If severe ongoing pain involving further operations is not one of the known complications, it is the responsibility of the doctor to inform the patient of a significant risk which would affect the judgement of a reasonable patient (21).”* Although the GMC advises clinicians to inform patients about "severe or frequently occurring risks" (20), there are no criteria for particular consequences that should be revealed. The quantity and amount of detail of the information on potential complications are left to the discretion of the individual doctor who is tasked with obtaining consent.

Research on how patients understand, perceive and process risk has important implications for self-determination in medical decision making (24) and the nature of informed consent. Although patients may claim to comprehend the advantages and risks of having their impacted third molars removed at the initial appointment, in court cases involving malpractice claims, individuals frequently deny that particular information was given to them. This creates two issues: 1) How much of the first information has been comprehended? 2) How much of the patient's information is maintained when there is a period of time between the first informed consent process and the surgical procedure. The salient work of Weinstein (25) in the 1980s introduced the concept that most patients show “*unrealistic optimism*” when reflecting on their personal risk and constantly underestimate it, believing that they are less at risk from a particular hazard than other people with similar characteristics or an “*average*” person. Thus, patients assume that messages about risk do not apply to them (25). The implication for health practitioners and individual clinical decision making is that communication about risk may fail because individuals presume they are invulnerable to risks. Reyna and Brainerd's Fuzzy-Trace Theory (24) insinuates that patients merely extricate the summary of any information and base their decision making upon this.

It has been demonstrated that patients who are given adequate information make better treatment decisions and are more satisfied with the treatment outcomes (26-28). Existing evidence on consent demonstrates that even after consultation and consent for treatment, a large number of patients do not fully comprehend or recollect the treatment options presented to them and the associated risks and benefits of each treatment option (29-34). Even though comprehensive reviews of the medical literature indicate that patients' understanding (35, 36) and recollection (36) of the information presented during the informed consent processes is generally poor, only a few empirical studies in dentistry (30, 31, 37) have considered these issues. Where the patient's comprehension is insufficient, the signed consent document merely represents a patient's acceptance of an incompletely understood procedure. A patient has not given informed consent if he or she signs a permission form without fully understanding the procedure, complications, and results. If the treatment outcome does not match the patient's expectations or problems arise without informed permission, physicians and healthcare providers may be prosecuted for violence or negligence (1, 38-40).

Furthermore, roughly half of the adult population in eight European countries have been reported to have poor health literacy abilities (41). "Health literacy is linked to literacy and entails people's knowledge, motivation and competencies to access, understand, appraise and apply health information in order to make judgments and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life during the life course" (42). The majority of research that looked at the link between health literacy and informed consent found that patients with low health literacy were less likely to engage in healthcare decision-making (43). According to a recent literature review, health-care consumers' literacy, along with other characteristics, is a significant indicator of a patient's ability to offer fully informed consent (36). According to this study, 21 to 86% of patients were able to recall the risks and problems associated with their medical treatment (36). Because most of the included studies used self-reported recollection, which is a flawed measure, this proportion could be even lower (44). To confound this problem further, many patients did not recognise their ability to change their minds and opt out of treatment following the informed consent process (31, 32). Recognition of individual autonomy should be viewed in the wider context of an emerging appreciation of basic human rights and human dignity which requires informed agreement to invasive treatment. These factors create a precarious position for the practitioner with the potential for significant legal ramifications.

According to the literature, much of the written material used in conventional informed consent forms is too complicated for patients to grasp (45, 46). Furthermore, McCarthy et al. (47) found that during consultations, physicians used considerably more complicated language than their patients, which might lead to ineffective communication for patients, particularly those with low literacy. Health practitioners are responsible for adapting to patients health literacy needs, for example, utilising different communication approaches (48) and video aids that take into consideration patients' health literacy, in order to change the circumstances of interactions with the patient(49). These adaptations have the potential to significantly enhance the informed consent process. Although some believe that full patient awareness is unachievable in informed consent, groups such as the American Medical Association, the Agency for Healthcare Research and Quality (AHRQ), and the National Quality Forum have advocated for changes in the process (50-52). Interventions

have been created and assessed, including improved consent forms, more textual information, better consent conversations, and the use of video technologies.

Among the various options for providing information to patients, the surgeon's most common method of conveying information is verbal communication. Previous research has found that patients' ability to recall the risks or consequences associated with surgery after it has been explained verbally is quite low (2, 4, 53). Other media, such as video content, patient information leaflets, or decision aids, have been characterised as a stand-alone or as a complement to the conventional spoken explanation (54). The most popular strategy for supplementing verbal information and improving retention of information given during the informed consent procedure is to provide written brochures (54). Previous research has demonstrated that using a printed information sheet to supplement verbal information improves information retention (55, 56). However, several studies found no difference between verbal and nonverbal strategies (57, 58). In the case of third molar extraction, a prior study found that adding textual content to the consent process increased patient understanding (59).

Sheridan et al. (60) performed a comprehensive evaluation of strategies aimed at reducing the negative impacts of low health literacy. They suggest that numerous health literacy approaches, such as integrating a video into the consent process might increase an individual's comprehension. A study on best practices and novel models of improving health literacy for informed consent (61) suggests that different tactics for simplifying written documents and clarifying verbal exchanges, as well as the use of multimedia formats and computerised exchanges, may alleviate constraints to communications required for informed consent.

The effectiveness of health literacy approaches aimed at improving the informed consent process has been studied (62-65). Kang et al. (64) used three distinct informed consent protocols to assess memory and comprehension of orthodontic informed consent among 90 pairs of children and their parents. Compared to an enhanced readability form or the normal informed consent form, a combination of increasing the readability of permission papers and using audio and visual cues during the informed consent procedure resulted in better recollection for the patients and better recall and comprehension for their parents. Smith et al. (65) compared a decision aid (booklet and DVD) particularly prepared for

people with limited reading abilities (N=357) to a conventional information booklet (N=173) on colon cancer screening in a randomised controlled experiment. They discovered that in the intervention group, the proportion of participants who made an educated decision was 22% higher than in the control group (34% versus 12%, P0.001). Matsuyama et al. (64) found that an education film co-designed by a patient health literacy expert increased patients' understanding of radiation therapy before they were requested to offer informed consent for the treatment (N=32). After seeing the film, respondents' mean number of accurate replies improved by 2.3 units in the 21-question survey (p0.0001; 95% confidence interval: 1.3-3.0). The authors observed that regardless of the participants' level of health literacy, the video intervention resulted in a considerable gain in knowledge.

The informed consent approach is often well received by patients (66-68). This satisfaction, on the other hand, is not correlated with the accuracy or comprehension of the information provided, but rather to the process itself (68). Additional information utilised to improve the patient's perceived knowledge and comprehension of the operation has been found to improve decision satisfaction but not the informed consent process itself (54).

Some additional issues with informed consent also arise. It can be difficult to accurately convey complicated medical information (69), and this can have a negative impact on patients (70). Obtaining informed permission has been shown to raise patients' anxiety (71, 72). Anxiety has been found to cause behavioural and physiological changes in patients. Physiological stress in response to an overly comprehensive informed consent form may hinder patients' capacity to completely absorb the information provided (72). Details and discussion of unfavourable outcomes, such as temporary or permanent sensory nerve injury may cause excessive stress and anxiety (73).

Dental anxiety is a complicated phenomenon that is influenced by a number of factors, including age, gender, educational level, financial situation, personal history, memory, and personality. Female gender, (74-77) young age, (78, 79) poor socioeconomic status, (79) and low education level have all been linked to elevated levels of anxiety (74, 76). According to studies, the third most anxiety-inducing element before surgery is a lack of knowledge regarding the surgical technique and the potential postoperative consequences. These outweigh the concern of experiencing discomfort throughout the procedure (80, 81).

Improving awareness about a surgical operation, including elements pertinent to recommended care and after recovery, has proven to be effective in controlling anxious patients and minimising situational anxiety (82, 83). Written materials have been utilised to effectively communicate information to surgical patients; however, not all patients are literate enough to read and comprehend a page of information (84). Although audio-visual information provision may have little or no effect on motivation to engage, they may improve knowledge or comprehension, leading to increased satisfaction (85). Some studies (86-88) found that providing patients with movies depicting the operations they will be undergoing reduced preoperative anxiety and boosted patient understanding; however, other studies (89, 90) found that these benefits were minimal. Conversely, some research has revealed contradictory outcomes with some studies reporting higher levels of preoperative anxiety following video consent (91, 92). As a result, the best method for providing preoperative information is unclear.

This research aims to assess if presenting information about third molar extraction via an informative, narrated, animated film improves the patient's satisfaction with and comprehension of the information from the consultation to the surgical intervention. The theory is that by utilising a video assisted consent, patients will be better equipped to comprehend crucial information about third molar extraction, be more satisfied with the amount of information provided and not have an associated increase in their levels of anxiety.

AIMS AND OBJECTIVES

This research aims to assess if presenting information about third molar extraction via an informative, narrated, animated video changes a patients' perception of risk associated with third molar extraction when compared to conventional verbal consent.

Primary research question

Does the use of video assisted consent for third molar extraction affect patient's self-reported level of understanding of the proposed procedure and the associated risks?

Secondary research questions

Does the use of video assisted consent for third molar extraction affect patient's self-reported level of anxiety about the proposed procedure and the associated risks?

Does the use of video assisted consent for third molar extraction affect patient's self-reported level of satisfaction with the consent process and the quality and quantity of information they receive about the proposed procedure and the associated risks?

Are certain patient demographics (age, sex, education level) more receptive to the use of video assisted consent for third molar extraction?

The null hypothesis

There will be no difference in patient's perception of the consent process, in the outcomes listed above, between the video-assisted consent (intervention) group and the verbal consent (control) group.

SCOPING REVIEW

Title

Informed consent for third molar extraction: a scoping review

Abstract

Background: Obtaining a valid informed consent is a critical, yet challenging, aspect of oral surgery which leads to dilemmas for the practitioner about the parameters of informed consent and ethical concerns regarding how treatment options and risks are presented.

Objective: To evaluate the existing research and literature on informed consent for third molar extraction.

Design: Original studies that investigated adult patients' perception/comprehension/response to the informed consent process for third molar extraction. The authors searched 3 electronic databases and assessed the risk of bias of the included studies via different validated tools in accordance with the study design.

Results: 18 studies were selected for inclusion: 5 randomised controlled trials, 8 cross-sectional studies, 4 cohort studies and 1 qualitative study. Methodologically, the studies were heterogeneous and the quality of the included studies varied significantly. 11 of the included studies evaluated patient recall following consent. 6 of the included studies evaluated the effect of informed consent on patient anxiety while the remaining study looked at patient satisfaction with regard to the consent process. 9 of the included studies used audio-visual aids as part of the informed consent process.

Conclusions: Patients undergoing third molar extraction do not consistently exhibit high levels of understanding or information recall following informed consent. The use of adjunctive audio-visual aids improves patient understanding and recall but is associated with higher levels of patient anxiety. Audio-visual aids should not replace oral informed consent but instead, they should complement and optimise the process.

Introduction

Rationale

Obtaining a valid informed consent is a critical, yet challenging, aspect of oral surgery which leads to dilemmas for the practitioner about the parameters of informed consent and ethical concerns regarding how treatment options and risks are presented.

To the authors' knowledge, no attempts have been made to synthesise evidence available on informed consent for third molar extraction. Therefore, this scoping review has been undertaken to systematically evaluate the available evidence regarding adult dental patients and the informed consent process for third molar extraction

Objectives

This scoping review aims to evaluate the existing research and literature on informed consent and third molar removal, intending to establish the following:

- To review what research, if any, has been conducted on informed consent for third molar procedures.
- To identify gaps in the literature that may highlight the need for further study.

Methods

Protocol and registration

The current review was reported in accordance with the Preferred Reporting Items for Scoping Reviews (PRISMA-ScR) guidelines (93).

Eligibility criteria

To be included in the review papers needed to meet the following criteria:

Inclusion criteria: The following inclusion criteria were applied:

- Original studies that investigated adult patients' perception/comprehension/response to third molar extraction information provided during informed consent processes.
- Studies that compare standard verbal and written informed consent processes with alternative methods of delivery of information, such as multimedia

- Studies that included an interaction between the dental professional and patient during the informed consent.
- Studies in English or translated to English

Exclusion criteria: The following exclusion criteria were applied:

- Studies in which the investigators analysed dental professionals' opinion concerning informed consent processes
- Studies that included patients with cognitive impairment
- Letters, reviews, and personal opinions.

Information sources

An electronic search was conducted (March 31, 2020) to identify literature reporting on informed consent in relation to third molar removal. The electronic search was performed in 3 online databases, MEDLINE (PubMed), Web of Science, and Cochrane Central Register of Controlled Trials. Detailed individual search strategies were used for each database.

Search

Searches were not restricted based on study type, subject size or date of publication. The following research keywords in English were used for MEDLINE(PubMed): ("Surgery, Oral"[Mesh] AND "Consent") and ("Molar, Third"[Mesh] AND " Consent"). The following research keywords in English were used for Web of Science, and Cochrane Central Register of Controlled Trials: ("Surgery, Oral" AND "Consent") ("Surgery, Maxillofacial" AND "Consent") ("Tooth, Wisdom" AND " Consent") ("Teeth, Wisdom" AND " Consent")and ("Molar, Third" AND " Consent").

Selection of sources of evidence

All references were imported using the Cochrane online systematic review management software; Covidence (94). All duplicate articles were removed. Two of the authors (C.M. and G.O'D.) independently screened the titles and abstracts for inclusion. Abstracts that met the inclusion criteria were selected for full-text review. In case of disagreement, the

study in doubt was also evaluated by a third reviewer (D.P.). Where abstracts did not offer enough information to include or exclude a study, the full-text article was obtained to support a final decision. Full-text articles were then reviewed for inclusion.

Data charting process

A data-charting form developed by the Cochrane online systematic review management software was used by the two reviewers to determine which variables to extract. The two reviewers individually input the data, discussed the results and updated the data-charting form in a continuous process.

Data items

The following data elements were extracted from each of the included studies; authors, year of publication, publication title, study design, methodology, sample size, outcomes of interest and conclusions (Table 1). One author (C.M.) collated all the data elements from each selected study. A second author (G.O'D) cross-checked the inputted information. Any disagreement that arose was resolved through discussion. The third author (D.P.) was involved when a consensus could not be made.

Critical appraisal of individual sources of evidence

The methodological and reporting quality of the included studies was rated using three separate risk of bias assessment tools: the Cochrane Collaboration's tool for the assessment of randomised studies (95), the National Heart, Lung, and Blood Institute tool for observational cohort and cross-sectional studies (96), and the Critical Appraisal Skills Programme tool (97). Two authors (C.M. and G.O'D.) independently assessed the risk of bias in each included study. The third reviewer (D.P.) resolved any disagreements if a final decision was not reached.

Synthesis of results

The studies were analysed, and a summary of the settings, populations and study designs for each group, along with the measures used, results and conclusions were recorded.

Results

Selection of sources of evidence:

The initial electronic data search identified 580 studies. One hundred and eighty-four duplicate studies were removed. The remaining 396 were screened and 368 studies were deemed irrelevant following title and abstract screening. Following a full-text screening of the remaining 28 studies, 10 studies were excluded as they did not meet the inclusion criteria. Ultimately, 18 articles were selected for final inclusion in the review (Figure 1).

Characteristics of sources of evidence:

A summary of the characteristics of and data elements extracted from the included studies is provided (Table 1).

Critical appraisal within sources of evidence:

Of the 18 articles selected for inclusion, 5 were randomised controlled trials, 8 were cross-sectional, 4 were cohort studies and 1 was a qualitative design. Of the included cross-sectional and cohort studies, only one study justified their sample size and none reported adjustment for confounding variables. Methodologically, the studies were heterogeneous and the quality of the included studies varied significantly (Tables A1-A4; Appendix A).

Study tool/methodology:

Among the 18 studies included in the review, 9 studies used audio-visual aids to aid informed consent processes. Of these 9 studies, 4 evaluated the effect of audio-visual aids on patient anxiety. Of the remaining 5 studies that used audio-visual aids, 4 of these studies evaluated patient recall and the remaining audio-visual study evaluated patient satisfaction

Of the 9 studies that did not use audio-visual aids, 5 studies simply evaluated patient recall following consent, 2 studies evaluated patient recall and the two-stage consent process. The final 2 studies evaluated the effect of consent on patient anxiety, with one study using a validated questionnaire and the other using physiological measures.

Figure 1: PRISMA Flowchart showing the results of the search process.

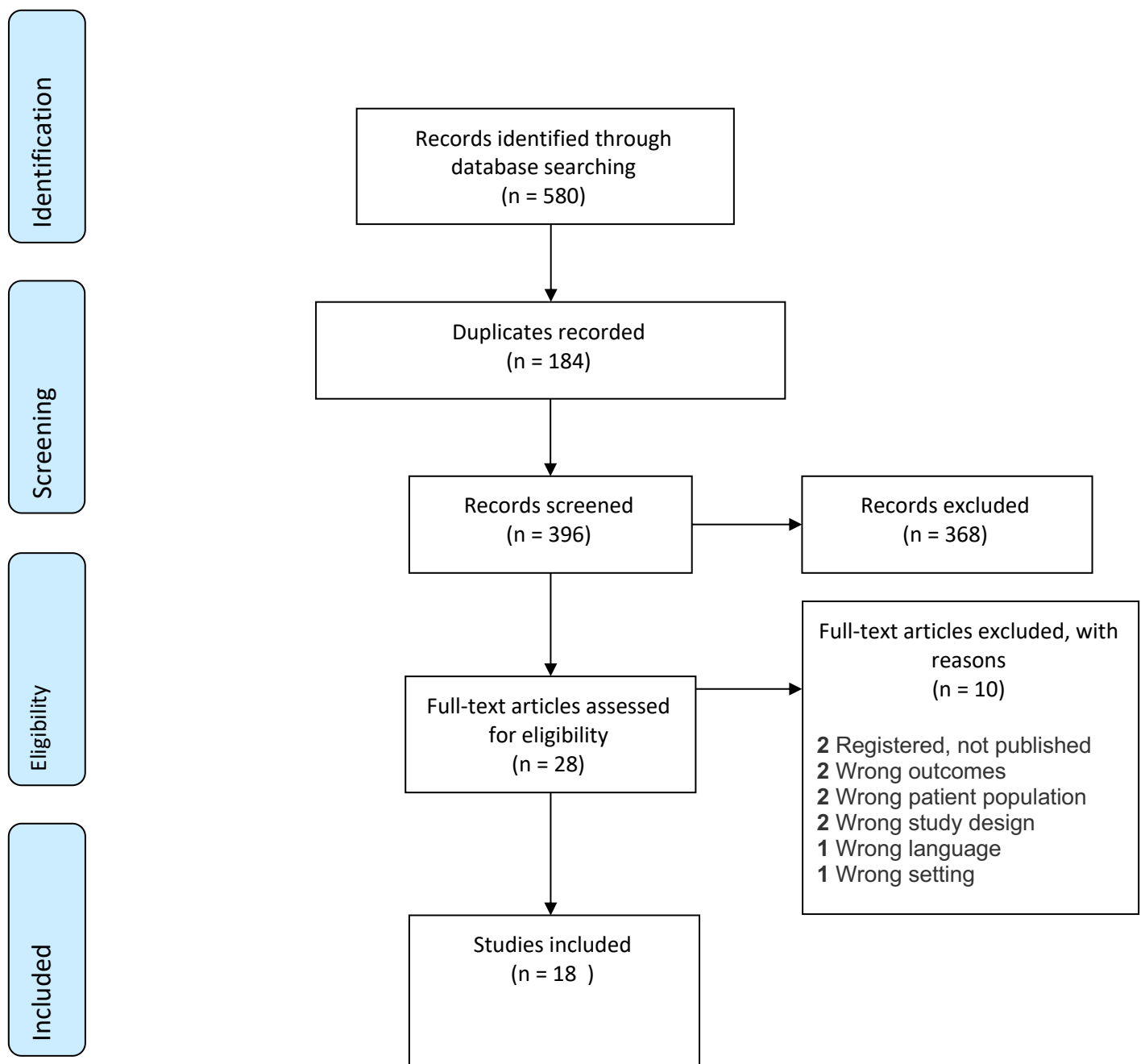


Table 1: Summary of characteristics of included studies.

STUDY	COUNTRY	STUDY DESIGN	STUDY TOOL/ METHODOLOGY	SAMPLE SIZE(N)	OUTCOMES	CONCLUSION
Ader and Colleagues, 1992 (98) <i>Information Seeking and Interactive Videodisc Preparation for Third Molar Extraction</i>	USA	RCT	A multiple choice quiz was given to patients following third molar consent to measure understanding	Total: n=60 Verbal consent only (n=25) Interactive video disk consent (n=18) Noninteractive video (n=17)	Quiz scores: Verbal consent only: 40% Interactive video disk: 72.6% Noninteractive videotape: 85%	Although the interactive disc group participants were less knowledgeable following consultation than the noninteractive tape group subjects, they were more satisfied with the amount of preparation than the noninteractive tape group.
Atchison and Colleagues, 2005 (99) <i>A Qualitative Report of Patient Problems and Postoperative Instructions</i>	USA	Qualitative	Focus groups were used to assess recall of complications discussed during informed consent	Total: n=34	20 of 34 patients remembered being given treatment risk information.	The rate of recall of complications discussed in informed consent varied between patients.

STUDY	COUNTRY	STUDY DESIGN	STUDY TOOL/ METHODOLOGY	SAMPLE SIZE(N)	OUTCOMES	CONCLUSION
Brosnam and Perry, 2009 (37) <i>"Informed" consent in adult patients: can we achieve a gold standard?</i>	UK	Cross-sectional	Questionnaires were given to patients following third molar consent to analyse their recall and understanding	Total: n=75 Questionnaires completed after consultation (n=53) Questionnaires completed on day of surgery (n=22)	Overall percentage of patients' awareness of complications: 69.5% Patients' awareness of the risk of complications: 87% knew about "all" or "some" of the risks. Information understood: 56% understood "all" of the information given to them	The desired standard in the informed consent was only partially met in most cases. However, most patients felt that the consent process had met their needs.
Casap and Colleagues, 2008 (100) <i>The Effect of Informed Consent on Stress Levels Associated With Extraction of Impacted Mandibular Third Molars</i>	Israel	Cohort study	Electrodermal activity (EDA) was measured before, during and after completion of the consent documents. Pulse and blood pressure were measured before and after completion of consent	Total: n=60 Control group for determination of basal EDA (n=20) Detailed informed consent (n=20) Simplified informed consent (n=20)	The relative changes in EDAs Detailed informed consent: Increase of 26% Simplified informed consent: increase of 15%	A detailed consent process is associated with increased changes in physiological parameters

STUDY	COUNTRY	STUDY DESIGN	STUDY TOOL/ METHODOLOGY	SAMPLE SIZE(N)	OUTCOMES	CONCLUSION
Choi and Colleagues, 2015 (87) <i>Effect of Audio- visual Treatment Information on Relieving Anxiety in Patients Undergoing Impacted Mandibular Third Molar Removal</i>	Korea	RCT	A postoperative questionnaire was given to patients 1 week post third molar removal assessing their recall of potential postoperative complications	Total: n=51 Written information leaflet and verbal explanation (n=26) Audio-visual informed consent (n=25)	Overall recall 1 week post op: Written information leaflet and verbal explanation 20.19% Audio-visual group: 30%	The audio-visual slide presentation reduced anxiety and improved patient knowledge of the potential postoperative complications involved in surgical extraction of an impacted mandibular third molar.
Ferrus-Torres and Colleagues, 2011 (101) <i>Informed Consent in Oral Surgery: The Value of Written Information</i>	Spain	Cross-sectional	An anxiety test and a questionnaire to assess recall was given to patients following consent. 1 week postoperative patients were interviewed	Total: n= 87	Recall of complications Changes in sensation of lower lip and chin (98%, n = 85) and of the tongue (86%, n = 75) were among the complications most recalled by the patients.	Patients did not remember the majority of the information they received before giving informed consent

STUDY	COUNTRY	STUDY DESIGN	STUDY TOOL/ METHODOLOGY	SAMPLE SIZE(N)	OUTCOMES	CONCLUSION
Gocmen and Colleagues, 2017 (102) Impact of informed consent on patient decision regarding third molar removal (2017)	Turkey	Cross-sectional	Patients were asked to complete Spielberger State-Trait Anxiety Inventory (STAI) before and after consent. The information was given in different orders for group A+B	Total: n=171 Group A (n= 85) Group B (n=86)	There were no significant differences in the anxiety scores of groups A and B.	Increased anxiety was not associated with the order in which information was presented in the informed consent form.
Kazancioglu and Colleagues, 2015 (91) <i>Does watching a video on third molar surgery increase patients' anxiety level?</i>	Turkey	Cross-sectional	Patients were asked to complete Dental Anxiety Scale (DAS) and Spielberger State-Trait Anxiety Inventory (STAI) before and after consent procedure	Total: n=300 Basic information given verbally (n=95) Basic information given verbally and through video (n=102) Information given verbally with no information on operative procedure and recovery (n=103)	The patients that were given information via video were significantly more anxious before the surgical procedure. The age, surgery time and education level were not correlated with anxiety or pain levels. However, female patients had higher levels of anxiety than the male patients.	Pre-operative multimedia information increases the anxiety of patients undergoing third molar surgery.

STUDY	COUNTRY	STUDY DESIGN	STUDY TOOL/ METHODOLOGY	SAMPLE SIZE(N)	OUTCOMES	CONCLUSION
Laskin, 2020 (103) <i>Patients' Preference for Receiving Informed Consent Information Regarding Third Molar Surgery</i>	USA	Cross-sectional	A questionnaire was given to patients following third molar consent with video and verbal consent	Total: n=50	Verbal consent: 78%: very helpful 22%: moderately helpful Video: 66%: very informative 30%: moderately informative 3%: slightly informative Participants that preferred video: 62% Patients that preferred verbal consent: 38%	There was no clear consensus among patients regarding the best format to receive information. Therefore, providing both a video and an oral presentation is suggested
Laskin and Colleagues, 2018 (104) <i>Does Viewing a Third Molar Informed Consent Video Decrease Patients' Anxiety?</i>	USA	Cohort	Participants completed a form to grade their anxiety before and after viewing an informational video about third molar teeth, risks of surgical removal and post-operative side effects	Total n=100	Viewing the video: Did not change the anxiety level: 57% Increased anxiety level: 31% Decreased anxiety level: 12%	Viewing the video increased or did not reduce the anxiety level in a significant number of patients. Therefore, it is important to complement this video with positive verbal and written reinforcement regarding patient comfort, procedural safety, and adequate pain control.

STUDY	COUNTRY	STUDY DESIGN	STUDY TOOL/ METHODOLOGY	SAMPLE SIZE(N)	OUTCOMES	CONCLUSION
Layton and Korsen, 1994 (2) <i>Informed consent in oral and maxillofacial surgery: a study of the value of written warnings</i>	UK	Cross-sectional	Structured open ended questions were used to interview patients following consent	Total: n=94 Preadmission group (n=51) Consent on day of surgery (n=43)	Total overall of patients' recall (with or without prompting): W+V : 93.6% V only: 85.6% Overall patients with no recall: W+V: 6.4% V only: 14.4% Overall patients with no recall in the W+V group: Group A (n 51): 4.7% Group B (n 43): 9.3%	Written preoperative information improved the quality of the informed consent process.
Layton, 1992 (4) <i>Informed consent in oral and maxillofacial surgery: a study of its efficacy</i>	UK	Cross-sectional	Structured interviews were conducted to assess warnings most commonly recalled by patients approximately 12 days post-operatively	N=100 Consent obtained at preadmission group (n =49): Consent obtained on admission group (n =51):	Overall patients' recall: All complications (prompted + unprompted): 61% Unprompted: 35.8% Prompted: 49.8% Total recall: 85.6% Total overall of patients with no recall: 14.4% Overall percentage of patients with no recall and timing of consent: Preadmission group: 17.2% On admission group:11.6%	There was no difference in patients' recall of information, whether the information was given at a preadmission clinic or on admission.

