CIA

CIA: Consent in Anaesthesia

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MAIN SPONSOR: Imperial College Healthcare NHS Trust
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STUDY COORDINATION CENTRE: St Mary's Hospital

IRAS Project ID: 305199
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Sponsor

Imperial College Healthcare NHS Trust is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

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Funder

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This protocol describes the CIA study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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GLOSSARY OF ABBREVIATIONS

AE	Adverse Event
ANOVA	Analysis of Variance
CSQ	Client Satisfaction Questionnaire
DMSC	Data Monitoring and Safety Committee
GA	General Anaesthesia
ICH GCP	International Conference for Harmonisation of Good Clinical Practice
ITT	Intention To Treat
NVS	Newest Vital Sign
PI	Principal Investigator
PIS	Patient Information Sheet
RA	Regional Anaesthesia
REC	Research Ethics Committee
SAE	Serious Adverse Event
SSA	Site Specific Assessment
SVC	Standard Verbal Consent
TMG	Trial Management Group
VAC	Video Assisted Consent

KEYWORDS
Consent
Video
Anaesthesia
Regional
Satisfaction
Knowledge

STUDY SUMMARY

TITLE	CIA: Consent in Anaesthesia
DESIGN	Prospective randomised-controlled trial
AIM	To determine whether presenting both techniques of general anaesthesia and regional anaesthesia in an unbiased manner, with video media, aids the anaesthetic consent process, compared to standard verbal consent alone.
OUTCOME MEASURES	Primary outcome: - Participants' satisfaction regarding the anaesthetic consent process Secondary outcomes: - Knowledge, attitudes and practices towards anaesthesia - Participants' choice of anaesthetic technique
POPULATION	General adult population (>18yrs), males and females
ELIGIBILITY	Adult participants (>18yrs) who give written, informed consent. Exclusion criteria: - Patients <18 years or vulnerable groups - Inability to communicate in English or language difficulty that requires an interpreter - Severe vision or hearing loss if lack of other communication channels - Private patients - Prisoners - Patients who reside outside the United Kingdom (home address) - Opt-out patients on GP register
DURATION	2 years

1. INTRODUCTION

Anaesthetists deliver just under 3 million anaesthetics in the United Kingdom every year[1,2]. General anaesthesia (GA) and regional anaesthesia (RA) are both routinely used for intraoperative anaesthesia. The estimated annual numbers (with percentage of all cases) of GA, sedation and awake cases were 2 766 600 (76.9%), 308 800 (8.6%), and 523 100 (14.5%), respectively[2].

Regional anaesthesia with central neuraxial or peripheral nerve plexus blockade has a proven track record for success in surgery and several potential benefits. It may be undertaken with or without sedation. General anaesthesia is associated with greater immediate post-operative pain and opiate use[3], whereas brachial plexus blockade may be associated with delayed rebound pain[4]. However, rebound pain may be modulated by an understanding of the dissipation of single-injection regional anaesthesia and attenuated by longer duration analgesia as well as multi-modal therapy[5,6]. When regional anaesthesia has been used instead of general anaesthesia, the median time to hospital discharge is shortened and the in-hospital mortality is also decreased.

There are a number of surgical procedures which may be undertaken under either general anaesthesia or regional anaesthesia. The Association of Anaesthetists of Great Britain and Ireland guidelines on consent state that for a decision by an individual to be valid, it must have been undertaken voluntarily, without coercion[8,9,10]. Although it may be good practice for the clinician seeking consent to indicate a preference for a therapeutic option, they should be aware that a vulnerable patient may feel coerced by the doctor's preference due to the imbalance of power and influence in the doctor-patient relationship. The anaesthetist seeking consent should be aware of this and not allow their preferences to override the patients autonomy[8,11]. When these principles are applied to the type of anaesthesia (GA vs RA) offered, it stands to reason that both options of GA and RA should be offered to patients, if both are feasible options for the surgery to be undertaken. Barriers to this are multifactorial and the time pressures of a busy anaesthetic list should not be underestimated.

Video assisted consent (VAC) offers a potential way to improve doctor-patient communication and to improve the consent process when compared to standard verbal consent (SVC)[12]. Hand-held, mobile media devices are becoming ever more prevalent and lend themselves to easy use within a busy hospital environment. The role of video-based education in the process of consent has shown promise in studies of surgical consent. Several studies have shown that video-based patient education have led to better patient comprehension and satisfaction as well as reduced patient anxiety during the consent process[12-15]. The acceptance of multimedia technology in preoperative surgical consent has been demonstrated across a spread of surgical disciplines, including ophthalmic surgery[16-17], urological surgery[12], orthopaedic surgery[15,18-19], bariatric surgery[20] and vascular surgery[21]. The use of video-assisted consent for invasive procedures on the intensive care unit has also had positive results[22].

The choice of general vs regional anaesthesia by a patient undergoing orthopaedic surgery has been demonstrated to change with patient education. In a randomised controlled trial in Cardiff, the use of informational internet web pages led to patients awaiting hip or knee arthroplasty altering their preferences from general anaesthesia to a neuroaxial technique[23]. Preoperative patient education of the advantages of neuroaxial anaesthesia was also shown to be associated with a higher number of patients choosing a regional anaesthetic in the setting of total knee arthroplasty[24].

A tertiary centre trial in the UK demonstrated that patient recall of consent for regional anaesthesia was poorer than that for surgical consent[25]. Video-assisted patient education during a preanaesthetic visit has been shown to lead to a better understanding of the procedure and risks of anaesthesia with no increase in patient anxiety[26]. This suggests that more effective strategies for patient education with regards to regional anaesthesia and consent for regional anaesthesia are required and video-assisted methods are likely to be beneficial.

Patient and Public Involvement and Engagement (PPIE) work consisted of consulting 40 members of the multidisciplinary theatre team, including consultants, trainees, operating department practitioners and nurses. Although 92% of those surveyed had not used a video-assisted consent process before, 95% felt that a video-assisted consent process would be a useful tool. 88% of those surveyed had not used or seen any type of online consent tool but 92% voted that an anaesthetic online consent process would be useful. The team has also spoken to patients and lay public who have also felt that a video-assisted consent process would help with their understanding and satisfaction of the consent process should they need to have an anaesthetic for surgery.

The COVID pandemic has brought about changes in pre-operative assessment and anaesthetic consent[27]. The need for social distancing has meant that family and friends are often no longer able to be present when the patient meets the anaesthetist on the day of surgery to discuss the anaesthetic process and options; as well as to obtain anaesthetic consent. The videos created specifically for video-assisted anaesthetic consent could not only be used to allow the patient to review the anaesthetic process in advance of the anaesthetic consent to allow time for informed consent, they could also be reviewed with family and friends that the patient may depend on for support and advice

2. STUDY OBJECTIVES

- The aim of this study is to determine if the use of video assisted consent during the anaesthetic consent process, for both GA and RA, affects the participants' satisfaction, knowledge of, and attitudes towards, anaesthesia.

- We hypothesise that using video media will improve participant knowledge, understanding and satisfaction of the anaesthetic consent process, thereby resulting in better quality informed consent.

3. RESEARCH PLAN AND METHODOLOGY

3.1. STUDY POPULATION

Study centre(s)

- Imperial College Healthcare NHS Trust

Study sample

- 206 participants

Inclusion criteria

- ≥ 18 years
- Presenting to pre-operative orthopaedic surgical clinic
- Informed consent