STUDY	COUNTRY	STUDY DESIGN	STUDY TOOL/ METHODOLOGY	SAMPLE SIZE(N)	OUTCOMES	CONCLUSION
O'Neill and Colleagues, 1996 (59) <i>The use of an information leaflet for patients undergoing wisdom tooth removal</i>	UK	RCT	A knowledge questionnaire was given to patients at the initial exam and again 2 weeks later prior to surgery.	Total: n=60 Consent, Third Molar Leaflet and prompt (n=16) Consent, Third Molar Leaflet, no prompt, (n=18) Consents and Oral health leaflet (n=16) Consent only (n=6)	% increase in knowledge post intervention Leaflet and prompt group: 3.8% Third Molar Leaflet group: 3% Consents and Oral health leaflet: 0.2% Consent only: 0.4%	A third molar information leaflet resulted in improved understanding in patients undergoing third-molar extraction.
Olsen and Colleagues, 2017 (105) <i>Patient Recall of Information on a Third Molar Informed Consent Video</i>	USA	Cohort	A questionnaire assessing patient recall was given to participants following video and verbal consent for third molar removal at initial consultation and again, on the day of surgery	Total: n=100 Private practice (n=50) Dental Hospital (n=50)	There was a significant difference in the number of correct responses between the 2 time points ($P = .0212$) and between patients from the 2 practice settings ($P = .0076$). The number of correct responses was not associated with age ($P = .1203$), gender ($P = .6647$), or number of days between testing ($P = .7272$)	Patients had good recall of the information provided by the informed consent video. However, because some information was forgotten, a presurgical review of the information is advisable

STUDY	COUNTRY	STUDY DESIGN	STUDY TOOL/ METHODOLOGY	SAMPLE SIZE(N)	OUTCOMES	CONCLUSION
Omezli and Colleagues, 2020 (106) <i>Does Watching Videos Increase the Perioperative Anxiety in Patients Undergoing Third Molar Surgery?</i>	Turkey	RCT	Patients were given 3 questionnaires to assess anxiety 1 week before wisdom tooth removal and again, after giving consent.	Total: n=113 Verbal consent (n=56) Video plus verbal consent (n=57)	The video plus verbal consent group had higher anxiety scores than the verbal consent only group immediately after the consent process (P < .05)	The verbal and written consent format resulted in satisfactory anxiety management.
Shakir and Colleagues, 2019 (107) <i>What information do patients recall from the third molar surgical consultation?</i>	USA	Cohort Study	An exam assessing patient recall was given to participants following an educational video and verbal consent for third molar removal at initial consultation. A subgroup completed the exam again 2 weeks later	Total: n=100 Completed the examination at consultation (n=100) Completed the examination for a second time 2 weeks later (n=44)	Correct responses ranged from 64% to 100% following consultation and from 37% to 100% for those that were re-examined 2 weeks later .	Patient comprehension and retention of pertinent pre-surgical information is poor, despite the use of an educational video to supplement the customary verbal consultation.

STUDY	COUNTRY	STUDY DESIGN	STUDY TOOL/ METHODOLOGY	SAMPLE SIZE(N)	OUTCOMES	CONCLUSION
Torres-Lagares and Colleagues, 2014 (92) <i>The effects of informed consent format on preoperative anxiety in patients undergoing inferior third molar surgery</i>	Spain	Cross-sectional	Patients were interviewed about their anxiety level post consent and asked if the consent process had any effect on their state of anxiety	Total: n=91 Written consent (n=31) Oral interview consent (n=30) Video recording consent (n=30)	Effect of informed consent of patient anxiety (on a scale of -3 to +3) Written consent: 0.29±0.97 Oral interview consent: 0.97±1.21 Video recording consent: 0.57±1.43	Both the oral and written formats of informed consent information relieved the patients to some extent. Conversely, the video recording increased patient's anxiety in a statistically significant manner.
Yusoff and Colleagues, 2019 (108) <i>Recall of Complications and Satisfaction of Consent in Mandibular Third Molar Surgery</i>	Malaysia	RCT	Recall of complications were assessed at 1. First consultation 2. Preoperatively 3. One week post operatively	Total: n=120 Verbal (n=60) Written-Verbal (n=60)	There was no statistically significant difference in the recall rate between the verbal compared to written-verbal group in all three phases.	The current practice of obtaining informed consent with verbal intervention is equivalent to the verbal and written intervention.

Risk of bias within studies: The methodological and reporting quality of randomised studies (Table 2) was found to be *Low Risk of Bias* or *High Quality* in only 2 of the included studies. 6 of the included studies were *Moderate Risk of Bias* or *Fair Quality*. Of the remaining 10 studies, 1 were *High Risk of Bias*, 6 were found to be of *Poor Quality* and the remaining 3 studies had an *Unclear Risk of Bias*. Of the included cross-sectional and cohort studies, only one study justified their sample size and none reported adjustment for confounding variables. Methodologically, the studies were heterogeneous and the quality of the included studies varied significantly (Tables A1-A4; Appendix A).

Table 2: Risk of bias assessment of included studies.

STUDY	STUDY DESIGN	RISK OF BIAS OR QUALITY
Ader and Colleagues (98), 1992	RCT	High risk of bias
Atchison and Colleagues (99), 2005	Qualitative	Moderate risk of bias
Brosnam and Perry (37), 2009	Cross-sectional	Poor quality
Casap and Colleagues (100), 2008	Cohort study	Poor quality
Choi and Colleagues (87), 2015	RCT	Unclear risk of bias
Ferrus-Torres and Colleagues (101), 2011	Cross-sectional	Poor quality
Gocmen and Colleagues (102), 2017	Cross-sectional	Poor quality
Kazancioglu and Colleagues (91), 2015	Cross-sectional	Good quality
Laskin (103), 2020	Cross-sectional	Fair quality
Laskin and Colleagues (104), 2018	Cohort	Fair quality
Layton and Korsen (2), 1994	Cross-sectional	Poor quality
Layton (4), 1992	Cross-sectional	Poor quality
O'Neill and Colleagues (59), 1996	RCT	Unclear risk of bias
Olsen and Colleagues (105), 2017	Cohort	Fair quality
Omezli and Colleagues (106), 2020	RCT	Unclear risk of bias
Shakir and Colleagues (107), 2019	Cohort Study	Fair quality
Torres-Lagares and Colleagues (92), 2014	Cross-sectional	Fair quality
Yusoff and Colleagues (108), 2019	RCT	Low risk of bias

Synthesis of results

Recall: Patient comprehension or recall was investigated in 11 of the included studies (2, 4, 37, 59, 87, 98, 99, 101, 105, 107, 108). 7 of the 11 aforementioned studies assessed recall by means of conventional professional-patient informed consent without the use of audio-visual aids. Patient understanding in these studies ranged from 40% to 81% (59, 98, 99, 101, 105, 107, 108) and recollection varied from 20% to 86% (2, 4, 87). When audio-visual aids were used as an adjunct to conventional verbal informed consent, recollection fluctuated between 30% to 90% (87, 98, 105, 107). All studies that used adjunctive aids, such as written leaflets or audio-visual aids, had better rates of patient understanding and comprehension (2, 59, 87, 98, 105, 107).

Anxiety: 8 of the included studies (87, 91, 92, 98, 100, 102, 104, 106) aimed to assess the effect of informed consent on patient anxiety. 6 of these studies (87, 91, 92, 98, 104, 106) used audio-visual adjunctive aids during the informed consent process. When audio-visual aids were used as an adjunct to conventional verbal informed consent, anxiety measured by the Dental Anxiety Scale (DAS) ranged between 9.48-16.11 (87, 91, 106) and 33.7-48.5 (91, 98, 106) on the Spielberger State Anxiety Inventory (STAI-S). Conversely, where conventional verbal informed consent without audio-visual aids was assessed, the anxiety measured by the Dental Anxiety Scale (DAS) ranged between 8.26-11.34 (87, 91, 106) and 33.5- 43.3 (91, 98, 106) on the Spielberger State Anxiety Inventory (STAI-S).

Patient satisfaction: 4 of the included studies (59, 98, 103, 108) assessed patient satisfaction with the informed consent process. Satisfaction ratings for verbal consent with or without written leaflets ranged from 66.7% to 97.5% (59, 103, 108), while satisfaction ratings for verbal consent with audio-visual aids ranged from 66%-81% (98, 103).

However, 62% of patients felt that the audio-visual presentation provided them with better information versus 38% that preferred the oral presentation (103).

Additional analysis: The data extracted from the included studies were notably heterogeneous. Therefore, a meta-analysis was deemed inappropriate.

Discussion

Summary of evidence:

Informed consent is an essential part of the patient journey and their autonomous decision-making process. Equally, it plays a central role in a dental professional's defence against litigation, but, it doesn't always negate liability in the constantly evolving legal landscape. The aim of this systematic review was to identify and evaluate the evidence available on adult dental patients and the informed consent process for third molar extraction.

Eighteen studies were included for review in this article. The reported evidence is of limited strength, with the majority of the studies being of poor or unclear quality and demonstrating high risk of bias. A wide variety of study designs were included in the review: randomised control trials, qualitative studies, cross-sectional studies and cohort studies. This allowed for a broader insight into the reported results, but the heterogeneity with respect to study design meant that a meta-analysis was not appropriate.

The evidence that is available on patient comprehension is limited. It suggests that a patient's understanding or recollection of the information relayed during the informed consent process for third molar extraction is variable and often insufficient to meet the threshold of informed consent. This was more prevalent where consent was given verbally

only. In many of the included studies “recollection” of information was equated to “comprehension” of information. This was deemed as a study flaw, as they are not interchangeable. Recollection is an exercise of memorisation; it may play a part in understanding, but recollection alone, without understanding, is not pertinent to the informed consent process.

The included studies suggest that the adjunctive use of multimedia, via interactive or non-interactive audio-visual presentations, optimised the informed consent process. These aids produce better results for recall and recollection than conventional methods with verbal explanation (87, 98). However, both the means by which the participants received the information and the participant knowledge assessment methodology, demonstrated substantial heterogeneity between studies. Although the included studies that investigated the use of audio-visual presentations were not free of bias, and none employed validated questionnaires, the findings consistently showed a higher level of recall (87, 98).

One study (4) used recollection of information as a method of evaluating the participants’ understanding of the information given during the process of third molar consent. It was found that only 61% of participants, after being prompted, recalled/recollected all of the risks and complications of which they had been informed. This finding raises concerns about the feasibility of dentists to sufficiently fulfil the ‘legal obligation’, to carry out their duty of care, in addition to satisfying the professional standards, by verbally obtaining informed consent, yet still not upholding the spirit of the law in conveying every material risk.

Olsen et al. (105) assessed the value of informed consent videos in participants’ understanding and retention of information. The results of their study endorsed the effectiveness of the audio-visual aids in imparting information to participants, in tandem

with a verbal discussion with the dental professional. However, the questionnaire used in the study consisted of true-false type questions, thus facilitating correct answers through guesswork on the part of the participant. The questions were subjectively simple and the participants were given information verbally, audio-visually and in writing. Nonetheless, Olsen et al. (105) found that the retention of information was suboptimal despite the use of adjunctive aids.

The efficacy of information transmission techniques has been found to be contingent on the attitude of the patient (109, 110). Patients can be classified as “vigilant” or “avoidant” (109, 110). Vigilant patients overcome stressful situations by educating themselves and gaining the maximum amount of information (109, 110). For these patients, the informed consent process reassures them and the anxiety of “the unknown” is reduced. Ferrús-Torres et al. (101) found that 59% of participants thought that the information that they received during informed consent was necessary for the decision-making process. Conversely, avoidant patients experience the informed consent process in a negative light and reject any information about the procedure. They overcome anxiety by staying oblivious and not ruminating about the problem. This may account for the inconsistencies in recall rates in the included studies. It may also suggest a rationale for outliers that could not recall any of the risks explained or the informed consent process itself. Other explanations include the patient that may be adamant that they want the surgery regardless of the risks, as is the case in patients with incessantly symptomatic third molars. This demographic of patients are less likely to seek information in any form about complications, as they remove their own choice from the informed consent process (111).

Torres-Lagares et al. (92) reported that the use of audio-visual aids for conveying information increased patient anxiety and provided no advantages for patients over

conventional consent. Audio-visual presentations showcasing elements of the surgical procedure, including the incision of the gingiva and bone removal, would invoke fear and anxiety. The benefit of increased knowledge gained might be offset by the increase in patient anxiety. Omezli et al. (106) suggested that audio-visual presentations in an animated format might alleviate the increase in patient anxiety.

Kazancioglu et al. (91) found that the utilisation of audio-visual aids in third molar extraction informed consent caused an increased level of anxiety in patients during the preoperative and postoperative periods. Conversely, Choi et al. (87) reported that the self-reported anxiety levels of participants who received audio-visual informed consent were lower following the surgery than those that received conventional consent. The authors hypothesised whether the diminished ambiguity of the procedure decreased the participants' anxiety. Ader et al. (98) found that participants were not anxious before or after watching a third molar information audio-visual presentation when viewed at the consultation visit. Hence, it is difficult to determine whether the video itself increases patient anxiety or if the anticipation and imminence of surgery plays a role.

Furthermore, the question arises whether an increase in self-reported anxiety can be interpreted as the patient understanding the consequence and the gravity of that consequence. In healthcare, accurate patient risk perception is fundamental to the provision of good quality care. Often within oral surgery, and in the general population, risk is associated with negative connotations, and there is a reluctance to engage with this topic. However, it is imperative to acknowledge that risk is not exclusively an undesirable concept; it is crucial to the legal process of informed consent and the patients' decision-making process.

Although the audio-visual consent process was largely considered more anxiety-provoking, participants were receptive to them. Participants reported higher satisfaction over conventional consent when audio-visual aids were used (98, 103). Laskin et al. (103) found that 62% of patients found that the audio-visual format provided the best information. Of those that preferred the video presentation, the average age of the participants was lower, and the educational level was generally higher. However, when asked about the helpfulness of the information sources, 66% found the audio-visual presentation helpful, while 62% found the verbal explanation helpful. This highlights that the use of audio-visual aids should not replace verbal informed consent but instead, it should complement and optimise the process.

Laskin et al. (103) found that 48% of the participants included in their study had access to the internet, with 34% of them accessing the internet for additional information about their procedure. Kazancioglu et al. (91) and Omezli et al. (106) stated anecdotally, based on their clinical experience, that participants that had accessed third molar information on a website before the surgical procedure were more anxious. Brosnam and Perry (37) reported that 9% of participants would like access to a website that provides the information given during the informed consent process in order to improve their understanding of complications. Higher education levels are significant predictors for pre-consultation online information-seeking (112). However, online information seeking is not associated with higher levels of third molar knowledge (112). As the internet contains a considerable amount of misinformation (113), dental professionals should direct their patients towards accurate, high-quality sites, as this may become an integral part of their understanding of the risks and benefits inherent in informed consent.

The possibility of acquiescence bias is a major concern within the included studies. While the majority of participants reported that they had understood the information, this was not the case when their knowledge was assessed objectively. This is an important finding when considering the informed consent process, as patients may falsely claim to be fully informed. This is particularly significant in consent for elective procedures where a patient may not be able to comprehend risks and weigh up all the information to make an informed decision. In fact, a lack of higher education has been associated with patients not recognising their right to refuse surgery. Ferrús-Torres et al. (101) reported that 16% of participants in their study thought that they could not refuse surgery, with 93% of these patients having only completed primary or secondary education. In these situations, patients may blindly agree to the professional recommendation with a greater risk of postoperative regret or dissatisfaction.

Many of the studies on consent for third molar extraction are based on the ability of a patient to recall a complication or a risk. There is a deficit of studies addressing patients' understanding of the qualitative nature or severity of outcomes and whether patients reflect on how it will alter their health and functional status/quality of life both in the present and in the future. While many of the studies included measured recall, none of them determined how the patient may view that information qualitatively. There is a lack of reported research examining how fully people understand the qualitative nature of risks. More research is needed to explore the factors that influence patients' understanding of the nature of risks as opposed to their ability to recall information. Risk perception is based on many different assumptions and experiences, and it is important to try to understand these. A systematic and rigorous approach to the delivery of information and shared decision making with patients is required to enhance the quality of patients' care. Therefore, it is of

paramount importance that dental professionals endeavour to tailor the informed consent process to the individual patient, so the quality of patients' dental care is enhanced and the patient can make a fully informed decision.

Conclusion

According to the current literature, adult dental patients undergoing third molar extraction do not consistently exhibit sufficient levels of understanding or information recall following the informed consent process. Conversely, patients generally believe that they have a good understanding of the information. This systematic review found that a direct improvement in understanding and recall capabilities among adult dental patients was observed when adjunctive audio-visual aids were used. Although a higher level of anxiety resulted from the audio-visual aids, patients reported higher satisfaction when they were utilised. Audio-visual aids should not replace verbal informed consent but instead, they should complement and optimise the process.

METHODOLOGY

Research Design

A single-blinded posttest-only control group trial comparing conventional verbal consent and video-assisted consent for third molar removal and their effect on the patient's level of understanding, anxiety, and satisfaction was conducted. The study followed the Helsinki Declaration's guidelines (114). The approval of the Local Ethical Committee was gained (Appendix B).

Patients attending the Dublin Dental University Hospital for mandibular third molar extraction from June 2020 to April 2022 were invited to participate in the study on the day of their proposed procedure and were given a patient information leaflet about the proposed research (Appendix C). Following an explanation of the study's goal, each patient was asked if he or she would like to participate. The participants were made aware that participation was completely voluntary and that there would not be any incentives and/or compensation (financial or otherwise) offered to participants. The patients that agreed to participate in the study consented to participate as per the ethical approval requirement (Appendix B). There were no vested interests. The consent form included the name and contact details of the researcher, the reason for conducting the survey and the intended usage of the collected data (Figure 2a and 2b). Respondents were informed that they could withdraw from the study at any point without any repercussions.

All patients that participated in the study had previously been assessed by a consultant and a specialist registrar, or a non-consultant hospital doctor in an outpatient clinic. When surgical extraction was agreed to be the appropriate surgical intervention for the patient's third molars, the patients were offered the choice of a local anaesthetic alone, a local anaesthetic with intravenous sedation, or a general anaesthetic. The procedure was outlined to the patient, along with the potential sequelae, side effects and consequences. If the patient agreed to proceed with the proposed treatment, they were given a patient information sheet that described the same potential sequelae, side effects and consequences in layman's terms to help them assimilate the information (Figure D1 and D2; Appendix D). Patients were asked to sign a copy of the patient information leaflet

indicating that they had read and understood the possible dangers and they were given a copy of this patient information leaflet to take home.

Figure 2a: Consent form for participation in the study

 Trinity College Dublin Coláiste na Tríonóide, Baile Átha Cliath The University of Dublin	
STUDY NAME: Patients' perception of risk associated with wisdom tooth extraction; a comparison of conventional oral consent versus video/website-assisted consent. Centre ID: Identification Number for study:	
Consent Form	
There are 2 sections in this form. Each section has a statement and asks you to initial if you agree. The end of this form is for the researchers to complete. Please ask <u>any</u> questions you may have when reading each of the statements. Thank you for participating. Please <u>Initial</u> the box if you agree with the statement. Please feel free to ask questions if there is something you do not understand.	
General	Tick box
I confirm I have read and understood the Information Leaflet for the above study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	
I understand that this study is entirely voluntary , and if I decide that I do not want to take part, I can stop taking part in this study at any time without giving a reason. I understand that deciding not to take part will not affect my future medical care.	
I understand that my dental notes and records may be looked at by my dentist at Dublin Dental University Hospital where it is relevant to the research. I agree that these individuals can access my records. I understand that all information will be kept private and confidential and that my name will not be disclosed.	
I understand that I will not be paid for taking part in this study .	
I know how to contact the research team if I need to.	

Figure 2b: Consent form for participation in the study

I agree to take part in this research study having been fully informed of the risks, benefits and alternatives which are set out in full in the information leaflet which I have been provided with.	
I agree to being contacted by researchers by email/phone as part of this research study	
Data processing	Tick box
I understand that personal information about me, including the transfer of this personal information about me outside of the EU, will be protected in accordance with the General Data Protection Regulation.	
[I understand that there are no direct benefits to me from participating in this study. I understand that results from analysis of my personal information will not be given to me].	
I understand that I can stop taking part in this study at any time without giving a reason and this will not affect my future medical care.	

Patient Name (Block Capitals)	Patient Signature	Date
-------------------------------	-------------------	------

Witness Name (Block Capitals)	Witness Signature	Date
-------------------------------	-------------------	------

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a way that they could understand. I have explained the risks and possible benefits involved. I have invited them to ask questions on any aspect of the study that concerned them.

I have given a copy of the information leaflet and consent form to the participant with contacts of the study team

Researcher name Ciara Mulvihill

Title and qualifications Dr Ciara Mulvihill BDS, MJDF, FFD (OSOM|)

Signature

Date

| | ||

3 copies to be made: 1 for patient, 1 for PI and 1 for hospital records.

Inclusion criteria

Patients attending the Dublin Dental University Hospital for mandibular third molar extraction who met the following criteria were included in the study:

- Patients that were sixteen years and older
- Patients that were diagnosed with a mandibular third molar that required surgical extraction.
- Patients that were deemed medically fit to undergo a surgical procedure i.e. healthy or well-controlled systemic disease (American Society of Anaesthesiology classification I or II.)
- Patients that were adequately able to understand/read and speak the English language.

Exclusion criteria

Patients attending the Dublin Dental University Hospital for mandibular third molar extraction who met the following criteria were excluded from the study:

- Patients with cognitive impairment, significant psychiatric ailments or who lacked the capacity to provide consent.
- Patients with an inability to adequately understand, speak and read the English language.
- Patients that had a previous mandibular third molar extraction.
- Patients having additional surgical procedures (i.e. treatment of a cyst)

Questionnaire Design

The Health Belief Model (HBM) (115) was used to aid in the composition of the patient survey used to carry out a pilot study on patients' perception of risk prior to third molar removal at Cork University Dental School and Hospital. This psychological model is widely accepted and is used to explain and predict health behaviours (116, 117).

The HBM (115) consists of four dimensions:

1. Perceived susceptibility: the subjective perception of risk or vulnerability to a health threat
2. Perceived severity: an individual's perception of the seriousness of the threat involved
3. Perceived benefits: efficacy of an action designed to prevent or reduce the threat of an illness
4. Perceived barriers: assessment of the negative consequences of undertaking the action.

The HBM (115) also addressed the “cue to action” to start the process to undergo the proposed procedure. The “cue to action” may be classed as internal (ie. pain, infection decay) or external (the belief that third molars will cause crowding, belief that third molars should be removed prophylactically). According to the HBM (116), the perceived barriers most frequently influenced health-related behaviour, followed by perceived susceptibility, benefits, and severity. The susceptibility and severity components trigger the patient to act, while the perceived benefits and barriers are used to select a chosen course of action.

Having developed an initial set of candidate questions for inclusion in the questionnaire based on the HBM, the acceptability of the questions was tested through piloting the survey and by consulting Eric Lacey B.A. Psychology, Trinity College Dublin. The first portion of the questionnaire is designed to collect information about the participants' demographics, such as age, sex, and level of education. Based on the results of the pilot study the questionnaire was revised and amended. Following piloting a Visual Analogue Scale for Anxiety (118) was added. The final questionnaire was uploaded to into SurveyMonkey for use in this study.

Consent Video

Spear Education (LLC) kindly provided the MP4 animated patient information video that was used in this study. They granted permission for its use for the purpose of this study. The original video was edited by the principal investigator to create a film for research purposes. The video's material was straightforward, jargon-free and tailored to the health literacy capabilities of the intended participants. The animated film lasted 2 minutes and 40 seconds (Figure 3) and contained the same information that the verbal consent group

would receive. The following potential sequelae, side effects and consequences were detailed:

Common risks:

- Pain and discomfort
- Swelling of the area
- Bleeding or bruising
- Limited mouth opening or stiffness of the jaw

Uncommon risks:

- An altered sensation of the lower lip and chin on the operated side: defined as a transient or permanent tingling, itching, or numbness of the area in nontechnical terms.
- An altered sensation of the tongue using the terms described above.
- Dry Socket
- Infections after surgery
- Communication with the maxillary sinus
- Damage to adjacent teeth or fillings
- A small piece of root left in the jaw
- Cracking or stretching of the corners of the mouth

Figure 3: Still shots demonstrating the animated consent video.



Sample Dimensions

A Power Calculation has been estimated based on performing a Chi-square test to determine whether there is an association between level of understanding and method of

consent. Using G*Power 3.1,9.2 software a Power Calculation has been estimated based on standard statistical criteria ($\alpha=0.05$, a medium effect size), and a minimum sample size of 41 individuals per group was determined, yielding a 90 per cent power for the study's primary outcome. To compensate for the anticipated loss of power due to study dropouts/loss to follow-up, 10% was added to each group at the start of the study. This yielded a sample number of 90 patients (45 in the control group, 45 in the intervention group.)

Collection of Data

Patients attending for mandibular third molar extraction were invited to participate in the study. Patients were reassured that if they refused to participate that this would have no impact on their treatment. To participate in the trial, all patients received a participant information leaflet (Appendix C) and signed a written informed permission form (Figure 2a and 2b). When a suitable patient agreed to participate in the study they were randomised, following the Consort Statement rules, into two groups using a random number generator. An online software program was used to randomly assign patients to one of two study groups (www.randomization.org) (119). Participants were then allocated to either the control group (verbal/written consent only) or the intervention group (video consent group). Patients in the control group received homogeneous and repeatable face-to-face verbal material from the principal investigator (CM). The duration and content of the third molar verbal information session was similar to the duration and content of the video session. For the verbal group, consent was obtained via face-to-face discussion and a written signed consent form. Patients in the video consent group received the same information via an informative animated video and were then asked to sign the consent form. The film was shown to participants in the intervention group before signing the consent form using an electronic tablet in a calm, quiet, private environment. The principal investigator (CM) was present at every step of the consent process to guarantee that all patients who agreed to participate in the trial were given all necessary information. Participants in both groups were asked if they had any additional questions. If the participant had any questions, they were answered before the patient signed the consent form.

After consent was obtained via verbal or video route, participants were given a tablet to complete an electronic survey on SurveyMonkey (Figure 4a and 4b). All participants returned 7-14 days following surgery for suture removal and a postoperative review. Participants in both groups were asked to complete a questionnaire at this review appointment rating their experience of the consent process retrospectively having gone through the recovery and postoperative period (Figure 4c).

Patient data collection

The principal investigator also recorded the following patient data:

Medical/Dental data

Medical history was recorded nominally as positive or negative. Conditions that detrimentally affected wound healing (ie. Chronic liver disease systemic immunodeficiency, diabetes, and other immune disorders or active malignancy) were considered positive findings. A positive dental history was recorded if the patient reported one or more of the following findings: difficulty with jaw movements, bruxing, needle phobia, dental phobia, history of difficult extraction or severe dental infection. The preoperative use of the oral contraceptive pill was also recorded. The presence or absence of tobacco use was also documented.

Anatomical data

The anatomic details recorded included the total number and specific tooth or teeth extracted for each patient, the mandibular third molar position based on the Winter's and Pell and Gregory classification systems, and the proximity of the inferior alveolar nerve (IAN) to the third molar root. Radiographic signs suggestive of an intimate anatomic association between the mandibular third molar and the inferior alveolar nerve were recorded. These radiographic signs included deviation or narrowing of the canal, loss of cortical outline, a shadow over the canal, and altered root morphology (16). The relationship of the mandibular third molar to the inferior dental canal was categorised as no superimposition between the roots and inferior alveolar canal, superimposition without the aforementioned radiographic findings, and superimposition with one or more of the above listed radiographic signs.

Operative data

The operative data recorded included the anaesthetic technique (local anaesthetic alone or local anaesthetic with intravenous sedation), and the operative technique (classified as nonsurgical, soft tissue impaction, partial bony impaction, and full bony impaction).

Data Management

When a patient consented to participate in the study they were allocated a number within the research project. This participant number was pseudonymised with their medical records number on an excel database by the principal investigator. The principal investigator had sole access to the key code to access the excel database. In order to handle information securely the Survey System, SurveyMonkey was used. In order to preserve the anonymity of the respondents the option to save time and date stamp with responses was disabled. The sole access to the SurveyMonkey account was by the principal investigator. The approval of the Local Data Protection Committee was gained (Appendix E).

Figure 4a: Post-consent questionnaire.

Post Consent Questionnaire			
Male ☐ Female ☐ Other ☐	Smoker yes ☐ no ☐		
Age			
Under 18	☐		
18-34	☐		
35-54	☐		
55+	☐		
Occupation _____	Education Background		
	No cert/junior cert ☐		
	Leaving Cert ☐		
	Third Level Education ☐		
Have you searched online for information on the following prior to your appointment today? (tick all that apply)			
Wisdom tooth pain	☐		
Wisdom tooth extraction	☐		
Other people's account of their experience with wisdom teeth	☐		
None of the above	☐		
How do you feel about having your wisdom tooth/teeth removed?			
Relaxed/Slightly worried	☐		
Fairly worried	☐		
Extremely worried	☐		
Do any of these statements reflect your understanding with regard to wisdom teeth?			
All wisdom teeth must be removed eventually	☐		
Wisdom teeth only need to be removed if they cause a problem	☐		
Wisdom teeth cause crowding of the teeth	☐		
Wisdom teeth can be a valuable part of a person's dentition	☐		
Wisdom teeth need to be removed if planning to get braces on teeth	☐		
Have your wisdom teeth caused the following symptoms (tick any that apply)			
Pain	☐		
Infection	☐		
Swelling	☐		
Decay	☐		
Crowding	☐		
Inability to properly clean these teeth	☐		
Which of the following sequelae/risks/complications would you expect to have after wisdom teeth removal (tick any that apply)?			
Pain	☐	Post-op Numbness (temporary, not associated with numbing injections)	☐
Infection	☐	Post-op Numbness to lip, chin, tongue (permanent)	☐
Swelling	☐	Dry Socket	☐
Bleeding	☐	None of the above	☐
Communication with maxillary sinus	☐		
Damage to nearby teeth	☐		
Don't know	☐	Other	_____

Figure 4b: Post-consent questionnaire.

Which of these possible sequelae/risks/complications concern you most? (Rate 0-10, 0 being not concerning 10 being most concerning)

Pain	—	Post-op Numbness (temporary, not associated with numbing injections)	—
Infection	—	Post-op Numbness to lip, chin, tongue (permanent)	—
Swelling	—	Dry Socket	—
Bleeding	—	Recovery time	—
Communication with maxillary sinus	—	Cost of treatment	—
Damage to nearby teeth	—		

Who made the decision that your wisdom teeth should be extracted?

I did myself ☐

My general dentist ☐

My Orthodontist ☐

An Oral Surgeon ☐

How do you feel that removing your wisdom teeth will most benefit you? (tick all that apply)

Alleviation of Pain ☐

Prevent Infection ☐

Prevent decay in adjacent teeth ☐

Prevent cyst formation ☐

Prevent crowding of teeth ☐

Other _____

Which factor(s) would be most likely to deter you from having your wisdom teeth removed? (Tick any that apply)

Pain	☐	Post-op Numbness (temporary, not associated with numbing injections)	☐
Infection	☐	Post-op Numbness to lip, chin, tongue (permanent)	☐
Swelling	☐	Dry Socket	☐
Bleeding	☐	Cost of treatment	☐
Communication with maxillary sinus	☐	None of the above	☐
Damage to nearby teeth	☐		
Recovery time	☐		

- Need to arrange time off work ☐
- Disruption to family/domestic situation ☐

Other _____

Rate your understanding of the information you have received about the proposed procedure? (P= poor, F= fair, G=good, VG= very good, E=excellent)

Details of what happens during the proposed procedure _____

The intended benefits of the proposed procedure _____

The risks/complications of the proposed procedure _____

The risks/complications if the proposed procedure is not performed _____

Would you like to have received more or less information on the sequelae/risks/complications of the proposed procedure?

More ☐

Less ☐

I was satisfied with the amount of information I received ☐

Did you feel that you were able to ask questions during the consent process?

yes ☐ no ☐

Do you think the use of video assisted consent would be beneficial in the future?

yes ☐ no ☐

Figure 4c: Review questionnaire.

Review Appointment Questionnaire

Do you feel that you were informed sufficiently about the following sequelae/risks/complications?

(Rate 0-10, 0: given no information 10: fully informed)

Pain	☐	Post-op Numbness (temporary, not	☐
Infection	☐	associated with numbing injections)	☐
Swelling	☐	Post-op Numbness to lip, chin, tongue	☐
Bleeding	☐	(permanent)	☐
Communication with maxillary sinus	☐	Dry Socket	☐
Damage to nearby teeth	☐	Cost of treatment	☐
Recovery time	☐	Other _____	☐

Rate your understanding of the information that you had received about the procedure? (P= poor, F= fair, G=good, VG= very good, E=excellent understanding)

Details of what happens during the proposed procedure	_____
The intended benefits of the proposed procedure	_____
The risks/complications of the proposed procedure	_____
The risks/complications if the proposed procedure is not performed	_____

Would you like to have received more or less information on the sequelae/risks/complications of the proposed procedure?

More	☐
Less	☐
I was satisfied with the amount of information I received	☐

If you have selected "more" please provide more detail on sequelae/risks/complications that you would have liked to have discussed further

How did you feel when discussing the sequelae/risks/complications of the proposed procedure during the consent process?

Relaxed/Slightly worried	☐
Fairly worried	☐
Extremely worried	☐

How satisfied were you with the amount of information that you received about the following sequelae/risks/complications?

(D= dissatisfied, S= satisfied, ES=Extremely satisfied)

Pain	—	Post-op Numbness (temporary, not	—
Infection	—	associated with numbing injections)	—
Swelling	—	Post-op Numbness to lip, chin, tongue	—
Bleeding	—	(permanent)	—
Communication with maxillary sinus	—	Dry Socket	—
Damage to nearby teeth	—	Cost of treatment	—
Recovery time	—	Other _____	—

Did you feel that you were able to ask questions during the consent process?

yes ☐ no ☐

Do you think the use of video assisted consent would be beneficial in the future?

yes ☐ no ☐

Data Analysis Strategy

1. Identification of the categories of analysis and development of the coding system.

A coding system was established to enable the conversion of the data into meaningful and specific units of information (codes or categories) amenable to statistical analysis using the Statistical Package for the Social Sciences (SPSS version 27.0.1.0; SPSS, Chicago, IL) software.

2. Coding of the data into the categories of analysis.

The output data from SurveyMonkey was extracted and entered into a Microsoft Excel spreadsheet. It was then organised and coded in a way that ensured reliability and meaningfulness, i.e., the previously defined categories (codes) were used to classify the content into explicative categories.

3. Analysis and interpretation.

When data was organised and coded, the statistical analysis was carried out using the Statistical Package for the Social Sciences. For $p < 0.05$, statistical significance was considered. Descriptive statistics for continuous data were given as the mean and standard deviation (SD), as well as the minimum and maximum value, whereas categorical variables, were reported as absolute frequencies and percentages. Pearson's chi-squared test was used to test independence between the categorical variables. Fisher's exact test was used when expected counts were less than five. The Chi-square test requires expected counts to be greater than 5. If this is not satisfied then Fisher's exact test is used. Fisher's exact test is used to determine whether there is an association between two variables.

Logistic regression models were used to determine the effect of groups on the level of understanding (poor/good) and patient satisfaction. The advantage of logistic regression is that it can adjust for additional factors/variables (age, sex, education level) and the corresponding odds ratios and corresponding 95% confidence intervals were estimated.

RESULTS

One hundred and five patients attending the Dublin Dental University Hospital for mandibular third molar extraction between June 2020 and April 2022 were identified for participation in the study. Of these 105 patients, 15 were excluded; 2 as they did not have adequate understanding of the English language and required a third-party translator, 8 as they were having additional surgical procedures, most commonly cyst enucleation and 5 as they had significant medical co-morbidities (ASA III). Thus, 90 patients participated in the study. At the review appointment, 1 patient from each group (n=44) was lost to follow-up (Figure 5).

Demographics

The demographic features of the sample are shown in Figures 6 and 7. There were 19 male patients (42%) and 26 female patients (58%) in the control group (Figure 6) versus 14 male patients (31%) and 31 female patients (69%) in the intervention group (Figure 6). In the control group, 27 participants (60%) were between 18 and 34 years old, 14 (31%) were between 35 and 54 years old and the remaining 4 participants (9%) were over the age of 55 (Figure 5). In the intervention group, 30 participants (67%) were between 18 and 34 years old, 13 (29%) were between 35 and 54 years old and the remaining 2 participants (4%) were over the age of 55 (Figure 7). The medical, dental, anatomical and operative data of the participants are shown in Table 3.

Figure 5: Flow diagram for data collection and participation.

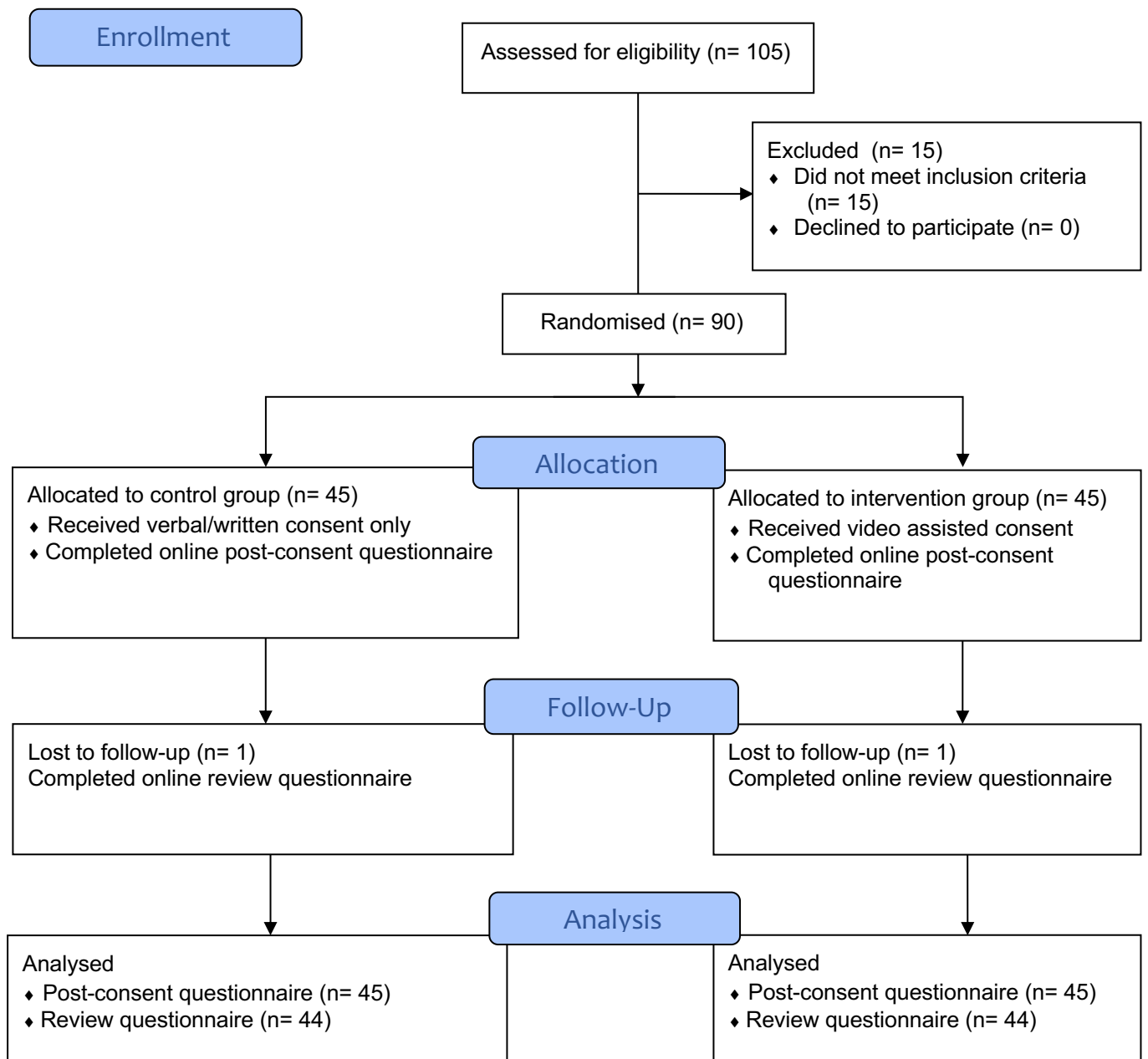


Figure 6: Age and gender demographics of participants in the verbal consent (control) group.

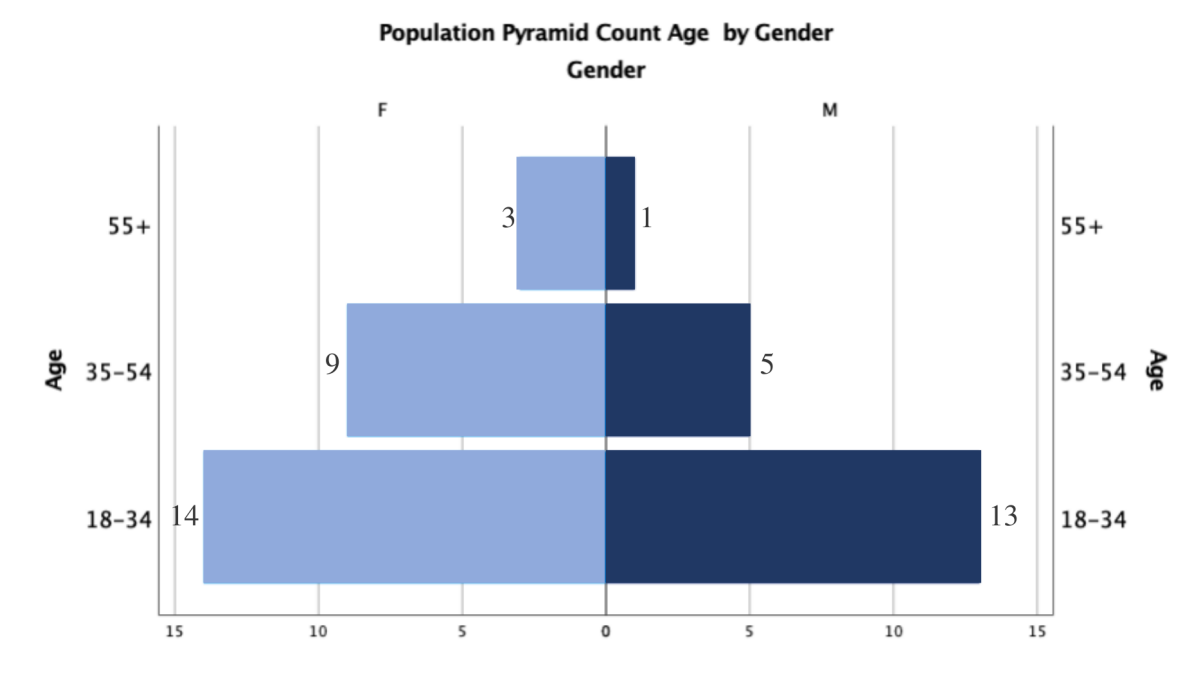


Figure 7: Age and gender demographics of participants in the video consent (intervention) group.

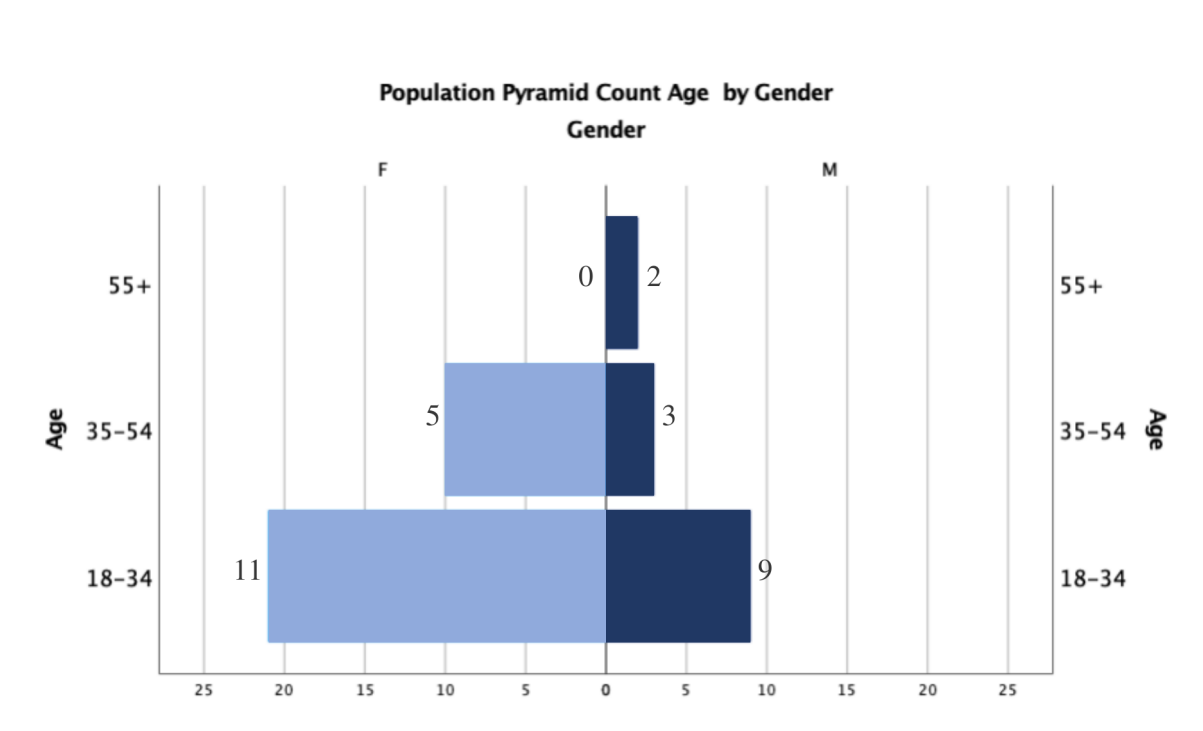


Table 3. Study variables grouped.

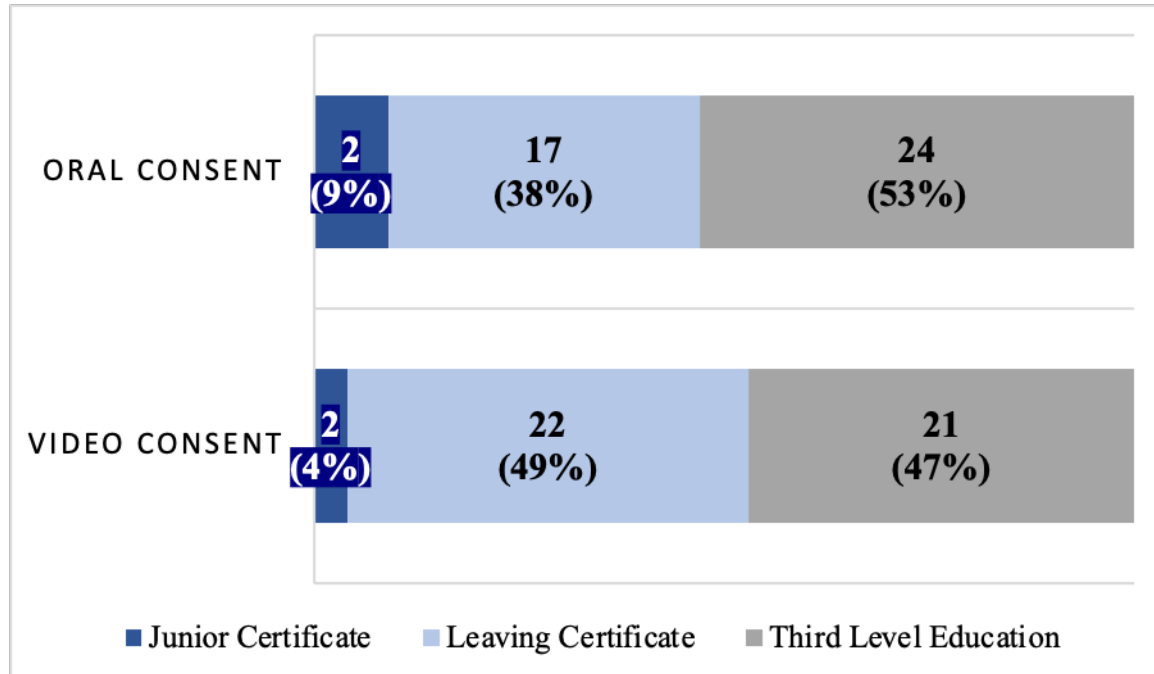
Variable	Control Group	Intervention Group
<u>Demographic</u>		
Sample size—patients	45	45
Sample size—teeth	76	98
<u>Medical/dental history (by patient)</u>		
Medical (positive)	7 (16%)	6 (13%)
Dental (positive)	19 (42%)	14 (31%)
Smoking (positive)	14 (13%)	11 (24%)
Oral contraceptive pill (positive)	3 (7%)	6 (21%)
<u>Anatomic</u>		
Tooth extracted		
Maxillary third molar	17 (22%)	33 (34)
Mandibular third molar	59 (78%)	65 (66%)
<u>Anatomic position of mandibular third molar</u>		
Winter's classification		
Horizontal	13 (22%)	9 (14%)
Mesioangular	8 (14%)	11 (17%)
Vertical	20 (34%)	23 (35%)
Distoangular	18 (31%)	22 (34%)
Transverse	0 (0%)	0 (0%)
Pell and Gregory (mandibular third molars only):		
IA	19 (32%)	20 (31%)
IB	12 (20%)	3 (5%)
IC	2 (3%)	0 (0%)
IIA	10 (17%)	21 (32%)
IIB	4 (7%)	4 (6%)
IIC	1 (2%)	0 (0%)
IIIA	6 (10%)	14 (22%)
IIIB	3 (5%)	3 (5%)
IIIC	2 (3%)	0 (0%)
Third molar radiographic proximity to nerve:		
No superimposition	22 (37%)	22 (34%)
Superimposition with radiographic changes	6 (10%)	15 (23%)
Superimposition without radiographic changes	31 (53%)	28 (43%)
<u>Operative</u>		
Anaesthesia		
Local	8 (18%)	7 (16%)
Local and Sedation	37 (82%)	38 (84%)
Operation:		
Nonsurgical	4 (7%)	4 (6%)
Soft tissue impaction	14 (24%)	25 (38%)
Partial bony	12 (20%)	10 (15%)
Full bony	29 (49%)	26 (40%)

Level of education

In the control group, 24 patients (53%) reported third-level education as their highest level of education. Seventeen patients (38%) reported Leaving certificate as their highest level of education while the remaining 4 patients (9%) reported that the junior certificate was their highest level of education. In the intervention group, 21 patients (47%) reported third-level education as their highest level of education. Twenty-two patients (49%) reported Leaving certificate as their highest level of education while the remaining 2

patients (4%) reported that the junior certificate was their highest level of education (Figure 8).

Figure 8: The highest level of education of the study participants.

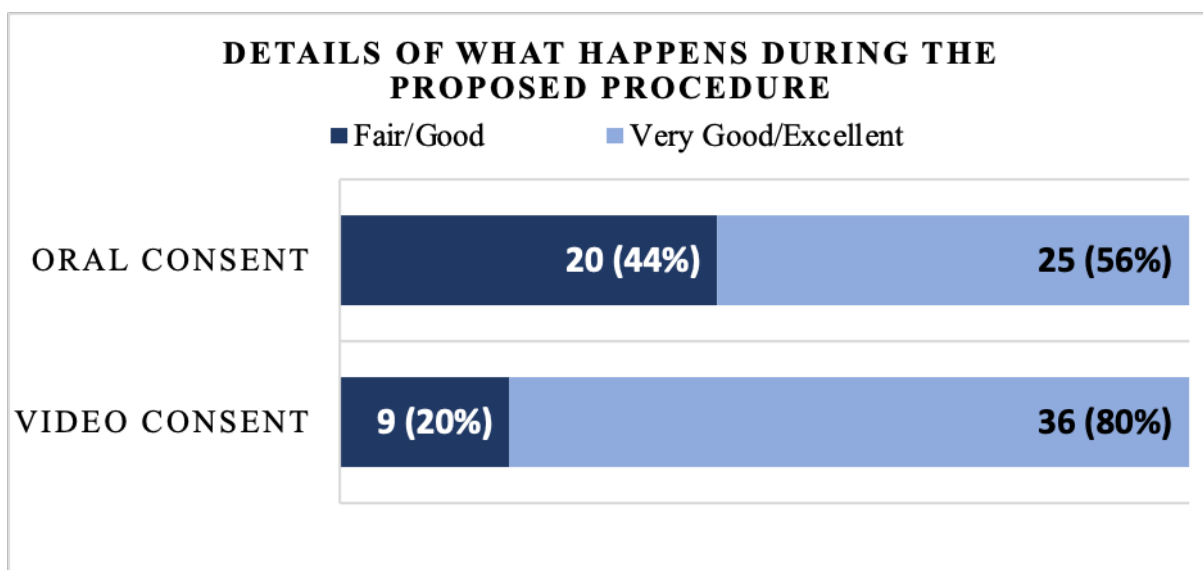


Patient understanding

Post Consent

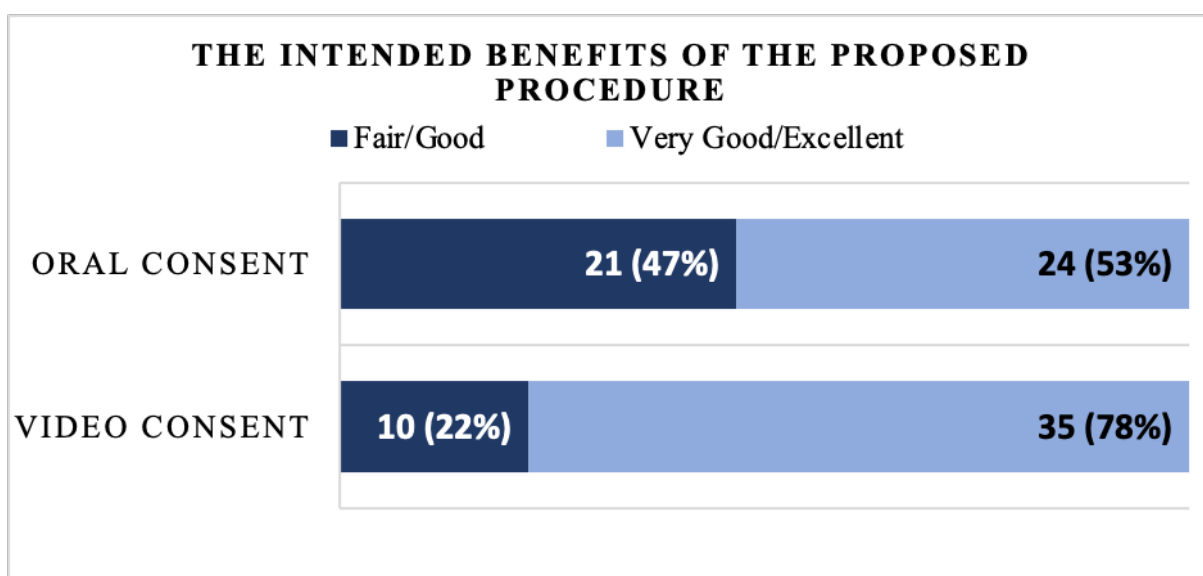
Immediately after the consent process, patients were asked to rate their level of understanding as fair, good, very good or excellent. In relation to patients' level of understanding about details of what would happen during the proposed procedure, 25 patients (56%) in the verbal consent group rated their understanding as very good or excellent versus 36 patients (80%) in the video consent group ($p=0.06$). The remaining patients rated their understanding as fair or good (Figure 9).

Figure 9: Patients' level of understanding of the details of what would happen during the procedure after the consent process.



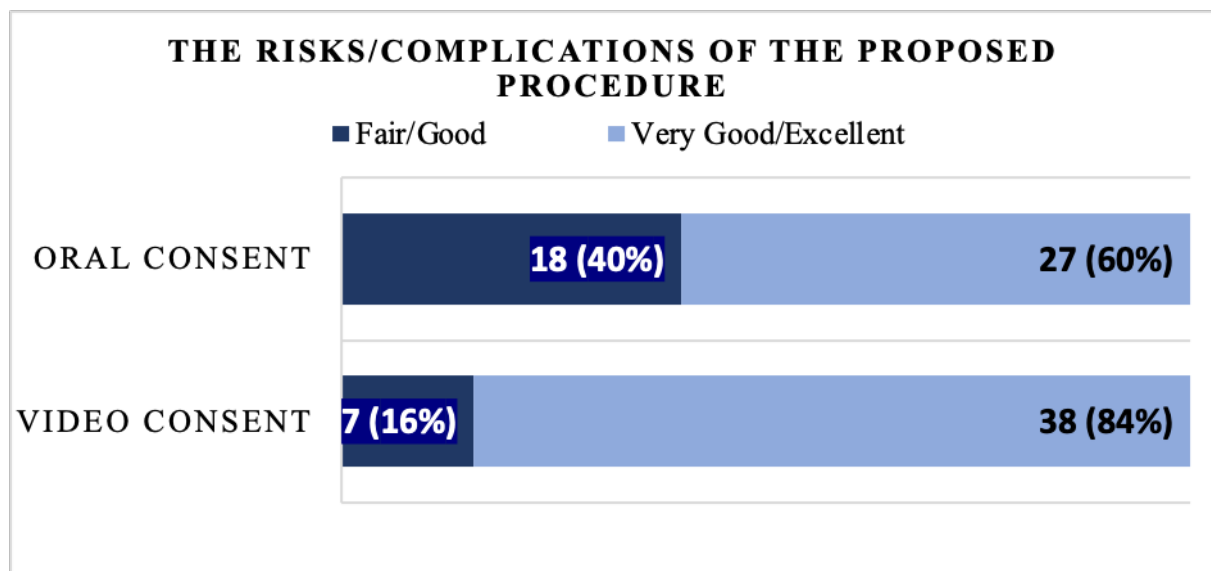
When asked about their level of understanding of the intended benefits of the procedure 24 patients (53%) of patients in the verbal consent group rated their understanding as very good or excellent versus 35 patients (78%) of those in the video consent group ($p=0.07$). The remaining patients rated their understanding as fair or good (Figure 10).

Figure 10: Patients' level of understanding of the intended benefits of the proposed procedure after the consent process.



With regard to patients' level of understanding of the risks or complications of the proposed procedure, 27 patients (60%) in the verbal consent group rated their understanding as very good or excellent versus 38 patients (84%) in the video consent group ($P = 0.05$ OR= 0.37, 95% CI [0.13, 1.02]). The remaining patients rated their understanding as fair or good (Figure 11). Logistic regression analysis was used to analyse the relationship between the use of video consent on patients' level of understanding of the risks and complications of the proposed procedure and their age, sex, and education level (Table 4).

Figure 11: Patients' level of understanding of the risks/complications of the proposed procedure after the consent process.

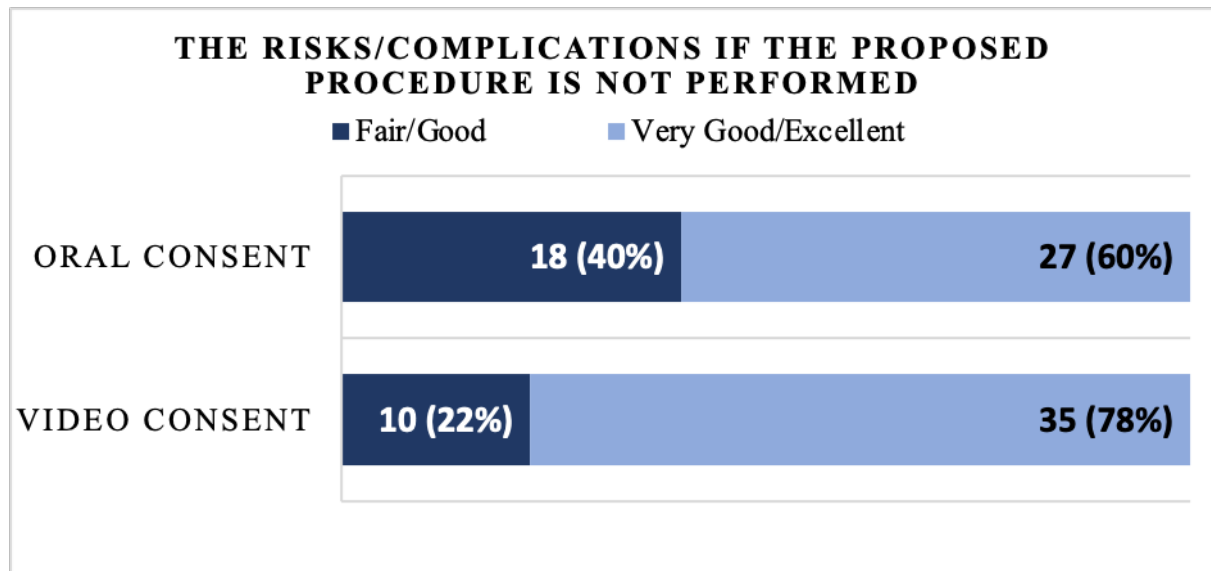


In relation to patients' level of understanding about details of the risks/complications if the procedure was not performed 27 patients (60%) of patients in the verbal consent group rated their understanding as very good or excellent versus 35 patients (78%) of those in the video consent group ($p=0.07$). The remaining patients rated their understanding as fair or good (Figure 12).

Table 4: Logistic regression analysis for patients' self-reported level of understanding about "The risks/complications of the proposed procedure".

		Odds ratio	95% C.I. for EXP(B)		P value
			Lower	Upper	
Crude odds ratio		0.368	0.133	1.019	0.054
Characteristic					
Variables in the Equation					
<u>Age</u>					
	55+				0.896
	35-54	1.297	0.205	8.214	0.783
	18-34	1.554	0.217	11.109	0.661
<u>Gender</u>					
	Gender	0.52	0.191	1.412	0.199
<u>Education Level</u>					
	Junior Certificate				0.784
	Leaving Certificate	1.873	0.19	18.444	0.591
	Third-level	0.843	0.304	2.338	0.743
		Odds ratio	95% C.I. for EXP(B)		P value
			Lower	Upper	
Adjusted Odds Ratio					
Characteristic					
Variables in the Equation					
<u>Age</u>					
	55+				0.895
	35-54	1.55	0.245	9.82	0.642
	Q8-34	1.513	0.214	10.668	0.678
<u>Gender</u>					
	Gender	0.451	0.158	1.282	0.135
<u>Education Level</u>					
	Junior Certificate				0.596
	Leaving Certificate	3.141	0.28	35.277	0.354
	Third-level				
	Education	0.87	0.298	2.545	0.8

Figure 12: Patients' level of understanding of the risks/complications if the proposed procedure is not performed after consent process.



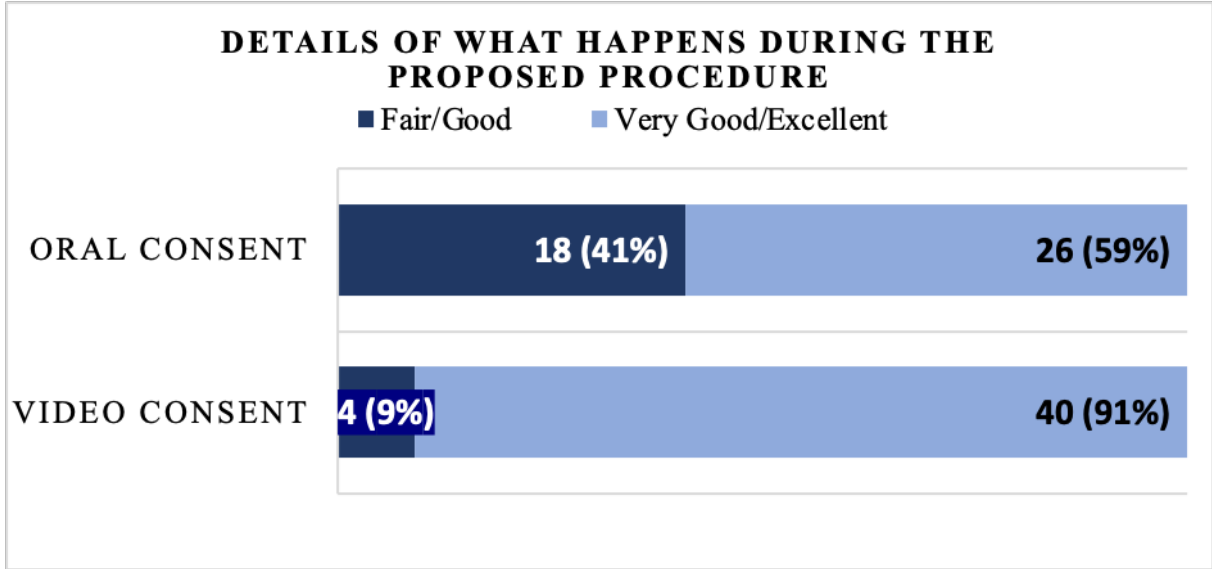
Following the consent process, 9 patients (20%) in the verbal consent group asked additional questions before signing the consent form, compared to 3 patients (7%) in the video consent group. Patients in the verbal consent group were more likely to ask additional questions about operative details (5 patients (11%)), followed by recovery time (3 patients (7%)) then trismus (2 patients (4%)). In the video consent group 1 participant (2%) asked an additional question about each of the following; operative details, recovery time and permanent paraesthesia.

Review appointment

Having had their third molar extraction and a recovery period of 7–14 days' patients were again asked at the review appointment to rate their level of understanding of details of what would happen during the proposed procedure. Twenty-six patients (59%) in the verbal consent group rated their understanding as very good or excellent versus 40 patients (91%) in the video consent group ($P = <0.001$ OR= 0.14, 95% CI [0.04, 0.48]). The remaining patients rated their understanding as fair or good (Figure 13). Logistic regression analysis was used to analyse the relationship between the use of video consent

on patients' level of understanding of details of what would happen during the proposed procedure and their age, sex, and education level (Table 5).

Figure 13: Patients' self-reported level of understanding of details of what would happen during the procedure at their review appointment at approximately 7-14 days post the procedure.



When asked about their level of understanding of the intended benefits of the procedure, 31 patients (70%) in the verbal consent group rated their understanding as very good or excellent versus 37 patients (84%) in the video consent group ($p=0.13$). The remaining patients rated their understanding as fair or good (Figure 14).

Figure 14: Patients’ self-reported level of understanding of the intended benefits of the proposed procedure at the review appointment at approximately 7-14 days post the procedure.

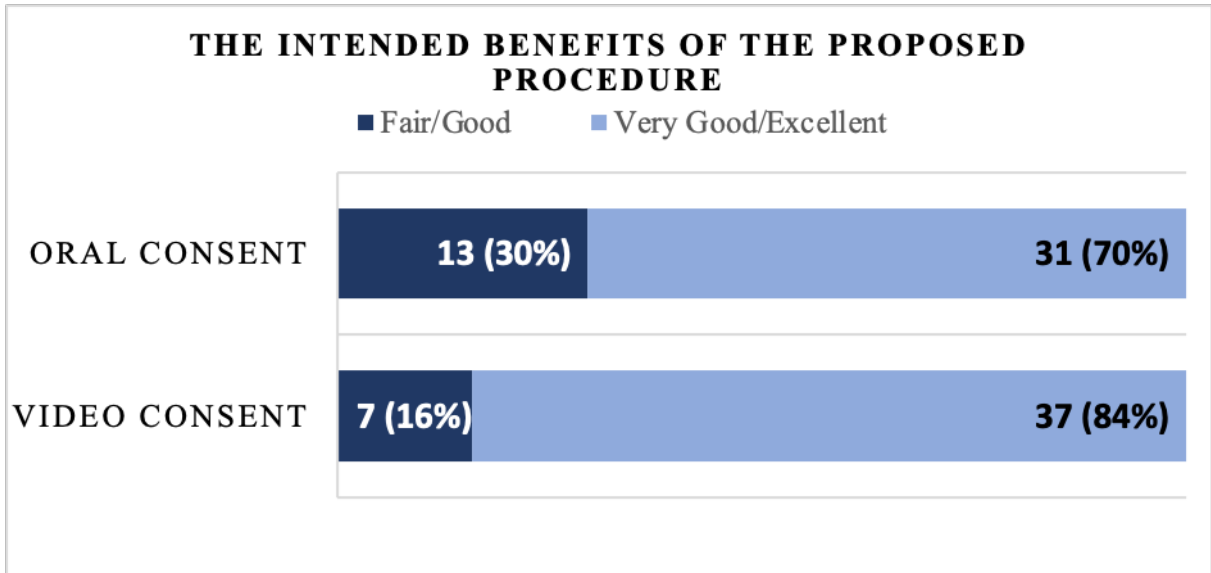


Table 5: Logistic regression analysis for patients' self-reported retrospective level of understanding about "Details of what would happen during the proposed procedure".

		Odds ratio	95% C.I.for EXP(B)		P value
			Lower	Upper	
Crude odds ratio					
Characteristic					
Variables in the Equation					
<u>Age</u>					
	55+				0.087
	35-54	1.963	0.297	12.974	0.484
	18-34	8.058	0.918	70.761	0.06
<u>Gender</u>					
	Gender	0.67	0.233	1.929	0.458
<u>Education Level</u>					
	Junior Certificate				0.904
	Leaving Certificate	1.736	0.157	19.168	0.653
	Third-level	1.041	0.354	3.062	0.942
		Odds ratio	95% C.I.for EXP(B)		P value
			Lower	Upper	
Adjusted Odds Ratio					
Characteristic					
Variables in the Equation					
<u>Age</u>					
	55+				0.094
	35-54	2.028	0.292	14.062	0.474
	Q8-34	8.215	0.944	71.523	0.056
<u>Gender</u>					
	Gender	0.65	0.207	2.043	0.461
<u>Education Level</u>					
	Junior Certificate				0.819
	Leaving Certificate	1.977	0.114	34.353	0.64
	Third-level				
	Education	1.339	0.418	4.284	0.623

With regard to patients' level of understanding of the risks of complications of the proposed procedure, 32 patients (73%) in the verbal consent group rated their understanding as very good or excellent versus 42 patients (95%) in the video consent group ($P = 0.004$ OR= 0.13, 95% CI [0.03, 0.61]). The remaining patients rated their understanding as fair or good (Figure 15). Logistic regression analysis was used to analyse the relationship between the use of video consent on patients' level of understanding of the risks of complications of the proposed procedure and their age, sex, and education level (Table 6).

Table 6: Logistic regression analysis for patients' self-reported retrospective level of understanding about "The risks/complications of the proposed procedure".

		Odds ratio (OR)	95% C.I. for EXP(B) Lower Upper		P value
Crude odds ratio		0.127	0.027	0.608	0.01
Characteristic					
Variables in the Equation					
<u>Age</u>					
	55+				0.155
	35-54	5.403	0.772	37.81	0.089
	18-34	8.064	0.914	71.127	0.06
<u>Gender</u>					
	Gender	1.245	0.355	4.364	0.732
<u>Education Level</u>					
	Junior Certificate				0.961
	Leaving Certificate	0.809	0.07	9.39	0.866
	Third-level	0.847	0.241	2.976	0.796
		Odds ratio	95% C.I. for EXP(B) Lower Upper		P value
Adjusted Odds Ratio					
Characteristic					
Variables in the Equation					
<u>Age</u>					
	55+				0.148
	35-54	5.928	0.763	46.052	0.089
	Q8-34	8.365	0.934	74.889	0.058
<u>Gender</u>					
	Gender	1.296	0.33	5.1	0.71
<u>Education Level</u>					
	Junior Certificate				0.907
	Leaving Certificate	0.943	0.046	19.275	0.97
	Third-level				
	Education	0.738	0.191	2.847	0.659

In relation to patients' level of understanding about details of the risks/complications if the procedure was not performed, 33 patients (75%) in the verbal consent group rated their understanding as very good or excellent versus 41 patients (93%) in the video consent

group ($P = 0.02$ OR= 0.22, 95% CI [0.06, 0.85]). The remaining patients rated their understanding as fair or good (Figure 16). Logistic regression analysis was used to analyse the relationship between the use of video consent on patients' level of understanding about details of the risks/complications if the procedure was not performed and their age, sex, and education level (Table 7).

Figure 15: Patients' level of understanding of the risks/complications of the proposed procedure at the review appointment.

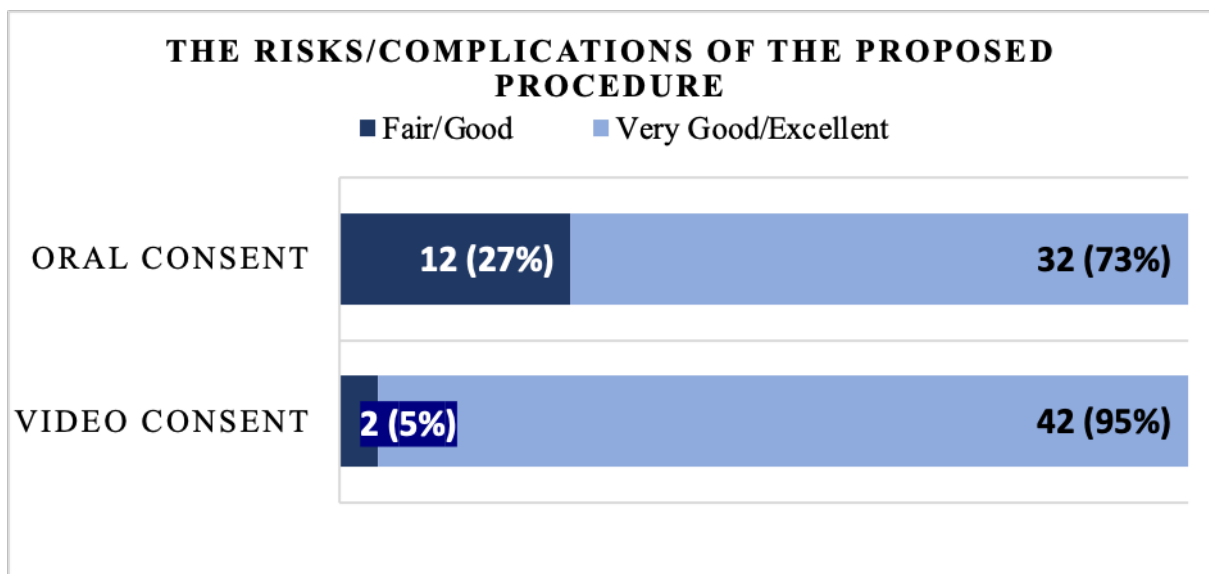


Figure 16: Patients' self-reported level of understanding regarding the risks/complications if the proposed procedure is not performed at the review appointment.

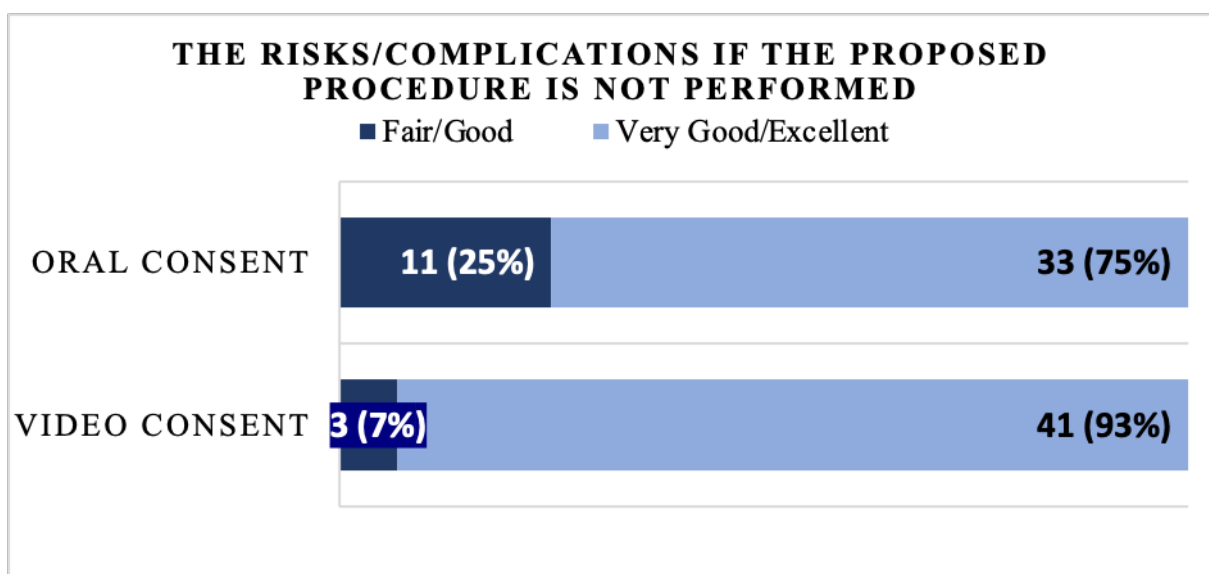


Table 7: Logistic regression analysis for patients' understanding about "The risks/complications if the proposed procedure was not performed".

	Odds ratio (OR)	95% C.I. for EXP(B)		P value
		Lower	Upper	
Crude odds ratio	0.22	0.057	0.608	0.028
Characteristic				
Variables in the Equation				
<u>Age</u>				
55+				0.96
35-54	0.794	0.078	8.108	0.845
18-34	0.935	0.08	10.892	0.957
<u>Gender</u>				
Gender	0.561	0.171	1.845	0.341
<u>Education Level</u>				
Junior Certificate				0.712
Leaving Certificate	0.662	0.058	7.54	0.74
Third-level	0.597	0.173	2.064	0.415
	Odds ratio	95% C.I. for EXP(B)		P value
		Lower	Upper	
Adjusted Odds Ratio				
Characteristic				
Variables in the Equation				
<u>Age</u>				
55+				0.998
35-54	0.96	0.086	10.678	0.974
Q8-34	0.926	0.08	10.733	0.951
<u>Gender</u>				
Gender	0.563	0.16	1.981	0.371
<u>Education Level</u>				
Junior Certificate				0.761
Leaving Certificate	0.911	0.065	12.801	0.945
Third-level				
Education	0.614	0.168	2.246	0.461

Patients were asked to retrospectively rate how sufficiently they were informed about each sequela/risk/complication using a 0-10 Likert-type scale (0 representing that they were given no information and 10 being completely informed). The weighted averages of the participants' responses are shown in Figure 17.

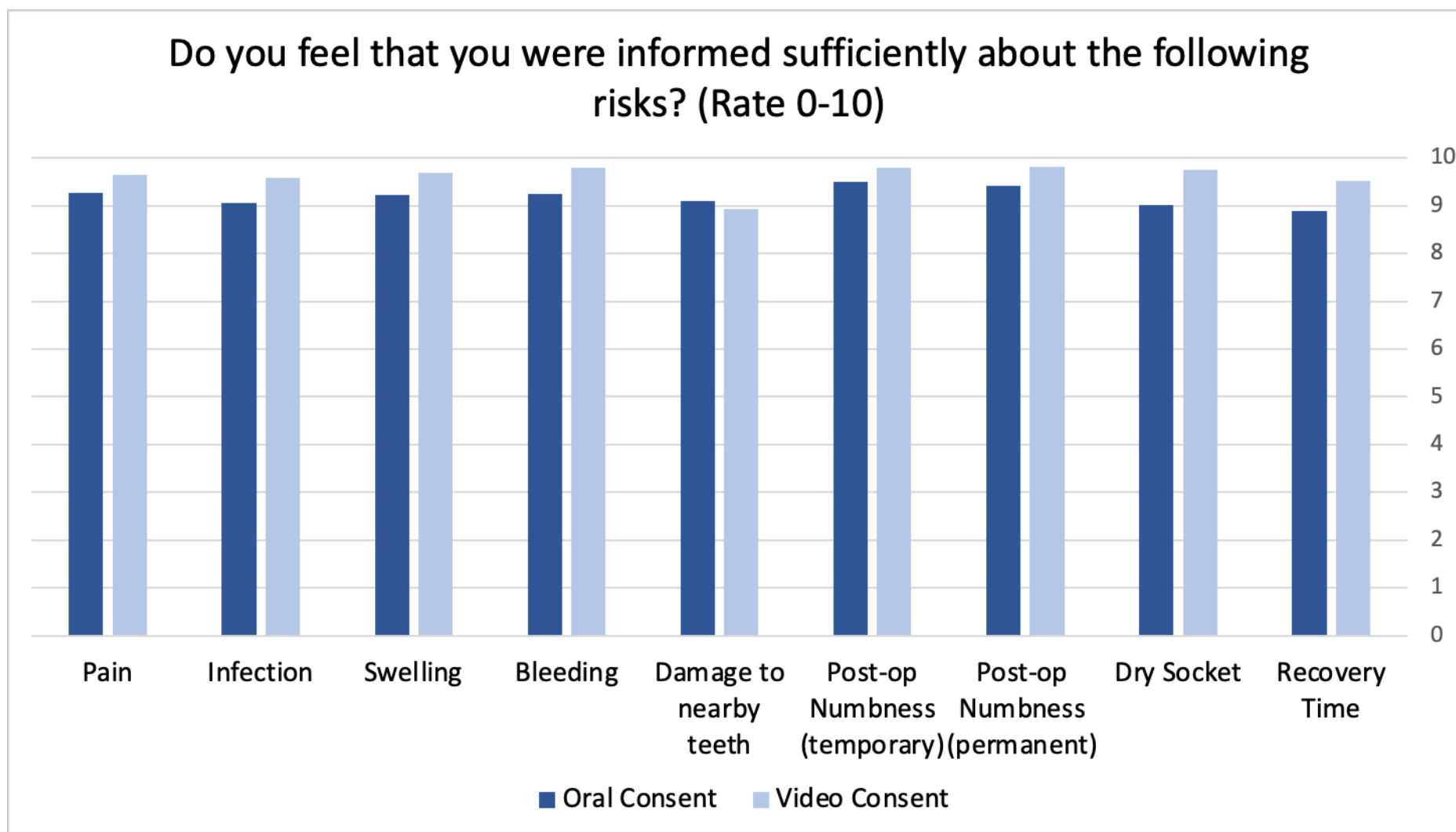


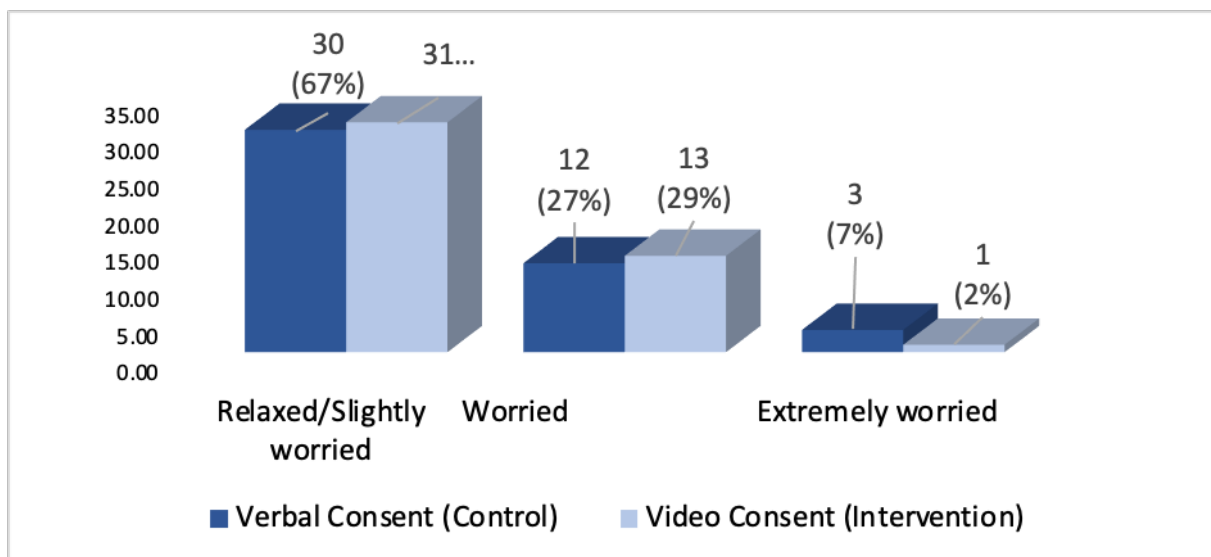
Figure 17: Weighted averages of participants' responses concerning how sufficiently they were informed about the following sequelae/risks/complications? (Rate 0-10, 0= given no information, 10= fully informed).

Patient Anxiety

Post Consent

Immediately after the consent process, patients were asked to rate their level of anxiety as relaxed/slightly worried, worried or extremely worried about the procedure. Thirty patients (67%) in the verbal consent group rated their level of anxiety as relaxed or slightly worried versus 31 patients (69%) in the video consent group. Twelve patients (27%) in the verbal consent group rated their level of anxiety as worried versus 13 patients (29%) in the video consent group. Of the remaining participants, 3 (7%) in the verbal consent group and 1 (2%) in the video consent group rated their level of anxiety as extremely worried (Figure 18). There were no statistically significant differences between the two groups ($P = 0.59$).

Figure 18: Patients' level of anxiety post consent.



Patients were asked to rate their level of concern about each sequela/risk/complication using a Likert type scale. The weighted averages of the participants' responses are shown in Figure 19.

Patients were also asked which sequela/risk/complication would be most likely to deter them from proceeding with the proposed treatment (Figure 20).

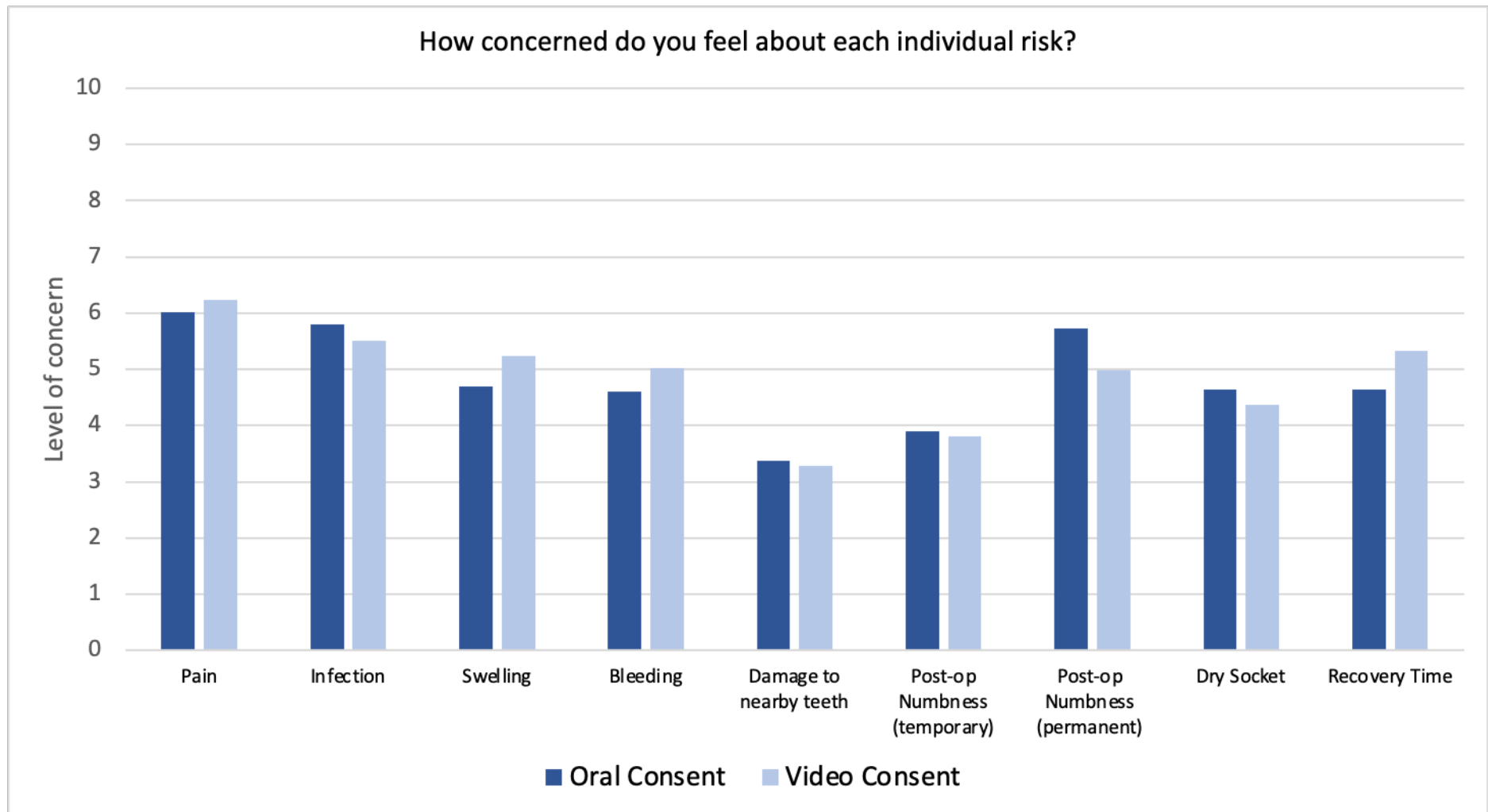


Figure 19: Weighted averages of participants' responses about their level of concern about each sequela/risk/complication? (Rate 0-10, 0= no concern, 10= extremely concerned).

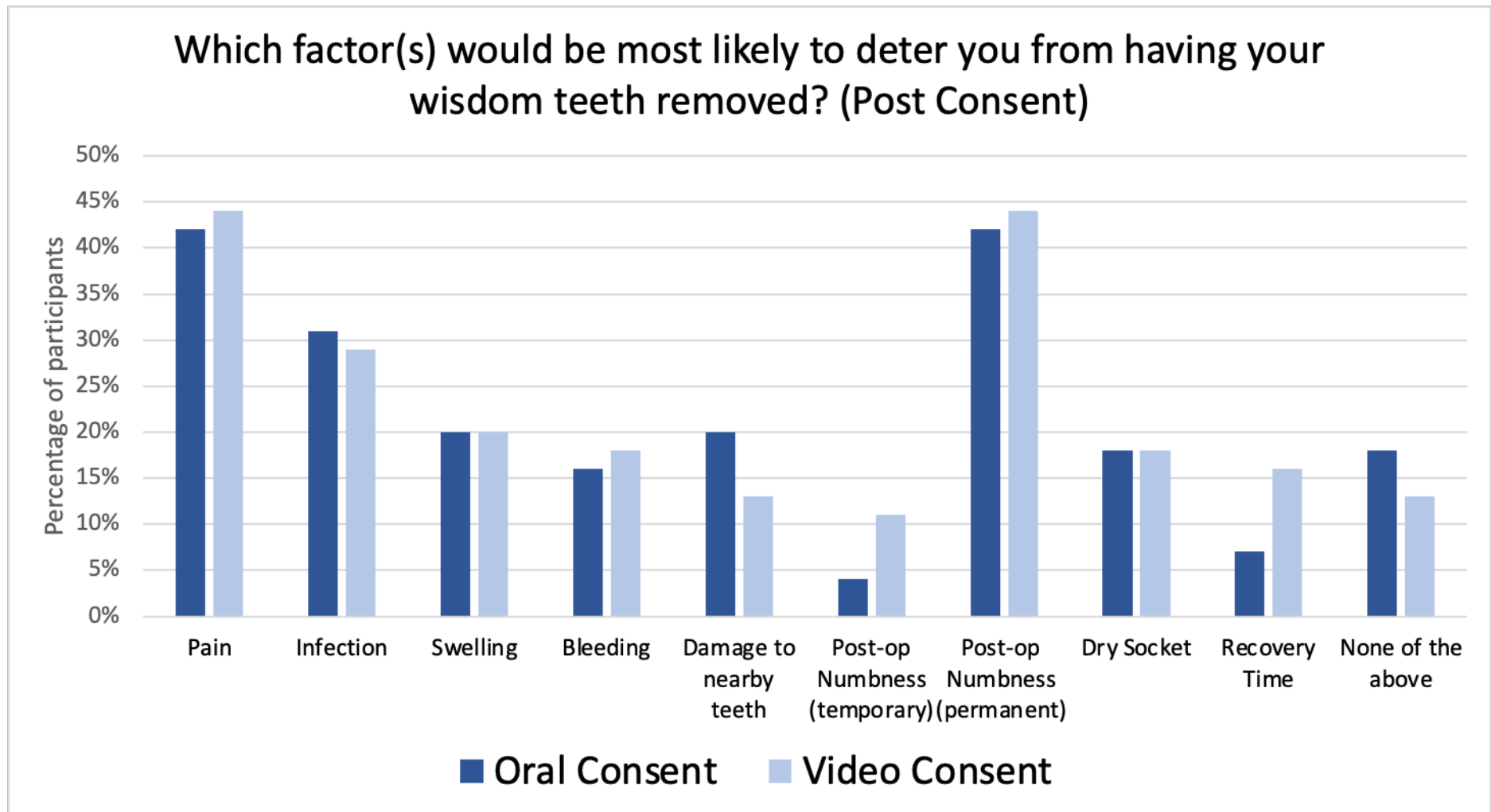
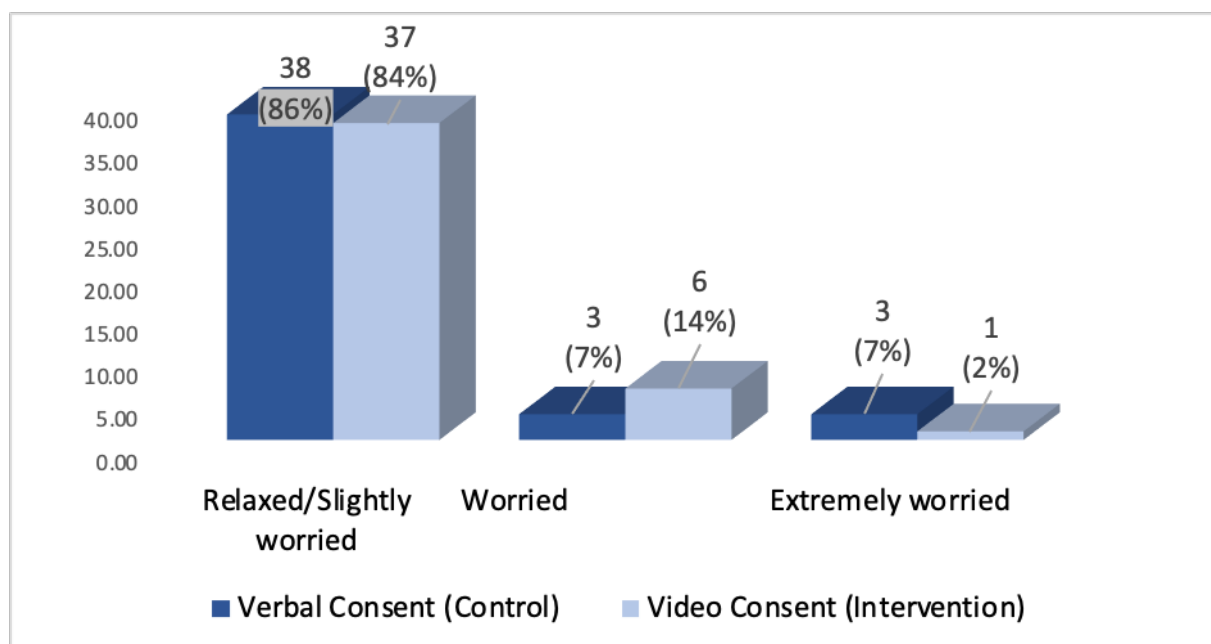


Figure 20: Participants' responses showing which complications would be most likely to deter them from proceeding with the proposed treatment.

Review appointment

Following their third molar extraction and a recovery period of 7-14 days' patients were asked again at their review appointment to rate their level of anxiety about the procedure retrospectively. Thirty-eight patients (86%) in the verbal consent group rated their level of anxiety as relaxed or slightly worried versus 37 patients (84%) in the video consent group. Three patients (7%) in the verbal consent group rated their level of anxiety as worried versus 6 patients (14%) in the video consent group. Of the remaining participants, 3 (7%) in the verbal consent group and 1 (2%) in the video consent group rated their level of anxiety as extremely (Figure 21). There were no statistically significant differences between the two groups.

Figure 21: Patients' level of anxiety reported at the review appointment.



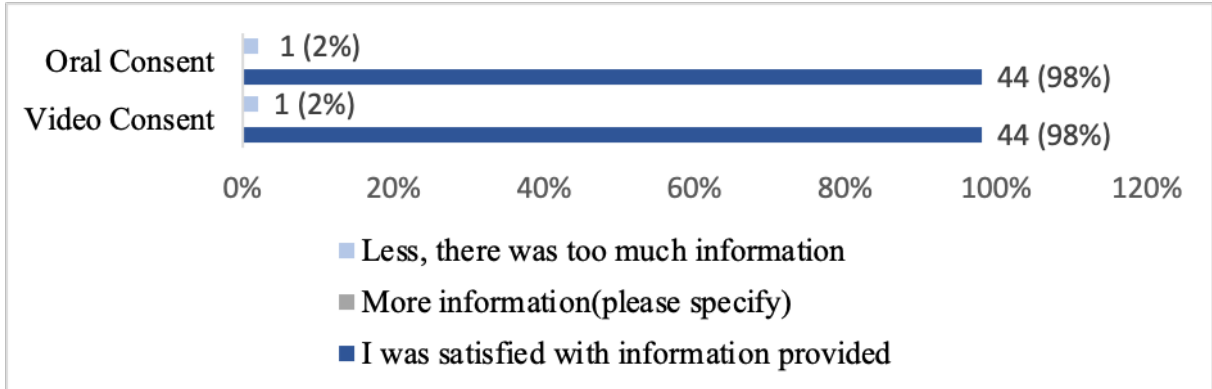
Patient Satisfaction

Post Consent

Immediately after the consent process patients were asked to rate their level of satisfaction with the amount of information that they received during the consent process. They had the following options to choose from: I was satisfied with the amount of information that I

received; I would have liked more information; I would have liked to receive less information. Forty-four patients (98%) in each group were satisfied with the amount of information that they received during the informed consent process. The remaining patient (2%) in each group would have liked to have received less information (Figure 22).

Figure 22: Patients’ response to the question regarding their satisfaction with the amount of information that they received during the consent process, immediately after consent.



When asked if participants thought the use of video-assisted consent would be beneficial in the future, 44 participants (98%) in the video consent group thought it was beneficial and endorsed its use in the future. In the verbal consent group, having not seen the video, 26 participants (58%) felt that a video-assisted consent would be beneficial in the future (Figure 23) (P = <0.001 OR= 32, 95% CI [4, 254]). Logistic regression analysis was used to analyse the relationship between the use of video consent on patients’ belief that video-assisted consent would be beneficial in the future and their age, sex, and education level (Table 7).

Figure 23: Patients’ response to the question regarding if video-assisted consent would be beneficial in the future.

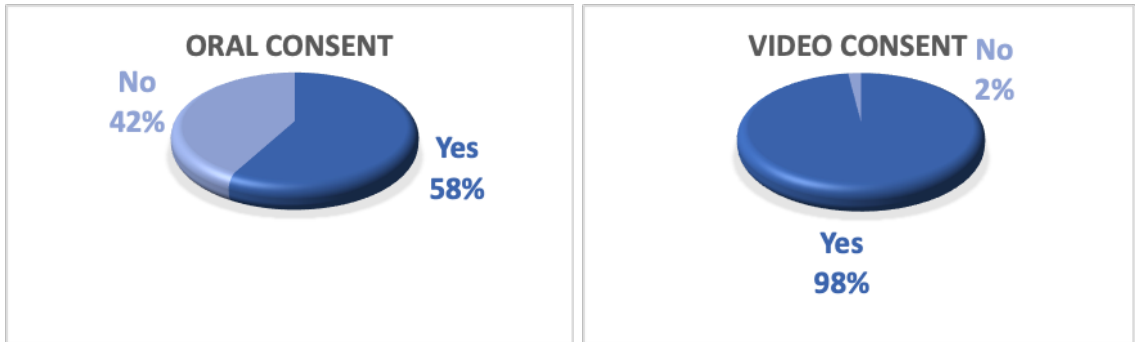


Table 8: Logistic regression analysis for question “ Do you think the use of video assisted consent would be beneficial in the future?”.

	Odds ratio (OR)	95% C.I.for EXP(B)		P value
		Lower	Upper	
Crude odds ratio				
Characteristic				
Variables in the Equation				
<u>Age</u>				
55+				0.729
35-54	2.567	0.241	27.366	0.435
18-34	2.138	0.18	25.391	0.547
<u>Gender</u>				
Gender	0.432	0.129	1.447	0.174
<u>Education Level</u>				
Junior Certificate				0.972
Leaving Certificate	0	0		0.999
Third-level	0.866	0.263	2.849	0.813

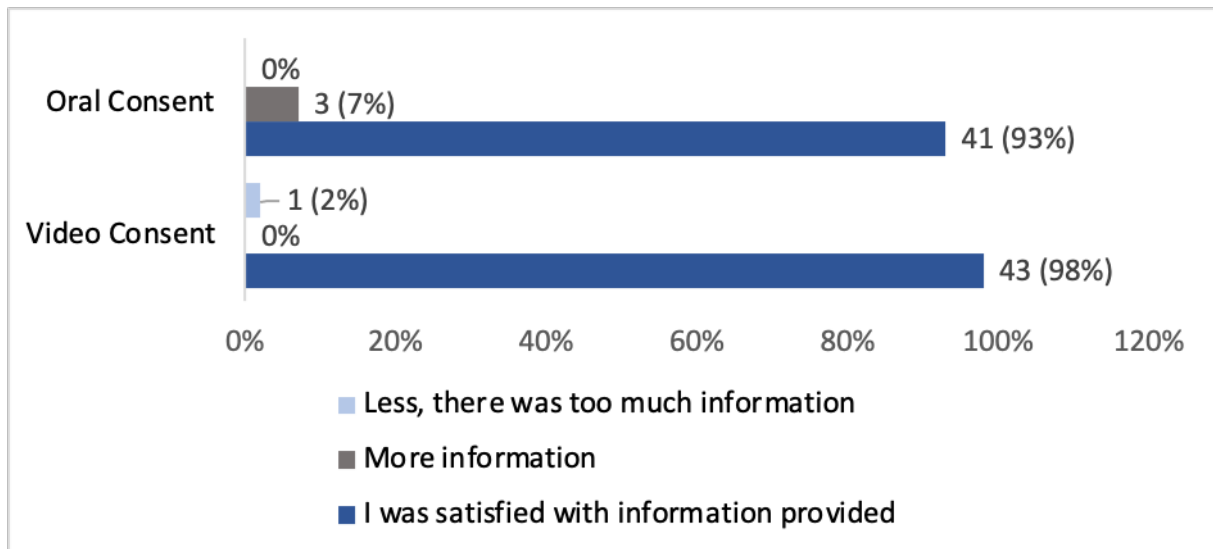
	Odds ratio	95% C.I.for EXP(B)		P value
		Lower	Upper	
Adjusted Odds Ratio				
Characteristic				
Variables in the Equation				
<u>Age</u>				
55+				0.759
35-54	2.727	0.192	38.735	0.459
Q8-34	2.292	0.159	32.996	0.542
<u>Gender</u>				
Gender	0.547	0.148	2.017	0.365
<u>Education Level</u>				
Junior Certificate				0.932
Leaving Certificate	0	0		0.999
Third-level				
Education	0.784	0.219	2.8	0.708

Review appointment

Following their third molar extraction and a recovery period of 7-14 days' patients were asked again retrospectively at their review appointment to rate their level of satisfaction with the amount of information that they received during the consent process. In the verbal consent group, 41 patients (93%) stated that they were satisfied with the amount of information that they received, with the remaining 3 patients (7%) stating that they would have liked to have received more information during the consent process. In the video consent group, 43 patients (98%) stated that they were satisfied with the amount of information that they received, with the remaining 1 patient (2%) said that they would have liked to have received less information during the consent process (Figure 24). There were no statistically significant differences between the two groups.

Patients were also asked to rate their level of satisfaction with the amount of information about each sequela/risk/complication. Figure 25 shows the number of patients that were extremely happy with the amount of information that they received.

Figure 24: Patients' response to the question regarding their satisfaction with the amount of information that they received during the consent process, at the review appointment.



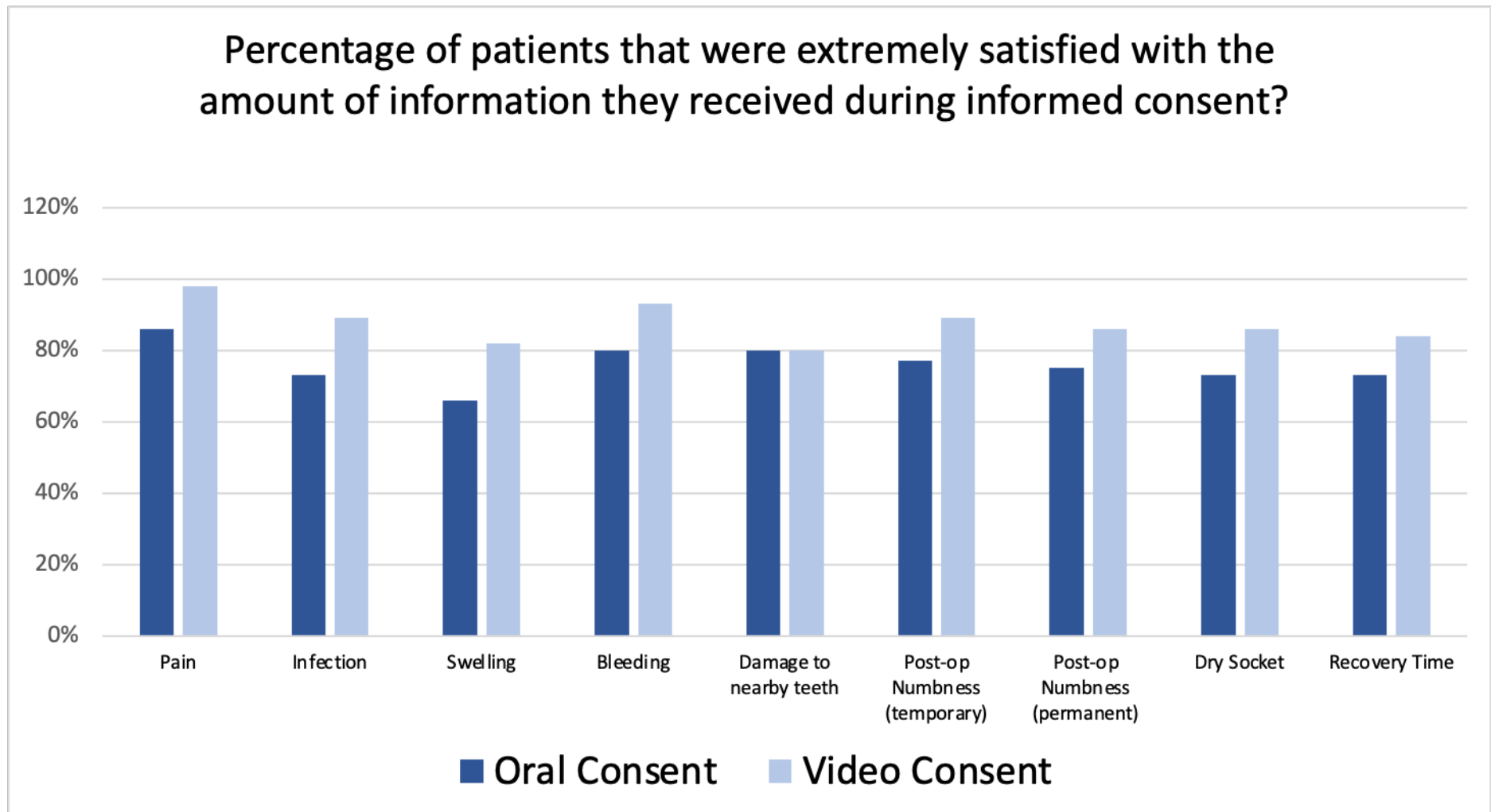


Figure 25: Percentages of participants that were extremely satisfied with the amount of information that they received about each sequela/risk/complication.

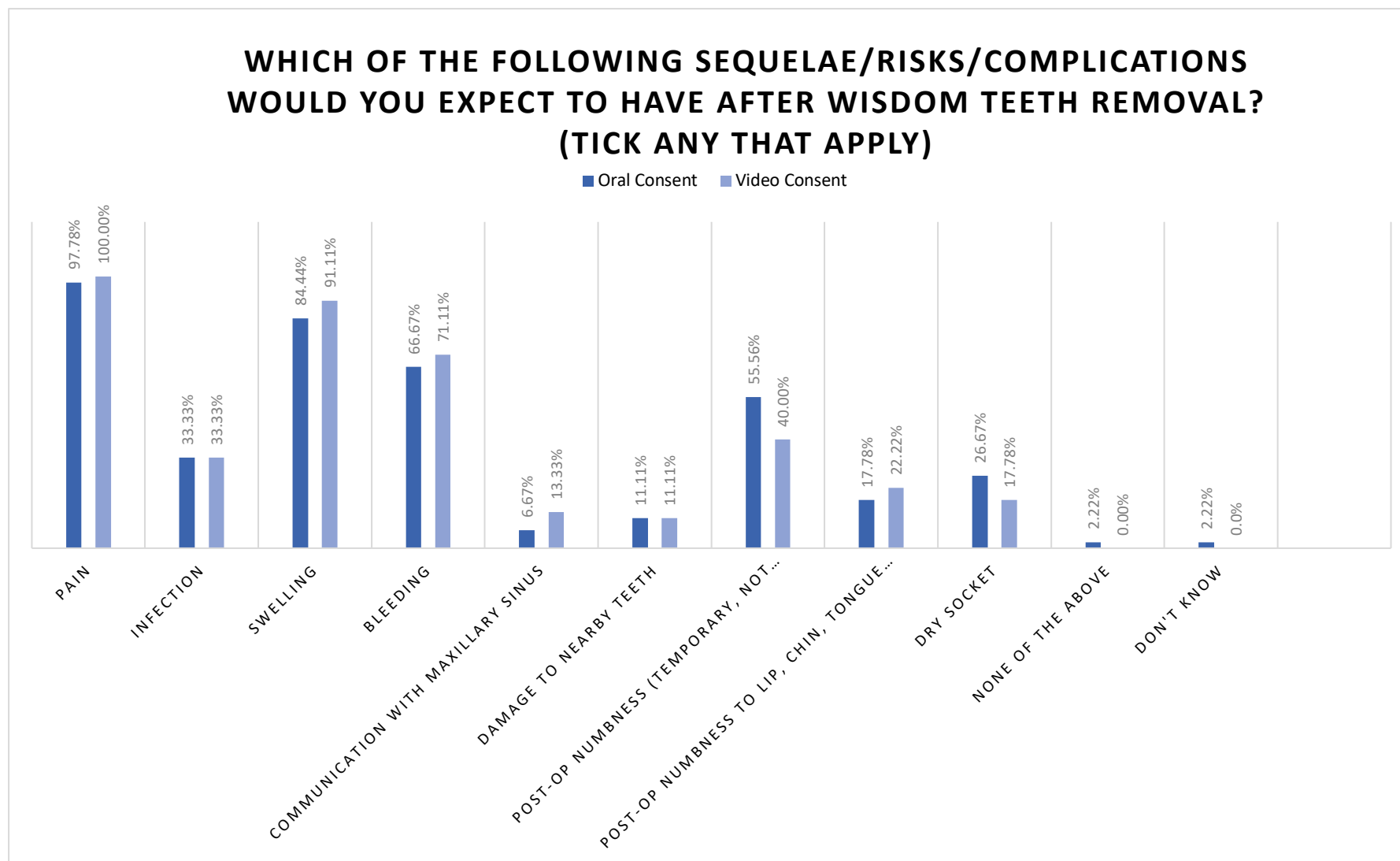


Figure 26: Participants' responses regarding which sequelae/risks/complications they expect to experience postoperatively.

Health Belief Model

Perceived susceptibility

Following the consent, participants were asked to select all of the post-operative sequelae/risks/complications that they expected to experience during the recovery period. Eight patients (18%) in the verbal consent group and 10 patients (22%) in the video consent group stated that they expected to have permanent postoperative altered sensation. Twelve patients (27%) in the verbal consent group and 8 patients (18%) in the video consent group stated that they expected to have a dry socket. In the verbal consent group, 1 patient (2%) expected to have no post-operative sequelae or complications while a further participant (2%) did not know which sequelae/risks/complications they would experience (Figure 26).

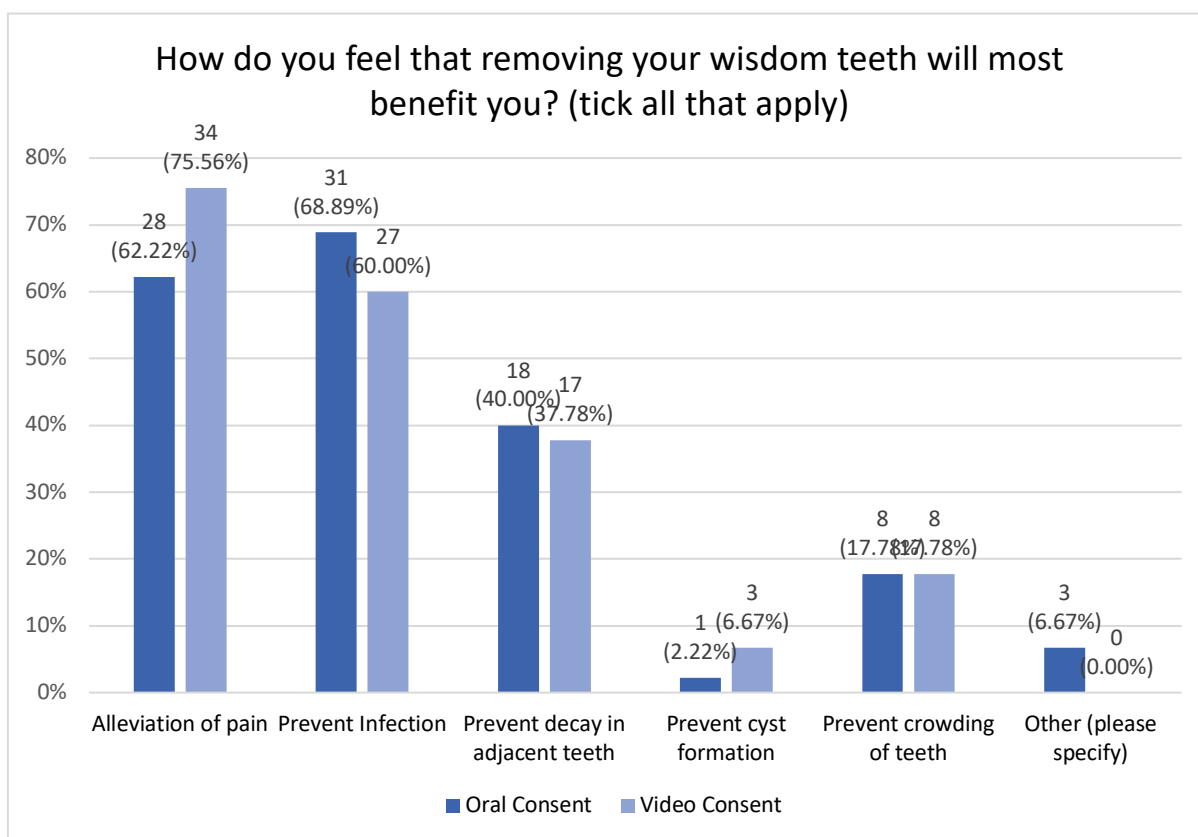
Perceived severity

Figure 19 outlines each participant's perceived level of severity/concern about each sequela/risk/complication.

Perceived benefits

Figure 27 outlines how participants felt that the removal of their third molars would benefit them. Eight patients (18%) in both the verbal consent group and the video consent group felt that removing their third molars would prevent crowding of their teeth. Three patients (7%) in the verbal consent group selected "other"; their responses included: "improve oral hygiene," "prevent potential problems" and benefit "my bone."

Figure 27: Participants' responses regarding the benefits they expect to experience as a result of third molar extraction.



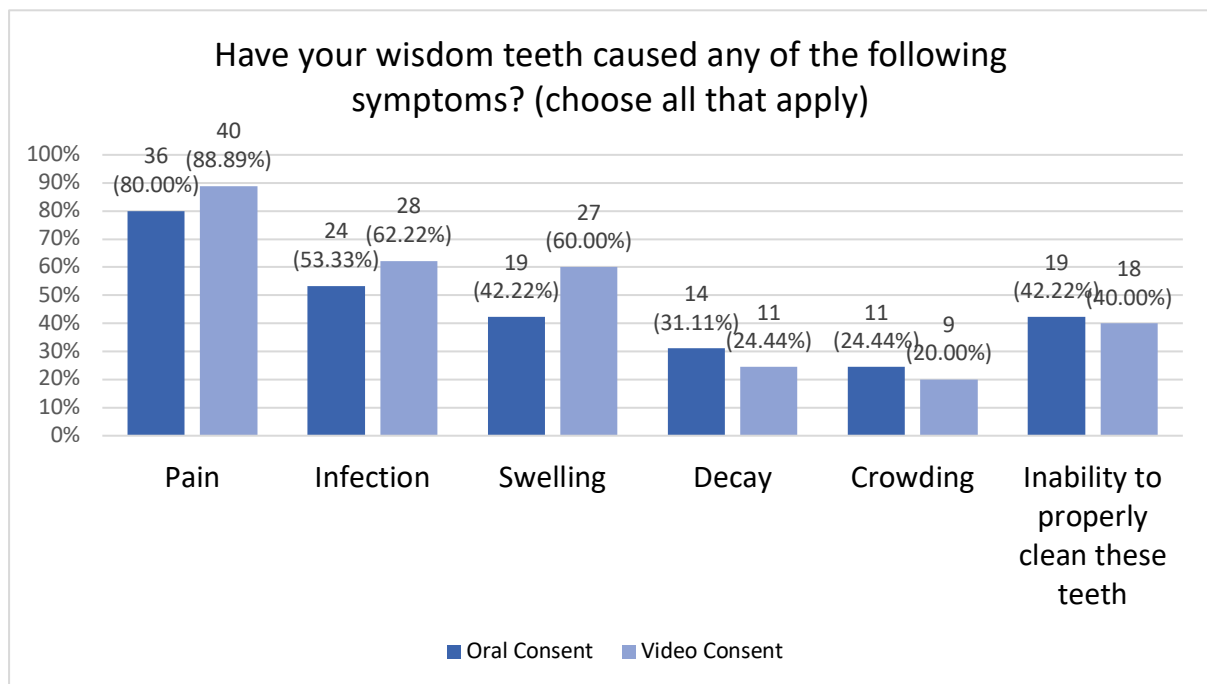
Perceived barriers

Figure 20 outlines the factors that were most likely to deter the participants from pursuing treatment.

Cue to action

Participants most commonly reported pain from their third molars with 36 patients (80%) in the verbal consent group and 40 patients (89%) in the video consent group reporting this symptom. The next most common symptom reported was infection, followed by swelling, inability to properly clean, and decay. Eleven patients (24%) in the verbal consent group and 9 patients (20%) in the video consent group reported that their third molars had caused crowding of their anterior teeth (Figure 28).

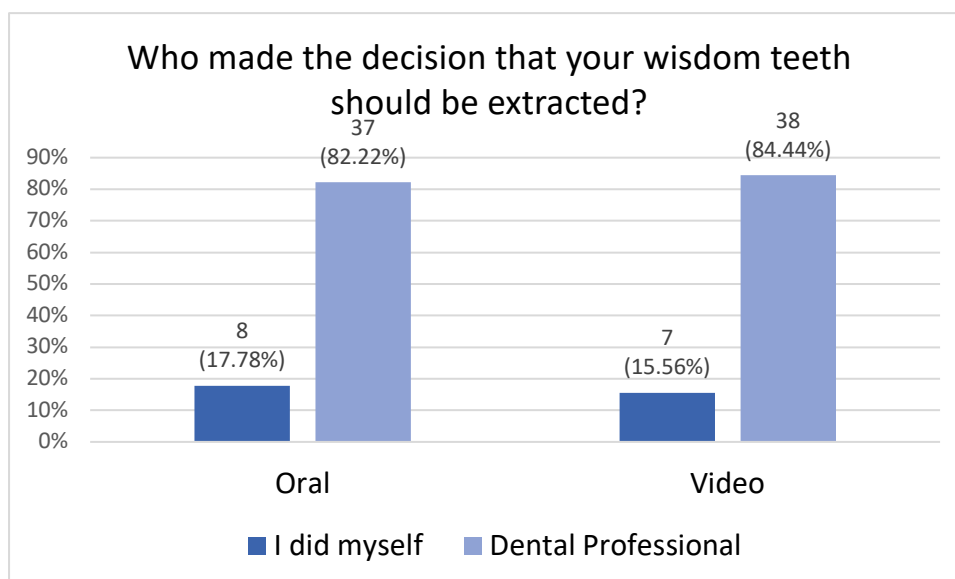
Figure 28: Frequency of symptoms related to third molar teeth reported by participants.



Self-efficacy

When participants were asked who had made the decision to have their third molar tooth/teeth extracted, 8 patients (18%) in the verbal consent group and 7 patients (16%) in the video consent group felt that they had made the decision themselves (Figure 29).

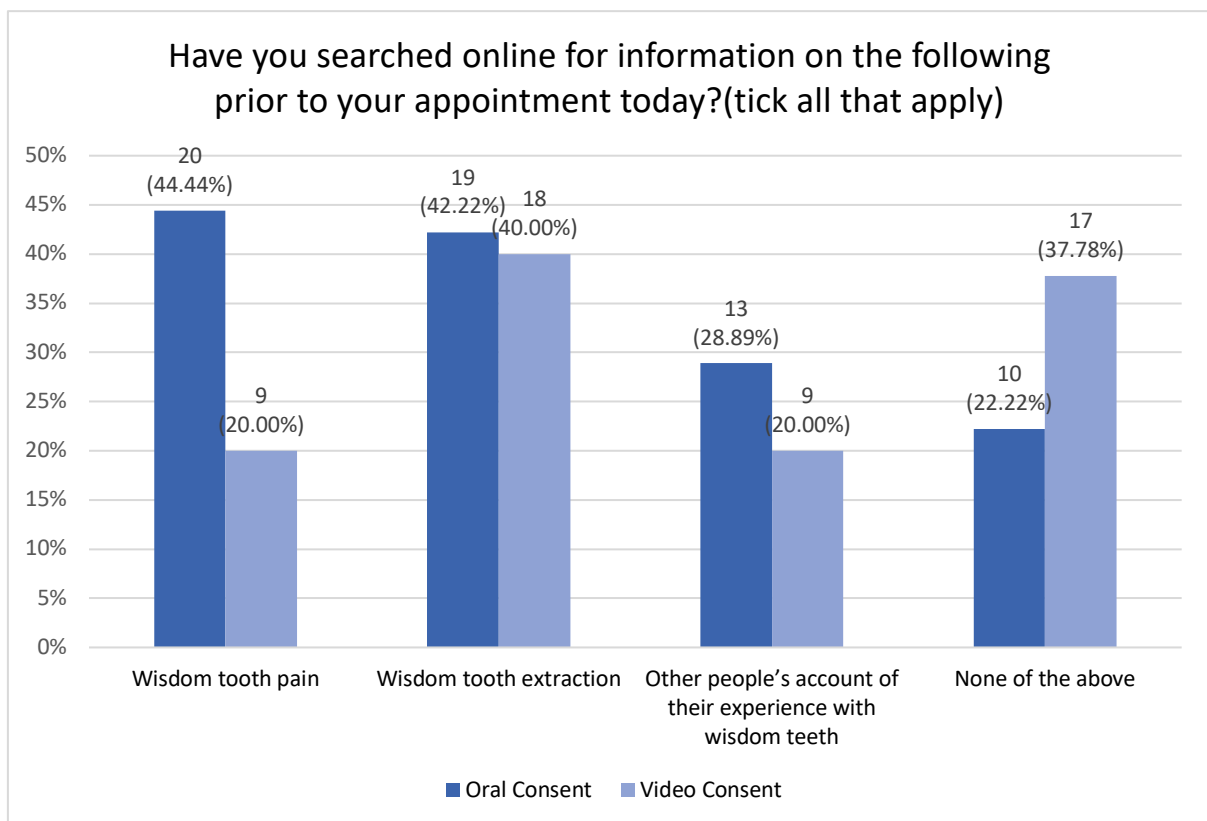
Figure 29: Participants' responses with regard to who made the decision to have their third molar tooth/teeth extracted.



Online Information

In the verbal consent group, 35 patients (78%) had searched for information online before attending for third molar extraction versus 28 patients (62%) in the video consent group. “Wisdom tooth extraction” was the most commonly searched term with 19 patients (42%) in the verbal consent group and 18 patients (40%) in the video consent group had searched for this term. “Wisdom tooth pain” was searched for by 20 patients (44%) in the verbal consent group and 9 patients (20%) in the video consent group. Patients also had searched for other people’s accounts of their experience of third molar extraction with 13 patients (29%) of those in the verbal consent group seeking this information online, versus 9 patients (20%) in the video consent group (Figure 30).

Figure 30: Frequency of online searches performed by participants before attending for third molar extraction.



DISCUSSION

Patients' level of understanding

The dental literature suggests that adjuncts to the consent process such as written information leaflets, and interactive or non-interactive multimedia should be included in the dental informed consent process. Thus, comprehensive strategies to streamline the perioperative care of patients requiring third molar extraction are necessary to ensure continued patient satisfaction and proper informed consent. Technology is being increasingly used in the outpatient perioperative surgical assessment to assist in patient education and informed consent. These technologies consistently produce more favourable outcomes than the typical verbal explanation of the procedure and the associated risks (2, 57, 85, 96, 103, 105). The major goal of the use of the video in the consent process is to provide patients with enough information about why impacted third molars should be removed, the advantages and dangers of the treatment, and any potential consequences so that they can make an educated decision about whether or not to proceed. The results of this study suggest that the use of non-interactive video consent improves patients' self-reported level of understanding. This outcome is consistent with the findings of previous studies in the literature (2, 57, 85, 96, 103, 105) that have demonstrated that when adjuncts to conventional verbal consent are used, patients have better levels of understanding and recall of the information given to them.

The study showed that the use of video-assisted consent resulted in higher levels of patient understanding about the details of what would happen during the procedure, the intended benefits of the procedure, the risks and complications and the risks if the procedure was not performed. At the review appointment, when asked retrospectively, patients in the video consent group still reported consistently higher levels of understanding. Having experienced the procedure and the postoperative recovery period, patients in the video consent group retrospectively rated higher levels of understanding about the details of what would happen during the procedure, the risks and complications and felt more sufficiently informed about each individual risk (Figure 16). This suggests that the use of the video consent either optimises patients' understanding or that the content in video format is more engaging than verbal consent,

thus improving patients' understanding. Educational videos present both visual and auditory information, have the potential to engage a diverse variety of people and provide a consistent message (120, 121). Research has shown that video-based health education, when formatted in an understandable way, is easier to comprehend for patients, as compared to other patient educational methods (122, 123).

A patient's understanding and perspectives can have a big impact on the decision-making process, especially when it comes to elective therapies. Hence, if a patient does not completely understand and appreciate the risks and benefits of an elective procedure, the patient may not be able to evaluate all relevant information and make the best decision based on their values and beliefs. This discrepancy may lead to a patient undergoing a procedure on the advice of a medical professional, ultimately increasing the risk of regret and litigation (124, 125).

According to the findings of some studies, some patients firmly state that they had not been informed of a particular risk (99), while others commented that the consenting clinician seemed rushed and they had felt that there wasn't the time for explanations or questions (126). The opportunity to ask questions is an integral part of the informed consent process and is required even when the video is the method of consent. Video-assisted consent still necessitates a follow-up engagement with the treating clinician to answer any questions and clarify any concerns. Interestingly in this study, patients in the verbal consent group were more likely to ask follow-up questions. This suggests that they had an incomplete understanding of the information given to them verbally. The most frequent questions asked by participants in the verbal consent group concerned operative details of the procedure. This suggests that the use of animated video provided more concise information about the operative procedure and reduced ambiguity for the patient.

Patient anxiety

Anxiety has a substantial impact on a patient's ability to process information cognitively. Accordingly, it is important that the consent process does not unnecessarily unnerve patients and impair their ability to make rational decisions. In this study, it was expected that patients in the video consent group would exhibit higher levels of stress after viewing the animated consent video. However, the data did not support the prediction that seeing

the video would make a large percentage of patients feel more anxious. In the studies that found higher levels of anxiety when audio-visual aids were used, the patients were not asked which components of the consent or expected treatment caused them the greatest anxiety (87, 91, 106). Therefore, it is impossible to say which aspect of the video was responsible for this outcome. However, the studies that found higher levels of anxiety in the audio-visual consent groups did use depictions of real patient procedures. The portrayal of the actual surgical procedure might be one aspect which could generate greater levels of patient anxiety. As an animated video was used in this study, it is possible, that this minimised the potential to increase participants' level of anxiety by not having to subject the participants to depictions of real-life procedures. This correlates with findings from other studies that use animated videos (127-129). The findings suggest that there is no statistically significant difference in anxiety levels between verbal and video consent when animated videos are used.

Patient satisfaction

The results of this study revealed that the use of non-interactive video consent resulted in higher levels of patient satisfaction. This outcome is consistent with the findings a previous study (103). Ninety-eight percent of patients who watched the video stated that they felt video-assisted consent would be beneficial in the future while over half of those who had been informed verbally stated that video-assisted consent would have been beneficial. Furthermore, patients who had been informed by video were significantly more satisfied with the amount of information that they received when asked retrospectively. On a patient level, adding the visual aid to verbal medical information ensures the use of more colloquial verbiage to communicate the surgical concepts simply, and breaks down health literacy or physical barriers (e.g., poor hearing, lack of concentration) to understanding the spoken word. The gamified interface may stimulate patient engagement and more active participation in the consent process.

The video-assisted informed consent process has the potential to make the consent process more attractive and beneficial to both patients and clinicians. At the clinical level, the video is designed to guide patients through the informed process in a user-friendly format that allows the patient to proceed at his/her own comfortable pace but does not necessitate

hands-on shepherding by the clinical staff. Thus, clinical staff were available to complete other clerical duties, which permitted a more streamlined clinical workflow.

Health Belief Model

Perceived susceptibility

There were no statistically significant differences between the verbal and video consent groups on the individual sequelae/risks/complications that participants were expecting to experience following third molar removal. However, the number of participants in both groups that expected to experience postoperative permanent paraesthesia or dry socket was much higher than was reported previously (23). In fact, in both the video consent group and the verbal consent group the incidence of permanent paraesthesia was reported as 0.005% or 1 in 200 patients. Despite this, 18% of participants in the verbal consent group and 22% in the video consent group expected to experience permanent postoperative altered sensation to the lip/chin and/or tongue. This is contradictory to Weinstein's "unrealistic optimism bias" theory (25), which predicts that patients show unrealistic optimism when it comes to their personal healthcare-related risks and tend to underestimate their own personal risks. The findings of this study suggest that patients overestimate their own personal risk for permanent inferior dental or lingual nerve paraesthesia. However, on orthopantomogram imaging, 13% of participants in the verbal consent group and 26% in the video consent group show radiographic signs consistent with an intimate anatomic association between the third molar to be removed and the inferior dental canal. Thus, these patients were informed that they were in the high-risk category for permanent altered sensation. Consequently, this result may not represent an overestimation of the patient's perceived personal risk but an acknowledgement of understanding of the high risk to the nerve that they were informed of.

Perceived severity and barriers

When each participant was asked about which individual risk they were most concerned about and which risk would most likely deter the participant from proceeding with the intended treatment, there were no statistically significant differences between the two groups. Interestingly, with regard to the weighted average responses for the risk that most

concerned patients, participants in both groups were more concerned with post-operative pain than the risk of permanent altered sensation of the area supplied by the inferior dental nerve and/or lingual nerve. Moreover, when asked which risk would most likely deter the patient from going ahead with third molar extraction, the weighted average response for pain (a guaranteed postoperative sequela) and permanent altered sensation (a quality of life-altering complication) were equal. This would suggest that participants in both groups do not fully comprehend the profound quality of life-altering effect that altered sensation to the lip, chin and/or tongue would have, regardless of the method of consent used.

Perceived benefits

There were no statistically significant differences between the two consent groups on the perceived benefits that participants were expecting from having their third molar tooth/teeth extracted. However, 18% of those in both the verbal and video groups felt that extraction would prevent crowding of their teeth, despite the fact that this was never mentioned to them at the assessment or during the preoperative consent process. A further 24% of patients in the verbal consent group and 20% in the video consent group reported that their third molars had caused crowding. This highlights the potential bias to which patients have been exposed from either online information sources or from anecdotal information that patients receive from their family and/or peers. Therefore, regardless of the method of consent used, it is important to assess patients' pre-conceived beliefs about the treatment at the time of the assessment and clarify any misconceptions or misinformation that they may have received.

Self-Efficacy

In healthcare ethics, autonomy is considered a core principle in contemporary medicine. The current processes of operationalising informed consent predominantly serve legal and administrative requirements, while unwittingly disempowering patients, and suppressing key aspects of their experience of shared decision-making. The Declaration of Helsinki (114) highlight the necessity of voluntary consent in medical decision-making. Despite reports that digital consent fosters better shared decision-making amongst patients and clinicians (130), just 18% of patients in the verbal consent group and 16% of patients in the video consent group felt that they themselves had made the decision regarding the

removal of their third molars. Patients may not recognise their autonomy and may feel coerced into a decision based on professional recommendations or based on the clinical setting. Perhaps patients should be reminded before signing consent forms that informed consent is a voluntary, uncoerced decision made by a competent autonomous patient to accept or reject a proposed course of action and thus defend their own autonomy.

Online Information

In the verbal consent group, 35 patients (78%) had searched for information online before attending for third molar extraction versus 28 patients (62%) in the video consent group. It is impossible to quantify how useful this information was in assisting patients to better understand the surgery process and its potential complications. It is also impossible to predict how accurate this information was, and how it may have biased or misinformed the patient. However, other investigations showed that there is a large amount of health-related misinformation on the Internet (131). The internet is an unregulated forum with sources of information of varying quality. The wealth and diversity of information and opinions expressed across the internet make the expertise and experience of clinicians more essential. Clinicians should be increasingly vigilant and ensure that a patient has consented to a given treatment option for the right reasons, based on reputable information.

Limitations of the study

A limitation of this study was that a validated tool was not employed to evaluate outcomes, thus reducing the overall robustness of the findings. An attempt was made to mitigate this issue by using a well-established and accepted psychological model (116), by consulting Eric Lacey B.A. Psychology, Trinity College Dublin and by using simple language. Additionally, the impact of dichotomisation associated with the use of Likert-type scales may be considered another limitation of the study. The consequence of their use includes loss of information about individual responses, spurious statistical significance and overestimation of the effect size when comparing two independent variables, as is the case in this study(132).

Furthermore, the power calculation for this study did not factor in logistic regression analysis. A substantially larger sample size would be required to perform multinomial

regression. Thus, the findings of this study must be interpreted with caution due to the low counts in some of the categorical variables.

Selection bias was reduced using randomisation and by the fact that no participant refused to participate in the study. However, patients with intellectual disabilities or with limited English proficiency who arguably would have benefitted most from the video were excluded. While local arrangements were in place to provide an interpreter for such patients, it was outside the scope of this study to generate patient information videos in multiple languages to accommodate these patients. This would be a consideration for future studies in this area to reduce the social exclusion of these patients and for results that more precisely represent the sample population.

Performance bias was reduced by blinding the study participants. However, performance bias is inherent to any patient agreeing to participate in a study. Attrition bias was reduced using electronic questionnaires which resulted in no incomplete data sets. However, two patients were lost to follow-up at the review appointment, 1 participant in each group.

CONCLUSION

Given the high number of medical malpractice claims involving mandibular third molar procedures, the informed consent process should be robust, thorough and engage the patient regardless of their health literacy abilities. The informed consent process must not only describe the operation in full, but also provide information on the procedure's rationale, alternative therapies, associated benefits, risks, and complications. Clinicians should strive to optimise all aspects of the informed consent process and be receptive to their patients' preferences and learning needs. Within the confines of the current study, it can be concluded that, based on the literature discussed, clinicians should attempt to incorporate adjunct resources, such as patient information leaflets, multimedia content, and informational videos when giving critical treatment information to patients.

In this study, the video-assisted consent was well received by patients with subjective improvements being made to their self-rated level of understanding, their level of satisfaction with the amount of information that they received and the means by which they received that information. This study did not find any significant increase in patients' level of anxiety following the video consent process. Although the findings from this study suggest that video-assisted consent may be beneficial to patients in the future, the author is not suggesting that video consent should replace a face-to-face discussion between patient and dentist. This interaction remains central to the patient-dentist relationship and provides a basis for shared decision-making. Video-assisted consent should not look to replace but to augment this core practice.

Although the reports of patients' understanding and satisfaction in this study suggest that dental patients display sufficient levels of comprehension and satisfaction with the conventional verbal informed consent procedure, there is always scope for improvement and optimisation of the process. The implementation of video-assisted consent may represent this optimisation. Granted, the set-up entails logistical and financial burdens initially but the benefits to the patients as stated in this study far outweigh any cost.

Metrics including quality and value of care, efficiency, and cost-effectiveness have grown increasingly relevant as dental care delivery advances. One solution to address these

expanding needs could be the use of physician-guided innovative technology such as video-assisted educational material. Using technology to increase thoroughness, uniformity, and fairness in patient consent while boosting physician productivity is possible with the use of these technologies.

In conclusion, the present study suggests that video-assisted consent could improve patient understanding of the potential postoperative risks and complications involved in surgical removal of an impacted mandibular third molar. This improved understanding did not increase patients' dental anxiety compared with conventional verbal/written consent. Additional studies are needed to evaluate the relationship between patient factors and the method of delivering treatment information in the informed consent process. Larger patient samples are recommended to validate the results of the present study.

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APPENDICES

Appendix A: Risk of bias assessment of scoping review studies

Table A1: Risk of bias assessment of included randomised studies.

CRITERION	Ader and Colleagues, 1992 ⁽⁹⁸⁾	Choi and Colleagues, 2015 ⁽⁸⁷⁾	O'Neill and Colleagues, 1996 ⁽⁵⁹⁾	Omezli and Colleagues, 2020 ⁽¹⁰⁶⁾	Yusoff and Colleagues, 2019 ⁽¹⁰⁸⁾
Random Sequence Generation (Selection Bias)	UNCLEAR	UNCLEAR	UNCLEAR	HIGH RISK	LOW RISK
Allocation Concealment (Selection Bias)	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR
Blinding of Participants and Personnel (Performance Bias)	UNCLEAR	UNCLEAR	UNCLEAR	LOW RISK	UNCLEAR
Blinding of Outcome Assessment (Detection Bias)	UNCLEAR	UNCLEAR	UNCLEAR	LOW RISK	LOW RISK
Incomplete Outcome Data (Attrition Bias)	UNCLEAR	UNCLEAR	LOW RISK	LOW RISK	LOW RISK
Selective Reporting (Reporting Bias)	UNCLEAR	UNCLEAR	LOW RISK	LOW RISK	LOW RISK
Other Sources of Bias	HIGH RISK	UNCLEAR	LOW RISK	HIGH RISK	LOW RISK
Overall Rating	HIGH RISK	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR

Source: Higgins JPT, Altman DG: Chapter 8: assessing risk of bias in included studies. In Cochrane Handbook for Systematic Reviews of Interventions. Edited by Higgins JPT, Green S. Chichester: John Wiley & Sons Ltd; 2008:187–241.

Table A2: Risk of bias assessment of included cohort studies.

CRITERION	Casap and Colleagues, 2008⁽¹⁰⁰⁾	Laskin and Colleagues, 2018⁽¹⁰⁴⁾	Olsen and Colleagues, 2017⁽¹⁰⁵⁾	Shakir and Colleagues, 2019⁽¹⁰⁷⁾
Was the Research Question or Objective in This Article Clearly Stated?	Yes	Yes	Yes	Yes
Was the Study Population Clearly Specified and Defined?	No	No	No	Yes
Was the Participation Rate of Eligible People at Least 50%?	Not reported	Not reported	Not reported	Not reported
Were All the Participants Selected or Recruited From the Same or Similar Populations (Including the Same Period)? Were Inclusion and Exclusion Criteria for Being in the Study Prespecified and Applied Uniformly to All Participants?	Not reported	Not reported	No	Yes
Was a Sample Size Justification, Power Description, or Variance and Effect Estimates Provided?	No	No	No	No
For the Analyses in This Article, Were the Exposures of Interest Measured Before the Outcomes Being Measured?	Yes	Yes	No	No
Was the Time Frame Sufficient So That One Could Reasonably Expect to See an Association Between Exposure and Outcome if It Existed?	Yes	Yes	Yes	Yes
Were the Exposure Measures (Independent Variables) Clearly Defined, Valid, Reliable, and Implemented Consistently Across All Study Participants?	No	Yes	Yes	Yes
Were the Outcome Measures (Dependent Variables) Clearly Defined, Valid, Reliable, and Implemented Consistently Across All Study Participants?	No	Yes	Yes	Yes
Were Key Potential Confounding Variables Measured and Adjusted Statistically for Their Effect on the Relationship Between Exposures and Outcomes?	No	No	No	No
Classification	Poor	Fair	Fair	Fair

Table A3: Risk of bias assessment of included cross-sectional studies.

CRITERION	Brosnam and Perry, 2009⁽³⁷⁾	Ferrus-Torres and Colleagues, 2011⁽¹⁰¹⁾	Gocmen and Colleagues, 2017⁽¹⁰²⁾	Kazancioglu and Colleagues, 2015⁽⁹¹⁾	Laskin, 2020⁽¹⁰³⁾	Layton and Korsen, 1994⁽²⁾	Layton, 1992⁽⁴⁾	Torres-Lagares and Colleagues, 2014⁽⁹²⁾
Was the Research Question or Objective in This Article Clearly Stated?	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Was the Study Population Clearly Specified and Defined?	No	Yes	Yes	Yes	Yes	No	No	Yes
Was the Participation Rate of Eligible People at Least 50%?	Yes	Not reported	No	Yes	Not reported	Not reported	Not reported	Yes
Were All the Participants Selected or Recruited From the Same or Similar Populations (Including the Same Period)? Were Inclusion and Exclusion Criteria for Being in the Study Prespecified and Applied Uniformly to All Participants?	Yes	No	Yes	Yes	Not reported	No	No	Yes
Was a Sample Size Justification, Power Description, or Variance and Effect Estimates Provided?	No	No	No	Yes	No	No	No	No
For the Analyses in This Article, Were the Exposures of Interest Measured Before the Outcomes Being Measured?	No	No	No	Yes	No	No	No	No
Was the Time Frame Sufficient So That One Could Reasonably Expect to See an Association Between Exposure and Outcome if It Existed?	No	No	Yes	No	No	No	No	No

Were the Exposure Measures (Independent Variables) Clearly Defined, Valid, Reliable, and Implemented Consistently Across All Study Participants?	No	Yes	Cannot determine	Yes	Yes	Yes	Yes	Yes
Were the Outcome Measures (Dependent Variables) Clearly Defined, Valid, Reliable, and Implemented Consistently Across All Study Participants?	No	Yes	No	Yes	Yes	Yes	Yes	Yes
Were Key Potential Confounding Variables Measured and Adjusted Statistically for Their Effect on the Relationship Between Exposures and Outcomes?	No	No	No	No	No	No	No	No
Classification	Poor	Poor	Poor	Good	Fair	Poor	Poor	Fair

Source: National Heart, Lung, and Blood Institute. Four of the original criteria were removed as they were not applicable.

Was loss to follow-up after baseline 20% or less?"

National Heart, Lung, and Blood Institute. Quality assessment tool for observational cohort and cross-sectional studies. Available at: <https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools> (Accessed April 15, 2020.)

Table A4: Risk of bias assessment of included qualitative studies.

CRITERION	ATCHISON AND COLLEAGUES 2005 ⁽⁹⁹⁾
Was There a Clear Statement of the Aims of the Research?	Yes
Is a Qualitative Methodology Appropriate?	Yes
Was the Research Design Appropriate to Address the Aims of the Research?	Yes
Was the Recruitment Strategy Appropriate to the Aims of the Research?	Yes
Were the Data Collected in a Way That Addressed the Research Issue?	Yes
Has the Relationship Between Researcher and Participants Been Considered Adequately?	Yes
Have Ethical Issues Been Taken Into Consideration?	Yes
Was the Data Analysis Sufficiently Rigorous?	No
Is There a Clear Statement of Findings?	Cannot tell
How Valuable Is the Research?	Yes
Overall Rating	8 of 10

Appendix B: Application Process for School of Dental Science REC

RESEARCH APPLICATION CHECKLIST

Please answer all question yes, no or not applicable as appropriate to the following questions. If you answer no to any question, please explain why and the relevant question number in the comment box at the end of the form

	YES	NO
1. Is this a level 1 application (as per website insert link)?	X	
2. Is this a level 2 application (as per website insert link)?		X

Please tick the appropriate box	YES	NO	NA
1. Are you undertaking the proposed research study in your capacity as a staff member of the School of Dental Science?		X	
2. Are you undertaking the proposed research study in your capacity as a student of the School of Dental Science?	X		
3. If you are a student, has your supervisor read, approved and signed the completed form?	X		
4. Have you signed the application form?	X		
5. Have you checked that your application meets the criteria for this research ethics committee?	X		
6. Are you recruiting participants for this study?	X		
7. Are the participants purposefully recruited from a vulnerable group?		X	
8. Is this a health research study?	X		
9. Does the study include a health intervention?		X	
10. Are you collecting personal or sensitive data?	X		
11. Have you completed and included a risk assessment (for data) for this study (<i>Risk Assessment Link</i>)?	X		
12. Do you require a Data Protection impact assessment?			X
13. If applicable (yes to Q8), have you completed a Data Protection impact assessment (<i>DPIA link</i>)?	X		
14. If accessing personal or sensitive data have you successfully completed Trinity GDPR online course? <i>LINK</i>	X		
15. If accessing collecting personal or sensitive data, and you are an undergraduate or master's student has your supervisor successfully completed Trinity GDPR online course?	X		
16. If accessing collecting personal or sensitive data, have all Trinity members of the research team listed, successfully completed Trinity GDPR online course? <i>LINK</i>	X		
17. Have you included a copy of the questionnaires, interview template, data extraction list?	X		
18. Are you collecting samples, no matter how small, that could be used for genetic testing?		X	
19. If applicable, have you included the consent form and participation	X		

information leaflet?			
20. If applicable, have you included all relevant letters of permission /access from external agencies/organizations/ schools/ industry / clinical site hosting the study, from the appropriate responsible people agreeing access included including access to databases?	X		
21. If applicable, have you included the letter to the participants?	X		
22. If applicable, have you included any posters/other material used to advertise the study?			X
23. If collecting personal or sensitive data, have you included detailed information on how you will implement security measures to protect the personal data in all its forms and all types e.g. device encryption?	X		
24. Have you included any other documents that are needed for your study i.e. Garda clearance, debrief documentation?			X
25. If collection personal or sensitive data do you agree to only use the minimum data necessary to carry out the research?	X		
26. Have you put in all the necessary security arrangements required to collect, process store and destroy any personal or sensitive data required for this study?	X		
27. Are there any contractual arrangement required in order to carry out this study?		X	
28. Have you read and will abide by the requirements regarding research reporting, data storage and reporting of adverse events ?	X		

If you have answered NO to any of the above questions (except 1,2, 6, 23) please explain:

- 7. Participants are not recruited from a vulnerable group
- 9. No health intervention
- 18. No samples being collected
- 27. No contractual arrangements required in order to carry out study

Section 2: Project Description

Name of Applicant
Ciara Mulvihill
Academic Supervisor/Lead Researcher
Mr. Dermot Pierse
Academic Division
Oral Surgery, Division III
Title of project
Informed consent for third molar extraction; a comparison of conventional verbal consent versus video-assisted consent
Timeframe of research

Gantt chart	Year 1			Year 2			Year 3		
Calendar Timeline									
D.Ch.Dent: Ciara Mulvihill	Q1	Q2	Q3	Q1	Q2	Q3	Q1	Q2	Q3
Protocol development	◆	◆							
Ethical submission/approval		◆	◆						
Data collection			◆	◆	◆	◆	◆		
Data analysis				◆	◆	◆	◆	◆	◆
Dissemination									◆
Supervisor meetings	◆	◆	◆	◆	◆	◆	◆	◆	◆
SPSS course				◆					
Cont. education lectures	◆	◆	◆	◆	◆	◆	◆	◆	
IDA conference			◆			◆			◆
IADR conference				◆			◆		
Publications			◆			◆			◆

Legend

Time that work is expected to take place on a work-package/objective = ◆

Purpose of research

This research aims to assess if presenting information about third molar extraction via an informative, narrated, animated video changes a patients' perception of risk associated with third molar extraction when compared to conventional verbal consent.

Primary research question

Does the use of video assisted consent for third molar extraction affect patient's self-reported level of understanding of the proposed procedure and the associated risks?

Secondary research questions

Does the use of video assisted consent for third molar extraction affect patient's self-reported level of anxiety about the proposed procedure and the associated risks?

Does the use of video assisted consent for third molar extraction affect patient's self-reported level of satisfaction with the consent process and the quality and quantity of information they receive about the proposed procedure and the associated risks?

Are certain patient demographics (age, sex, education level) more receptive to the use of video assisted consent for third molar extraction?

Participants in the research

Inclusion criteria

Patients attending the Dublin Dental University Hospital for mandibular third molar extraction who met the following criteria were included in the study:

- Patients that were sixteen years and older
- Patients that were diagnosed with a mandibular third molar that required surgical extraction.
- Patients that were deemed medically fit to undergo a surgical procedure i.e. healthy or well-controlled systemic disease (American Society of Anaesthesiology classification I or II.)
- Patients that were adequately able to understand/read and speak the English language.

Exclusion criteria

Patients attending the Dublin Dental University Hospital for mandibular third molar extraction who met the following criteria were excluded from the study:

- Patients with cognitive impairment, significant psychiatric ailments or who lacked the capacity to provide consent.
- Patients with an inability to adequately understand, speak and read the English language.
- Patients that had a previous mandibular third molar extraction.
- Patients having additional surgical procedures (i.e. treatment of a cyst)

Recruitment procedures

There will not be any incentives and/or compensation (financial or otherwise) offered to participants.

Methods

Patients attending for mandibular third molar extraction will be invited to participate in the survey. Participants will be randomly assigned to one of two categories; A. oral consent only, B. video-assisted consent. Once consent is obtained, participants will be given a tablet to complete an online survey. Patients in both groups will receive the same information (via different delivery methods) and questionnaires. Patients attending for review appointments 7-14 days post-operatively will be invited to complete a survey rating their experience of the consent process. Respondents will be told that they can exit the survey at any point of the study. The consent procedure will be outlined in a Consent Statement at the beginning of an electronic survey as per ethical approval requirement. This will include the identity of the researcher, contact details, the reason for conducting the survey and the uses to be made of the data. A paper version of the survey will also be available in case of device malfunction.

Decision-making theories were explored and ultimately The Health Belief Model (HBM)²² was used to aid in the composition of the patient survey used to carry out a pilot study on patients' perception of risk prior to third molar removal at Cork University Dental School and Hospital. This psychological model is widely accepted and is used to explain and predict health behaviours

Having developed an initial set of candidate questions for inclusion in the questionnaire, the acceptability of the questions was tested through piloting the survey and by consulting Eric Lacey B.A. Psychology, Trinity College Dublin. Based on the results of the pilot study the questionnaire was revised and amended. In order to handle information securely, the encrypted Survey System, SurveyMonkey was used to create the finalized questionnaire included below.

Baseline Questionnaire

Male ☐ Female ☐

Age

- Under 18 ☐
 18-24 ☐
 25-34 ☐
 35-44 ☐
 45+ ☐

Occupation

Smoker yes ☐ no ☐

Education Background

- No cert/junior cert ☐
 Leaving Cert ☐
 Third Level Education ☐

Ciara Mulvihill

To allow for cross comparison with perceived risk of dry socket

Ciara Mulvihill

May suggest a patients' level of medical literacy/comprehension

Have you searched online for information on the following prior to your appointment today? (tick all that apply)

- Wisdom tooth pain ☐
 Wisdom tooth extraction ☐
 Other peoples account of their experience with wisdom teeth ☐

Ciara Mulvihill

Indication of exposure to potential bias prior to appointment

Do any of these statements reflect your understanding with regard to wisdom teeth?

- All wisdom teeth must be removed eventually ☐
 Wisdom teeth are problematic teeth that need to be removed ☐
 Wisdom teeth only need to be removed if they cause a problem ☐
 Wisdom teeth cause crowding of the teeth ☐
 Wisdom teeth can be a valuable part of a person's dentition ☐
 Wisdom teeth need to be removed if planning to get braces on teeth ☐

Ciara Mulvihill

Address HBM external "cue to action" and "perceived susceptibility"

Have your wisdom teeth caused the following symptoms (tick any that apply)

- Pain ☐
 Infection ☐
 Swelling ☐
 Decay ☐
 Crowding ☐
 Inability to properly clean these teeth ☐

Ciara Mulvihill

Address HBM internal "cue to action"

Which of the following sequelae/risks/complications would you expect to have after wisdom teeth removal (tick any that apply)?

- Pain ☐ Post-op Numbness (temporary, not associated with numbing injections) ☐
 Infection ☐ Post-op Numbness to lip, chin, tongue (permanent) ☐
 Swelling ☐ Dry Socket ☐
 Bleeding ☐ None of the above ☐
 Communication with maxillary sinus ☐
 Damage to nearby teeth ☐
 Don't know ☐ Other

Ciara Mulvihill

Measures HBM "perceived susceptibility" (subjective perception of risk) and patients level of understanding

Which of these possible sequelae/risks/complications concern you most (Rate 0-10, 0 being not concerning 10 being most concerning)

- Pain Post-op Numbness (temporary, not associated with numbing injections)
 Infection Post-op Numbness to lip, chin, tongue (permanent)
 Swelling Dry Socket
 Bleeding Recovery time
 Communication with maxillary sinus Cost of treatment
 Damage to nearby teeth

Ciara Mulvihill

Measures HBM "perceived severity" (perception of the seriousness of the threat involved)

How do you feel removing your wisdom teeth will most benefit you? (tick all that apply) Alleviation of Pain ☐ Prevent Infection ☐ Prevent decay in adjacent teeth ☐ Prevent cyst formation ☐ Prevent crowding of teeth ☐ Other _____		Ciara Mulvihill Measures HBM "perceived benefit"														
Which factor(s) would be most likely to deter you from having your wisdom teeth removed? (tick any that apply) <table border="0"> <tr> <td>Pain ☐</td> <td>Post-op Numbness (temporary, not associated with numbing injections) ☐</td> </tr> <tr> <td>Infection ☐</td> <td>Post-op Numbness to lip, chin, tongue (permanent) ☐</td> </tr> <tr> <td>Swelling ☐</td> <td>Dry Socket ☐</td> </tr> <tr> <td>Bleeding ☐</td> <td>Cost of treatment ☐</td> </tr> <tr> <td>Communication with maxillary sinus ☐</td> <td>None of the above ☐</td> </tr> <tr> <td>Damage to nearby teeth ☐</td> <td></td> </tr> <tr> <td>Recovery time ☐</td> <td></td> </tr> </table> • Need to arrange time off work ☐ • ~~Disruption~~ to family/domestic situation ☐ • Disruption with studies/sport ☐ Other _____		Pain ☐	Post-op Numbness (temporary, not associated with numbing injections) ☐	Infection ☐	Post-op Numbness to lip, chin, tongue (permanent) ☐	Swelling ☐	Dry Socket ☐	Bleeding ☐	Cost of treatment ☐	Communication with maxillary sinus ☐	None of the above ☐	Damage to nearby teeth ☐		Recovery time ☐		Ciara Mulvihill Measures HBM "perceived barriers" (negative consequence of undertaking the action)
Pain ☐	Post-op Numbness (temporary, not associated with numbing injections) ☐															
Infection ☐	Post-op Numbness to lip, chin, tongue (permanent) ☐															
Swelling ☐	Dry Socket ☐															
Bleeding ☐	Cost of treatment ☐															
Communication with maxillary sinus ☐	None of the above ☐															
Damage to nearby teeth ☐																
Recovery time ☐																
<u>For Clinical Staff</u> Consultation ☐ Day of Surgery ☐ Oral <u>Consent</u> ☐ Video Consent ☐ Teeth to be extracted <u>Upper</u> Lower Circle the teeth, which you would consider to be in close association with ID nerve/Sinus <u>8/8</u> 8/8																

Post Consent Questionnaire

Who made the decision with regard to having your wisdom teeth extracted?

- ☒ I did myself
☐ My general dentist
☐ My Orthodontist
☐ An Oral Surgeon

Ciara Mulvihill

Address level of self-autonomy

Which of the following sequelae/risks/complications do you expect to have after you have your wisdom teeth extracted (tick any that apply)?

- | | |
|---|---|
| ☐ Pain | ☐ Post-op Numbness (temporary, not associated with numbing injections) |
| ☐ Infection | ☐ Post-op Numbness to lip, chin, tongue (permanent) |
| ☐ Swelling | ☐ Dry Socket |
| ☐ Bleeding | ☐ None of the above |
| ☐ Communication with maxillary sinus | ☐ Other _____ |
| ☐ Damage to nearby teeth | |
| ☐ Don't know | |

Ciara Mulvihill

Measures HBM "perceived susceptibility" (subjective perception of risk) and patients level of understanding

Which of these possible sequelae/risks/complications concern you most? (Rate 0-10, 0 being not concerning 10 being most concerning)

- | | |
|---|---|
| ☐ Pain | ☐ Post-op Numbness (temporary, not associated with numbing injections) |
| ☐ Infection | ☐ Post-op Numbness to lip, chin, tongue (permanent) |
| ☐ Swelling | ☐ Dry Socket |
| ☐ Bleeding | ☐ Recovery time |
| ☐ Communication with maxillary sinus | ☐ Cost of treatment |
| ☐ Damage to nearby teeth | |

Ciara Mulvihill

Measures HBM "perceived severity" (perception of the seriousness of the threat involved)

How do you feel removing your wisdom teeth will be of most benefit to you? (tick all that apply)

- ☐ Alleviation of Pain
☐ Prevent Infection
☐ Prevent decay in adjacent teeth
☐ Prevent cyst formation
☐ Prevent crowding of teeth
☐ Other _____

Ciara Mulvihill

Measures HBM "perceived benefits"

What factor would be most likely to deter you from having your wisdom teeth removed? (tick all that apply)

- | | |
|--|---|
| ☐ Pain | ☐ Post-op Numbness (temporary, not associated with numbing injections) |
| ☐ Infection | ☐ Post-op Numbness to lip, chin, tongue (permanent) |
| ☐ Swelling | ☐ Dry Socket |
| ☐ Bleeding | ☐ Cost of treatment |
| ☐ Communication with maxillary sinus | ☐ None of the above |
| ☐ Damage to nearby teeth | |
| ☐ Recovery time | |
| ☐ Need to arrange time off work
☐ Disruption to family/domestic situation
☐ Disruption with studies/sport | |

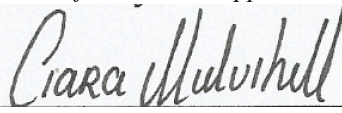
Ciara Mulvihill

Measures HBM "perceived barriers" (negative consequence of undertaking the action)

Tuesday

Mark-

Rate from 1-10 your understanding of the information you have received about the proposed procedure? (1=little understanding 10= complete understanding) Details of what happens during the proposed procedure — The intended benefits of the proposed procedure — The risks/complications of the proposed procedure — The risks/complications if the proposed procedure is not performed — Would you like to have received more or less information on the sequelae/risks/complications of the proposed procedure? More ☐ Less ☐ I was satisfied with the amount of information I received ☐ If you have selected "More" for the previous question, please provide more detail on sequelae/risks/complications that you would have liked to discuss further Review Appointment Questionnaire Do you feel that you were informed sufficiently about the following sequelae/risks/complications? (Rate 0-10, 0= given no information 10: fully informed) <table border="0"> <tr> <td>Pain ☐</td> <td>Post-op Numbness (temporary, not associated with numbing injections) ☐</td> </tr> <tr> <td>Infection ☐</td> <td>Post-op Numbness to lip, chin, tongue (permanent) ☐</td> </tr> <tr> <td>Swelling ☐</td> <td>Dry Socket ☐</td> </tr> <tr> <td>Bleeding ☐</td> <td>Cost of treatment ☐</td> </tr> <tr> <td>Communication with maxillary sinus ☐</td> <td>Other _____ ☐</td> </tr> <tr> <td>Damage to nearby teeth ☐</td> <td></td> </tr> <tr> <td>Recovery time ☐</td> <td></td> </tr> </table> • Need to arrange time off work ☐ • Disruption to family/domestic situation ☐ • Disruption with studies/sport ☐ Rate from 1-10 your understanding of the information that you received about the procedure? (1=little understanding 10= complete understanding) Details of what would happen during the proposed procedure — The intended benefits of the proposed procedure — The risks/complications of the proposed procedure — The risks/complications if the proposed procedure was not performed — Would you like to have received more or less information on the sequelae/risks/complications of the procedure? More ☐ Less ☐ I was satisfied with the amount of information I received ☐ If you have selected "more" please provide more detail on sequelae/risks/complications that you would have liked to have discussed further	Pain ☐	Post-op Numbness (temporary, not associated with numbing injections) ☐	Infection ☐	Post-op Numbness to lip, chin, tongue (permanent) ☐	Swelling ☐	Dry Socket ☐	Bleeding ☐	Cost of treatment ☐	Communication with maxillary sinus ☐	Other _____ ☐	Damage to nearby teeth ☐		Recovery time ☐		Ciara Mulvihill Measures patients perceived level of understanding
Pain ☐	Post-op Numbness (temporary, not associated with numbing injections) ☐														
Infection ☐	Post-op Numbness to lip, chin, tongue (permanent) ☐														
Swelling ☐	Dry Socket ☐														
Bleeding ☐	Cost of treatment ☐														
Communication with maxillary sinus ☐	Other _____ ☐														
Damage to nearby teeth ☐															
Recovery time ☐															
Ethical considerations and potential risks to participants The anticipated ethical issues raised by the project are in relation to data handling and protecting the anonymity of participants. In order to handle information securely the Survey System, SurveyMonkey will be used. In order to preserve the anonymity of the participants the option to save time and date stamp with responses will be disabled. The sole person allowed access to the SurveyMonkey account will be by the principal investigator															
Published ethical guidelines to be followed Irish Dental Council code of practice relating to 'Professional Behaviour and Ethical Conduct' section 7: "Patient Consent"															

Signature of applicant: <i>I declare that I have read the TCD Ethics Policy and will follow the guidelines therein.</i> For student applications: <i>I also confirm that this application has already been reviewed and is supported by my supervisor.</i> 
--

Section 3: Consent

3.1 Will you obtain consent for this research?

☒ Yes ☐ No

If the answer is **no**, please skip to section 4.

3.2 Please specify the type of consent:

Informed consent (from an ethical perspective)

Irrevocably anonymised data, or pseudonymised data that is anonymised in the hands of the Data Controller carrying out the health research. Specifically, there is no means or no intention to process the data in a manner that could identify the data subject

Explicit consent (for health research only)

Explicit consent: informed consent that is documented, (you must maintain evidence that it has been recorded). Please note that explicit consent is now a mandatory safeguard under the Health Research Regulations unless data are irreversibly anonymized (no key held) or a consent declaration has been obtained from the health research consent declaration committee HRCDC) See here for further information.

NB: *Consent to the use of personal data is not an appropriate legal basis for health research or any other research given the imbalance which exists between the data subject and the researcher. Please ensure you use scientific research¹ in the public interest² as your legal basis.*

3.3. How will you ensure informed / explicit consent is obtained from the research participants?

See below; page 19 onwards

N.B. Please indicate if you have modified the consent form and/or the participant information leaflet included in the link above?

Yes ☐ No ☒

If **yes** please highlight the changes made and why these were necessary.

If template is changed substantially - this will need to be reviewed by Deputy DPO for Research: email: researchDPO@tcd.ie

3.4 What is the time interval between giving information and seeking consent or participation?

The time interval between giving information and obtaining consent is within the same appointment. The justification for this is that the research aims to measure patients perception of risk prior to consultation and immediately after assessment.

3.5 Will the participants be purposefully recruited from any of the following groups (tick as appropriate) (i.e. children, prisoners, adults with mental illness where having/had a mental illness is an inclusion criterion of the study population)

¹ Article 9, 2, (j)

² Article 6

	YES	NO	Not known
Children under 18 years of age		X	
Adults with learning disabilities		X	
Adults with communication difficulties		X	
Adults who are unconscious or very severely ill		X	
Adults who have a terminal illness		X	
Adults with mental illness		X	
Adults suffering from dementia		X	
Prisoners		X	
Young Offenders		X	
Those who could have been considered to have a particularly dependent relationship with the investigator, e.g. those in care homes, students, line manager of participants		X	
Other groups who may be considered vulnerable (Please specify below)		X	
<i>NB: Inclusion of these groups will likely raise the risk level of the project to Level 2 and as such, Should be submitted to a level 2 committee.</i>			

3.6 If participants are to be recruited purposefully from any of the potentially vulnerable groups listed above, please complete the following:

- (a) The extra steps taken to ensure that participants from any of these vulnerable groups are as fully informed as possible about the nature of their involvement
NA Vulnerable groups not purposefully recruited
- (b) Who will give consent NA Vulnerable groups not purposefully recruited
- (c) How consent will be obtained (e.g. will it be verbal, written or visually indicated?)
NA Vulnerable groups not purposefully recruited
- (d) When consent will be obtained NA Vulnerable groups not purposefully recruited
- (e) The arrangements that have been made to inform those responsible for the care of the research participants of their involvement in research NA Vulnerable groups not purposefully recruited

3.7 Will participants include women of childbearing potential?

Yes ☒
IF NO, PLEASE EXPLAIN WHY

No ☐

NOTE: This information is required regardless of whether there are potential implications for the well-being of participants

3.8 If women of childbearing potential are to be involved, do the study design and the Participant Information Leaflet address the 9 essential points listed in the linked checklist, found here: <https://www.tcd.ie/dental/research/research-ethics/Research-on-women-of-childbearing-potential.pdf>

Yes ☒

No ☐

NOTE: This information is required regardless of whether there are potential implications for the well-being of participants

Section 4: Confidentiality, data protection, data processing and data storage

4.1 Does the study involve collecting, using, accessing or sharing personal data³?

Please read footnotes 1 & 2 to ensure you are answering this question correctly

³ Personal data is information which can identify a person – in particular: a name, address, email, telephone number, an identification number, location data, an online identifier, or and IP address.

Yes

☒

No

☐

If you are not collecting personal data, please skip to question 4.2

If yes please give details of the personal data to be collected and list all media/ forms utilised: online, hard copy, audio, video, photographs etc. and processing activity. Finally, please indicate how the personal data being collected relate to the aims and objectives of the study. (Justification)

Data Collected	Justification	Processing Activity
<i>EXAMPLE: Participant hospital number</i>	<i>To correlate data from assessment, day of surgery and post treatment data</i>	<i>Excel database, situated in 'Student' Drive on 'hospital' desktop computer at DDUH site</i>
<i>EXAMPLE: Participant email/mobile number</i>	<i>Identification, so that the patient can be sent link to information website</i>	<i>Salud, Excel database, situated in 'Student' Drive on 'hospital' desktop computer at DDUH site</i>

4.2 Does the study involve collecting, using, accessing or sharing sensitive data⁴?

Yes

☒

No

☐

If you are not collecting personal or sensitive data, please skip to question 4.14.

If yes please give details of the sensitive data collected.

Please indicate below how collecting such data is relevant to the aims and objectives of the study.

Data Collected	Justification	Processing Activity
<i>EXAMPLE: Participant hospital number</i>	<i>To correlate data from assessment, day of surgery and post treatment date</i>	<i>Excel database, situated in 'Student' Drive on 'hospital' desktop computer at DDUH site</i>
<i>EXAMPLE: Participant email/mobile number</i>	<i>Identification, so that the patient can be sent link to information website</i>	<i>Salud, Excel database, situated in 'Student' Drive on 'hospital' desktop computer at DDUH site</i>

4.3 Who will determine the 'how' and 'why' the data is used? (i.e. data controller or joint controllers if more than one)

DDUH are the data controllers

4.4 Specify the name/s of any personnel who will have access to the personal and/or sensitive data? Please list all individuals including those who are employees or students of other institutes/hospitals etc. Indicate the format in which they will receive the data i.e. identifiable or pseudonymised?

(For other personnel working under contract - such as data inputters and transcribers see 4.5)

Personnel names	Data access to	Format available to these
-----------------	----------------	---------------------------

⁴ Sensitive personal data means genetic, biometric and health data, as well as personal data revealing racial and ethnic origin, political opinions, religious or ideological convictions or trade union membership.

4.5 Specify the name/s of any service providers such as transcribers, third party's carrying out analysis, data collection etc.?

Indicate the format in which they will receive the data i.e. identifiable or pseudonymised? Please confirm and attach the agreement that is in place with the service provider.

Personnel names	Data access to	Format available to these
EXAMPLE: Maria Van Harten (DDUH statistician)	Monkey Survey data	Monkey Survey data

4.6 During and after the study, what steps will you take to protect the confidentiality of personal or sensitive personal data collected as part of the project? (e.g. Participant identities, contact details, consent forms, code keys that link personal or sensitive personal data to other data, data collected from patient/client records). Please specify details for all that apply and likewise for all media forms utilised (online, hard copy, audio etc.)

Data will only be stored for the legal minimal requirement. Double encryption will be applied to all computers, laptops and mobiles devices. Personal data will not be stored on portable devices.

Personal/sensitive data type	Media Format	Storage Details:
Pseudo anonymized patient number vs research number	Excel spreadsheet	DDUH student network

4.7 Please specify that you have a log and controls in place to record who accesses, changes, discloses or erases all personal data collected. In the case of repository data, changes and erasures only need to be logged

NA

4.8 Indicate clearly when processing (i.e. pseudonymisation, anonymization, deletion) will occur. Please indicate who will be responsible for these processes and who will retain the key code if applicable

When participants consent to participation in the research project they will be allocated a number within the research project. This will be pseudonymized with their DDUH patient number on an excel database by the principle investigator (CMulvihill). The principle investigator (CMulvihill) will have the sole access to the key code to access the excel database.

4.9 Accepted best practice recommends secure retention of personal non-anonymised (of all the types listed previously) for 7 years. If there is any reason to apply for a variation from these guidelines, please give details and provide a justification.

Consent forms used will be retained for 7 years, as evidence of consent in compliance with GDPR.

The principle investigator will handover all data to supervisor/equivalent if/when they leave Trinity.

Personal/sensitive data type and media format	Format	Retention time, when it will be destroyed
EXAMPLE: DDUH number vs research number	Pseudonymized.	7 years
EXAMPLE: consent form	Paper format	7 years

4.10 If identifiable data or material (photographs etc.) will be retained after the study is completed, is it stated on the informed consent form that this will be done and that material will not be used in future unrelated studies without further specific permission being obtained?

Yes ☐ No ☒

4.11 Researchers must allow the participant access to their personal data including their transcript if they so wish (right of access and right of rectification). Please give details of these arrangement.

Patients will have right of access to their personal data at any time during the study

4.12 How will you ensure the participants can use their other rights as required under GDPR?

These include:

- right to erasure;
- right to object to processing based on public interest;
- right to data portability;
- right to object to profiling or making decisions about individuals by automated means?

Participant rights' shall be outlined in the invitation to participate in the study

These include

- right to erasure;
- right to object to processing based on public interest;
- right to data portability;
- right to object to profiling or making decisions about individuals by automated means?

4.13 Do you have a procedure in place if a data subject wishes to withdraw from the

study for example? Please expand.

Should a participant wish to withdraw participation in the study, their DDUH number will be correlated to their research number via the excel database and their data will be deleted from the research study

4.14 Are there any potential confidentiality issues through identification of the study site?

Yes ☐ No ☒

If yes, please expand.

4.15 Are there elements of genetic testing involved in the proposed project? If yes please explain. If yes, please note that you must contact *researchDPO@tcd.ie* and conduct a DPIA.

Yes ☐ No ☒

If yes, please explain and please note that you must contact *researchDPO@tcd.ie* and conduct a DPIA . *here*.

SECTION 5 - RISK, BENEFIT AND HARM

5.1 What is the potential for an adverse outcome (for example, illness, pain, discomfort, distress, inconvenience) for research participants?

NOTE: for the protection of both the investigator and the participant, this list must be suitably comprehensive and must also appear in full in the participant information leaflet.

Any substantive adverse events must be reported to the Dental School Ethics Committee.
NA

5.2 Will individual or group interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting

If Yes, give details of procedures in place to deal with these issues. Give specific names of counselling or other support services that might be offered to participants.

NA

5.3 Is it possible that criminal or other disclosures requiring action could take place during the study

If yes, please provide specific detailed procedures in place to deal with these issues and who will be informed if disclosures occur. This information needs to be also included in the participant information leaflet.

NA

5.4 If participants are to undergo a clinical assessment, what is the nature and extent of this assessment?

NA

5.5 If applicable will there be ongoing clinical supervision of the participants by a duly insured clinical practitioner during the study?

NA

5.6 Will the research participant's General Practitioner be informed that they are taking part in the study?

no

5.7 Will permission be sought from the research participants to disclose information

NA

5.8 What is the potential for benefit for research participants? please outline only the direct benefits.

NA

SECTION 6 - FUNDING & PAYMENT

6.1 Outline sources of funding for the study if applicable and how you will manage possible conflict between the funders of the study and the aims and results of the study (if applicable).

NA

6.2 Will the results of the study will be used or disclosed for commercial purposes? If yes please also indicate in the participant information leaflet and indicate that the participant will not commercially benefit.

NA

6.3 Will payment be made to research participants?

NA

6.4 If you answered YES to question 6.3, please specify for what purpose the payment will be made and the amount to be provided to each participant.

NA

SECTION 7 – ETHICAL APPROVAL FROM OTHER COMMITTEES, FROM NON-TRINITY FACILITIES

Ethical approval from Trinity research committees if granted, does not supersede any requirements that outside bodies which may have the need for similar applications to be made to local ethical approval bodies in advance of the study commencing.

7.1 Has ethical approval been sought from any other organisation(s) in which the study will take place?

YES

NO

NA : *If NA, please explain why.*

If you answer YES go to question 7.2

If you answer NO go to question 7.3

7.2 If you have answered YES to question 7.1, where has approval been sought from and has ethical approval been given? If a DPIA was required for this application please insert as an appendix to this application.

YES	Awaiting Reply	NO	<i>If No, please explain why</i>
------------	---------------------------	-----------	----------------------------------

7.3 If you have answered NO to question 7.1, is it your intention to seek ethical approval from the organisation(s) in which the study will take place?

The study will only take place in DDUH

No

7.4 Do you require, and have you sought access to collect data from specific groups either within or outside Trinity to conduct your research please list them here and attach the letter(s) of permission to your application. This includes sports clubs, hospitals, care facilities, community services, etc.

Facility/Institute

Responsible Contact

NA

NA

SECTION 8 - DECLARATION OF APPROVAL AND SIGNATURES

The lead investigator/student (if applicable) must provide all data below and sign:

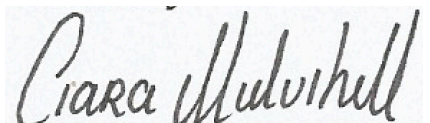
- 8.1 If applicable please state briefly what preparatory work you will need to undertake to become competent in your chosen method of data collection (e.g. training in the use of a standardised schedule/test, clinical procedures, or practice in conducting an interview).

N/A

8.2 LEAD INVESTIGATOR / STUDENTS DECLARATION:

I confirm that the information provided in this document is correct and that I am not aware of any other ethical issue not addressed within this form. I understand the obligations to and the rights of participants particularly concerning their safety and welfare and their data protection.

I undertake to provide an annual report within 12 months of the date of approval to the Dental School Research Ethics Committee with details of the number of participants who have been recruited, the number who have completed the study and details of any adverse effects. Any serious adverse effects will be reported immediately to the Dental School Research Ethics Committee, and, if involving medication this will also be reported to the Irish Medicines Board.

NAME: (BLOCK CAPITALS)		Ciara Mulvihill		
STAFF / STUDENT I.D. No.		16335785		
SCHOOL / DEPARTMENT:		DDUH/Oral Surgery		
COURSE STUDY: (if appropriate)	OF (if appropriate)	Oral Surgery D CH Dent	YEAR	2019
SIGNATURE:			DATE:	27/02/2020

RESEARCH SUPERVISOR Student applicants are required to have their Research Supervisor complete this section. Name of Supervisor: Mr Dermot Pierse Position: Consultant Maxillofacial Surgeon State the educational value of this research: The aim of the proposed research is to study a patients' perception of risk before and after the consent process. This will include examining the factors that affect the perception of risk, which risks do patients attach significance to, possible explanations for why patients' risk perception is not always accurate and if multimedia resources can optimise a patients perception of risk. I confirm that I have reviewed this application and I am not aware of any ethical issue not addressed within this form. I undertake to ensure that the student provides an annual report within twelve months of the date of approval, yearly thereafter and a final project report within 6 months of the completion of the study to the DDUH Ethics committee with details of the number of participants who have been recruited, the number who have completed the study and details of any adverse effects, complaints and the date of completion of the project. Any serious adverse effects must also be reported immediately to the Dental School Research Ethics Committee I undertake to make arrangements with the student regarding the storage and destruction of the data .

Signature of the Supervisor: 

Date: 16/03/2020

Appendix C: Participant Information Leaflet

Name of Study: Patients' perception of risk associated with wisdom tooth extraction; a comparison of conventional oral consent versus video/website-assisted consent.

Site	Oral Surgery Department
Principal Investigator(s) and Co-Investigator(s) (insert names, titles and contact details)	Ciara Mulvihill Oral Surgery Postgraduate Student Ciara.mulvihill@dental.tcd.ie
Study Organiser/ Sponsor (if applicable)	DDUH
Data Controllers	Trinity College Dublin
Data Protection Officer	Data Protection Officer Secretary's Office Trinity College Dublin Dublin 2 Data Protection Officer of [hospital]: [INSERT CONTACT DETAILS HERE].

You are being invited to take part in a research study that is being done by Ciara Mulvihill at Dublin Dental University Hospital.

Before you decide whether or not you wish to take part, please read this information sheet carefully. Ask Ciara Mulvihill any questions. Don't feel rushed or under pressure to make a quick decision. You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. You may wish to discuss it with your family, friends or GP.

This leaflet has five main parts:

Part 1 – The Study

Part 2 – Data Protection

Part 3 – Costs, Funding and Approval

Part 4 – Further Information

Part 1 – The Study

Why is this study being done?

We are doing this study to determine a patients' perception of risk before and after the consent process. This will include studying the factors that affect the perception of risk, which risks do patients attach significance to, possible explanations for why patients' risk perception is not always accurate and if multimedia resources can optimise a patients perception of risk.

Why have I been invited to take part?

- *You have been invited to participate in the study because you are attending regarding third molar (wisdom tooth) removal.*
- *The research aims to survey up to 100 participants over the age of 18 that are attending for third molar tooth (wisdom tooth) extraction*

Do I have to take part? Can I withdraw?

You don't have to take part in this study. It is entirely voluntary. If you decide not to take part it will not affect your current or future medical care. You can change your mind about taking part in the study and opt out at any time even if the study has started. If you decide to opt out, it won't affect your current or future medical care. You don't have to give a reason for not taking part or for opting out. If you wish to opt out, please contact Ciara Mulvihill, Oral Surgery Post Graduate Student (Ciara.mulvihill@dental.tcd.ie) who will be able to organise this for you.

What happens if I change my mind?

You can change your mind at any time by contacting your study Dentist at Ciara.mulvihill@dental.tcd.ie. If you choose not to continue to take part, this will not affect your medical care in any way. If you choose not to take part any more, you will be asked to fill in a withdrawal form. If you wish, you can ask to have any of your data that has been stored to be destroyed. If you request this, we will destroy all data that is still in our possession. We will no longer use your data for research from this point onwards. However, it will not be possible to destroy data already used in research studies prior to this time.

How will the study be carried out?

Patients attending for mandibular third molar extraction will be invited to participate in the survey. Participants will be randomly assigned to one of two categories; A. oral consent only, B. video-assisted consent. Once consent is obtained, participants will be given a tablet to complete an online survey. Patients in both groups will receive the same information (via different delivery methods) and questionnaires. Patients attending for review appointments 7-14 days post-operatively will be invited to complete a survey rating their experience of the consent process.

Respondents will be told that they can exit the survey at any point of the study. The consent procedure will be outlined in a Consent Statement at the beginning of an electronic survey as per ethical approval requirement. This will include the identity of the researcher, contact details, the reason for conducting the survey and the uses to be made of the data. A paper version of the survey will also be available in case of device malfunction.

What will happen to me if I decide to take part?

Respondents will be told that they can exit the survey at any point of the study. The consent procedure will be outlined in a Consent Statement at the beginning of an electronic survey as per ethical approval requirement. This will include the identity of the researcher, contact details, the reason for conducting the survey and the uses to be made of the data. A paper version of the survey will also be available in case of device malfunction.

. What will happen to my Samples and Data?

Your pseudonymized data will be used only by local researchers.

Are there any benefits to taking part in this research?

Taking part in this study will not benefit you directly. However, the research results from the surveys that you complete may help DDUH to obtain a better understanding of patients' perception of risk and may result in new approaches to obtaining consent. This is a long-term research project, so the benefits of the research may not be utilized for several years. By participating, you are helping to advance science and medicine for future generations.

Are there any risks to me or others if I take part?

- **Health Information (Data):** *There is a risk that a connection to your identity could be made. Great care will be taken to ensure the confidentiality of all data and the risk to participants of a breach of confidentiality is considered very low*

Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?
--

The results of the study will be reported in medical/scientific journals and disclosed at medical/scientific conferences. No information which reveals your identity will be disclosed.

Part 2 – Data Protection

What information about me (personal data) will be used as part of this study? Will my medical records be accessed?

- The **data** relating to the participants in the survey will be pseudonymised to protect the identity of the participants

What will happen to my personal data?

- *Your personal data will be processed **only as is necessary** to achieve the objective of the study and will not be processed in a way that damage or distress will be caused to the participant.*
- *Data will only be stored for the legal minimal requirement of 7 years in a pseudonymized format . After this time the data will be destroyed*

Who will access and use my personal data as part of this study?

- *The principle investigator, Ciara Mulvihill, will have access to the participant's pseudonymized personal data as part of this study.*

Will my personal data be kept confidential? How will my data be kept safe?

Your privacy is important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe. Here are some examples of how we do this:

- *Data will only be stored for the legal minimal requirement. Double encryption will be applied to all computers, laptops and mobiles devices. Personal data will not be stored on portable devices.*
- *A Risk Assessment of the data protection implications of the health research carried out and an indication of the level of risk was identified prior to the commencement of this research.*
- *Any presentation or publication arising from the study will not identify the participant.*
- *The persons carrying out the research are bound by a professional code of secrecy (like doctors)*
- *Training in data protection law and practice has been provided to those individuals involved in carrying out the research.*

What is the lawful basis to use my personal data?

By law,⁵ we can use your personal information for scientific research⁶ (in the public interest⁷). We will also ask for your explicit consent to use your data as a requirement of the Irish Health Research Regulations.

What are my rights?

You are entitled to:

- *The right to access your data and to receive a copy of it*
- *The right to restrict or object to processing of your data*
- *The right to object to any further processing of the information we hold about you (except where it is de-identified)*
- *The right to have inaccurate information about you corrected or deleted*
- *The right to receive your data in a portable format and to have it transferred to another data controller*
- *The right to request deletion of your data*

By law you can exercise the following rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. You can exercise these rights by contacting Ciara Mulvihill or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

⁵ The European General Data Protection Regulation (GDPR)

⁶ Article 9(2) (j))

⁷ (Article 6(1)(e))

Part 3 – Costs, Funding and Approval

Has this study been approved by a research ethics committee?

Yes, this study has been approved by Dublin Dental University Hospital Research Ethics Committee. Approval was granted on 30/03/2020.

Who is organising and funding this study? Will the results be used for commercial purposes?

- *Dublin Dental University Hospital is conducting the research. There is no funding or commercial purposes associated with this research*

Is there any payment for taking part? Will it cost me anything if I agree to take part?

No, we are not paying patients to take part in the study.

Part 4 – Further Information

Who should I contact for information or complaints?

If you have any concerns or questions, you can contact:

- *Principal Investigator: Ciara Mulvihill*
- *Data Protection Officer of Dublin Dental University Hospital*
- *Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.*

Under GDPR, if you are not satisfied with how your data is being processed, you have the right to lodge a complaint with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie.

Will I be contacted again?

If you would like to take part in this study, you will be asked to sign the Consent Form on the next page. You will be given a copy of this information leaflet and the signed Consent Form to keep.

Appendix D: Patient information leaflet on third molar extraction

Figure D1: Patient information leaflet on third molar extraction.

Removal of wisdom teeth

Removal of wisdom teeth is an operation and like every other operation has side-effects and complications and usually involves the placement of one or more sutures (stitches)

What are the side-effects?

These occur after every operation to some degree. Soreness, swelling and stiffness of the jaw with restricted mouth opening usually clears up after about a week or so after the operation. Some bleeding during the operation is inevitable but this is rarely severe or troublesome.

What are the complications?

These are much less common but do occur from time to time. Because the nerve to your lip runs through your jaw and the nerve to your tongue lies on your jaw near the wisdom tooth these are at risk of being damaged. This may produce alteration in the feeling in the lip or tongue. This may be felt as numbness (anaesthesia) or as "pins and needles" (paraesthesia) It does not involve any paralysis of the lip or tongue. It does not cause any deformity. It can be permanent but this is relatively rare.

Does every wisdom tooth removal carry the same risk?

No! It depends on the type and difficulty of the impaction and other factors.

The figures below are based on several studies and give some idea of the frequency.

Sensory alteration in the tongue: 1:200 (0.5%)

Sensory alteration in the lip: 1:250 (0.4%)

The staff will be happy to discuss this further with you and will try to answer any queries you may have. If you wish to contact the hospital by phone the number is: 612 7200 or you can e-mail us: patient@dental.tcd.ie

I confirm that I have read this information sheet and have been shown my X-ray, which has been explained to me.

Patient's Signature:.....

Date:...../...../.....

Witness's Signature:.....

Date:...../...../.....

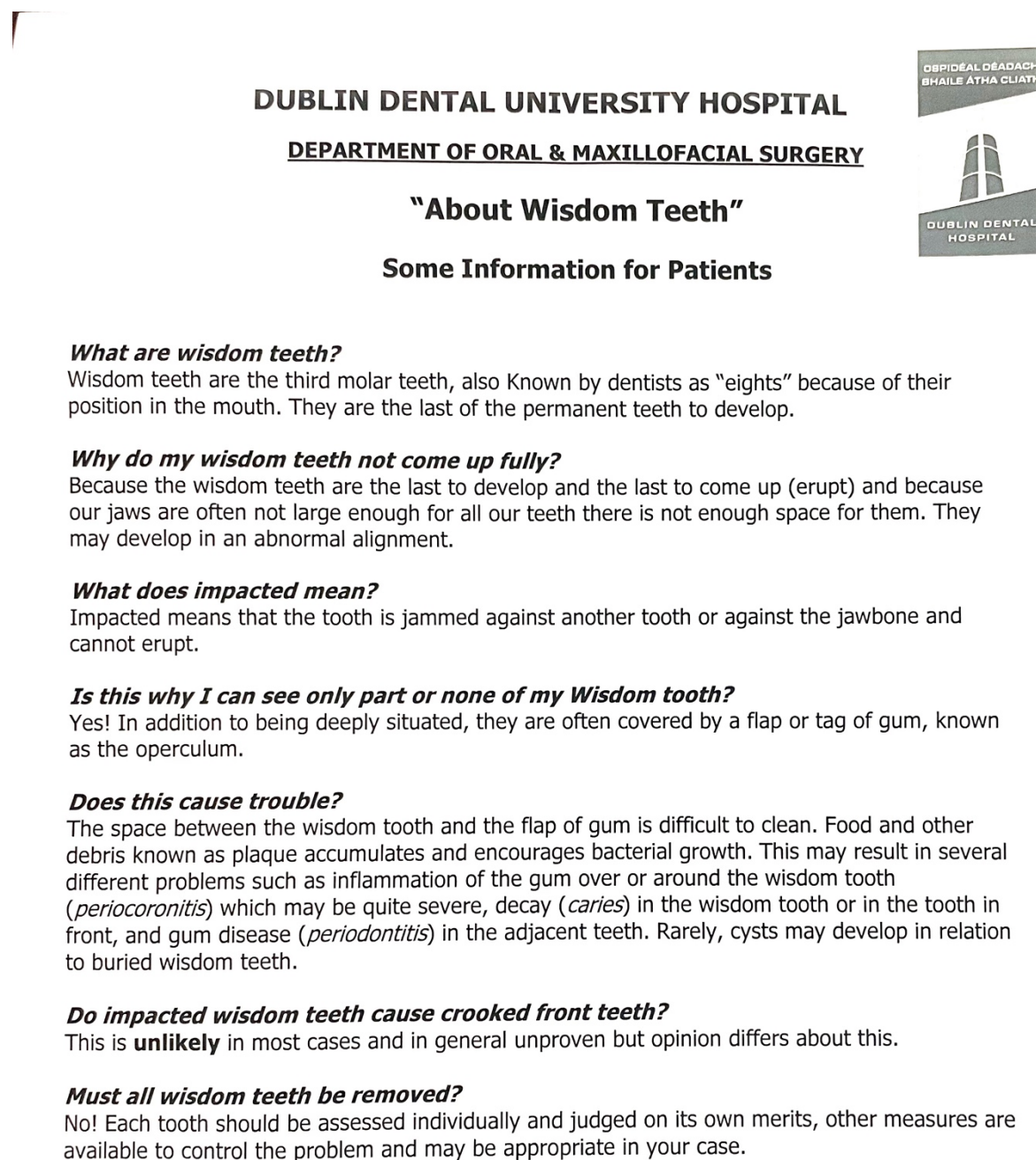
(Examining dentist or student)

The decision to proceed with removal of your wisdom tooth (or teeth) can only be made by you. You may discuss it with your family or friends.

You do not have to make up your mind immediately.

W:\Printing\New Order Form Sept 2010\Information Leaflets\PR60 Wisdom Tooth Information Sheet.doc

Figure D2: Patient information leaflet on third molar extraction.



p.t.o.

Appendix E: Data Protection Impact Assessment (DPIA)

Please review the TCD *Data Protection Risk Assessment* document before undertaking a DPIA.

Process/System/Project/Other ('Project') Name:

Informed consent for third molar extraction; a comparison of conventional verbal consent versus video-assisted consent

Date: 16/03/2020

Project Owner: Ciara Mulvihill

Site: DDUH

Email: Ciara.mulvihill@dental.tcd.ie

TEMPLATE VERSION CONTROL

Reference	Date	Author	Comments
2.0	June 2019	TCD DPO	

DPIA CIRCULATION

Name	Date	Reviewed/Consulted
TCD DPO	16/03/2020	TCD DPO

Project description

Name: Informed consent for third molar extraction; a comparison of conventional verbal consent versus video-assisted consent

Scope: Patients will complete online questionnaires. When participants consent to participation in the research project they will be allocated a number within the research project. This will be pseudonymized with their DDUH patient number on an excel database by the principle investigator (CMulvihill). The principle investigator (CMulvihill) will have the sole access to the key code to access the excel database.

Purpose: This research aims to assess if presenting information about third molar extraction via an informative, narrated, animated video changes a patients' perception of risk associated with third molar extraction when compared to conventional verbal consent.

Primary research question

Does the use of video assisted consent for third molar extraction affect patient's self-reported level of understanding of the proposed procedure and the associated risks?

Secondary research questions

Does the use of video assisted consent for third molar extraction affect patient's self-reported level of anxiety about the proposed procedure and the associated risks?

Does the use of video assisted consent for third molar extraction affect patient's self-reported level of satisfaction with the consent process and the quality and quantity of information they receive about the proposed procedure and the associated risks?

Are certain patient demographics (age, sex, education level) more receptive to the use of video assisted consent for third molar extraction?

Frequency: Patient questionnaires will be processed at the time of surgery and at the review appointment.

Number of individuals: The research aims to survey up to 100 participants over the age of 18 that are attending for mandibular third molar tooth (wisdom tooth) extraction.

Parties and third parties: The principle investigator will have sole access to the SurveyMonkey data. Other processors will include the research supervisor and Maria Van Harten (DDUH statistician)

Systems: SurveyMonkey and SPSS survey software

Does the activity involve processing data on a large scale? If so, provide detail.	No
Does the activity involve matching or combining datasets? If so, provide detail.	Yes, When participants consent to participation in the research project they will be allocated a number within the research project. This will be pseudonymized with their DDUH patient number on an excel database by the principle investigator (CMulvihill). The principle investigator (CMulvihill) will have the sole access to the key code to access the excel database. This will be matched to the dataset from the day of surgery survey data
Does the activity involve data concerning vulnerable individuals or children? If so, provide detail.	No
Does the activity involve new, or innovative uses of, technological or organisational solutions? If so, provide detail.	Yes, Video aided consent will be used
Could the activity prevent individuals from exercising a right, using a service, or fulfilling a contract? If so, provide detail.	No
Why the use of personal data is necessary for this activity?	Sex, age, level of education and smoking status are needed for comparison amongst groups
Who will benefit from the activity?	Patients consenting to dental treatments
Could the use of the personal data for this activity result in any harm to the individual?	No

PERSONAL DATA

List the types of personal data that will be **collected, used, accessed or shared** for the purpose of this activity.

Data collected	Justification	Processing activity
EXAMPLE: <i>Participant hospital number</i>	<i>To correlate data from assessment, day of surgery and post treatment data</i>	<i>Excel database, situated in 'Student' Drive on 'hospital' desktop computer at DDUH site</i>
EXAMPLE: <i>Participant email/mobile number</i>	<i>Identification, so that the patient can be sent link to information website</i>	<i>Salud, Excel database, situated in 'Student' Drive on 'hospital' desktop computer at DDUH site</i>

TRANSPARENCY OF PROCESSING

How will you notify affected individuals about the data processing that will be carried out using their personal data? Provide details and **attach copies** of the Consent Form(s) and Privacy Notices (Privacy Statements).

Transparency of processing

Participant rights' shall be outlined in the invitation to participate in the study

These include

- **right to erasure;**
- **right to object to processing based on public interest;**
- **right to data portability;**
- **right to object to profiling or making decisions about individuals by automated means?**

Should a participant wish to withdraw participation in the study, their DDUH number will be correlated to their research number via the excel database and their data will be deleted from the research study

DATA SECURITY – STORAGE AND SHARING

Describe in detail the technical and organisational security measures which will be taken to protect personal data including but not limited to: access controls, data sharing restrictions, encryption, pseudonymisation, anonymisation etc.

Data security – storage and sharing

The anticipated ethical issues raised by the project are in relation to data handling and protecting the anonymity of participants. In order to handle information securely the Survey System, SurveyMonkey will be used. In order to preserve the anonymity of the participants the option to save time and date stamp with responses will be disabled. The sole person allowed access to the SurveyMonkey account will be by the principal investigator

When participants consent to participation in the research project they will be allocated a number within the research project. This will be pseudonymized with their DDUH patient number on an excel database by the principle investigator (CMulvihill). The principle investigator (CMulvihill) will have the sole access to the key code to access the excel database.

Data will only be stored for the legal minimal requirement. Double encryption will be applied to all computers, laptops and mobiles devices. Personal data will not be stored on portable devices.

DATA MINIMISATION

Have you ensured that you will only collect the minimum data that you need or that is necessary for the activity? Provide details.

Data minimisation

Only data necessary to study will be collected

LAWFUL BASIS – ORDINARY PERSONAL DATA

If processing 'Ordinary' personal data then you must satisfy at least one of the lawful bases as set out under [Article 6 GDPR](#):

Consent	
Performance of a contract	
Legal obligation	
Public interest or exercise of official authority	
Vital interests of data subjects	
Legitimate interests	

INTERNAL DATA SHARING

Will the data be shared internally? i.e. with departments or business units within the organisation? If so, provide details on the data sharing including information on the necessity for the processing, the format of the data that is to be shared, with whom the data will be shared and confirmation of the security measures in place to protect the data in transit.

Internal data sharing

Results from the data will be shared with DDUH statistician

THIRD PARTIES

Will the data be shared with third parties including IT service providers, Cloud-based solutions, sub-contractors etc.? If so, provide details including information on the contractual arrangements in place and confirm what due diligence has been carried out.

Third parties

Not applicable

INTERNATIONAL DATA TRANSFERS

Will the data be transferred or stored outside the EEA at any point or placed with Cloud providers that store data outside the EEA? Provide details. If you are transferring personal data outside the EEA have you ensured that suitable conditions for transferring the data are in place? Provide details or state if unsure. These include:

- Adequate jurisdiction
- US Privacy Shield
- Standard Contract Clauses
- Binding Corporate Rules
- Authorisation from the Data Protection Commission

International data transfers

Not applicable

DATA RETENTION

How long will the data be retained for and why? Provide details.

Data retention

Data will only be stored for the legal minimal requirement. Double encryption will be applied to all computers, laptops and mobiles devices. Personal data will not be stored on portable devices.

DATA SUBJECT RIGHTS

What plans are in place for responding to a request from an individual in relation to their data protection rights?

These include:

- right of access;
- right to rectification;
- right to erasure;
- right to object to processing based on legitimate or public interest;
- right to data portability;
- right to object to profiling or making decisions about individuals by automated means.

Data subject rights

[INSERT DETAILS HERE] Participant rights' shall be outlined in the invitation to participate in the study

These include

- **right of access;**
- **right to erasure;**
- **right to object to processing based on public interest;**
- **right to data portability;**
- **right to object to profiling or making decisions about individuals by automated means?**

TRAINING

What guidance and training will be provided to individuals involved in this project or activity to enable them to understand their data protection responsibilities? Provide details.

Training

Not applicable

PROCESSING RISKS - TABLE

Describe the source of risk and nature of potential impact on individuals. Include associated Compliance and Corporate risks as necessary.

Risk detail	Risk rating (High, medium, low)	Solutions/Mitigating Actions	Effect	Outcome	Measure approved
<i>Hacking into computers where project data is stored.</i>	<i>Low</i>	<i>All computers storing data are password protected. The external hard drive and remotely accessible computer are also encrypted and locked in an office (on Trinity's campus). Access is restricted to designated staff only.</i>	<i>Reduced</i>	<i>Low</i>	<i>YES</i>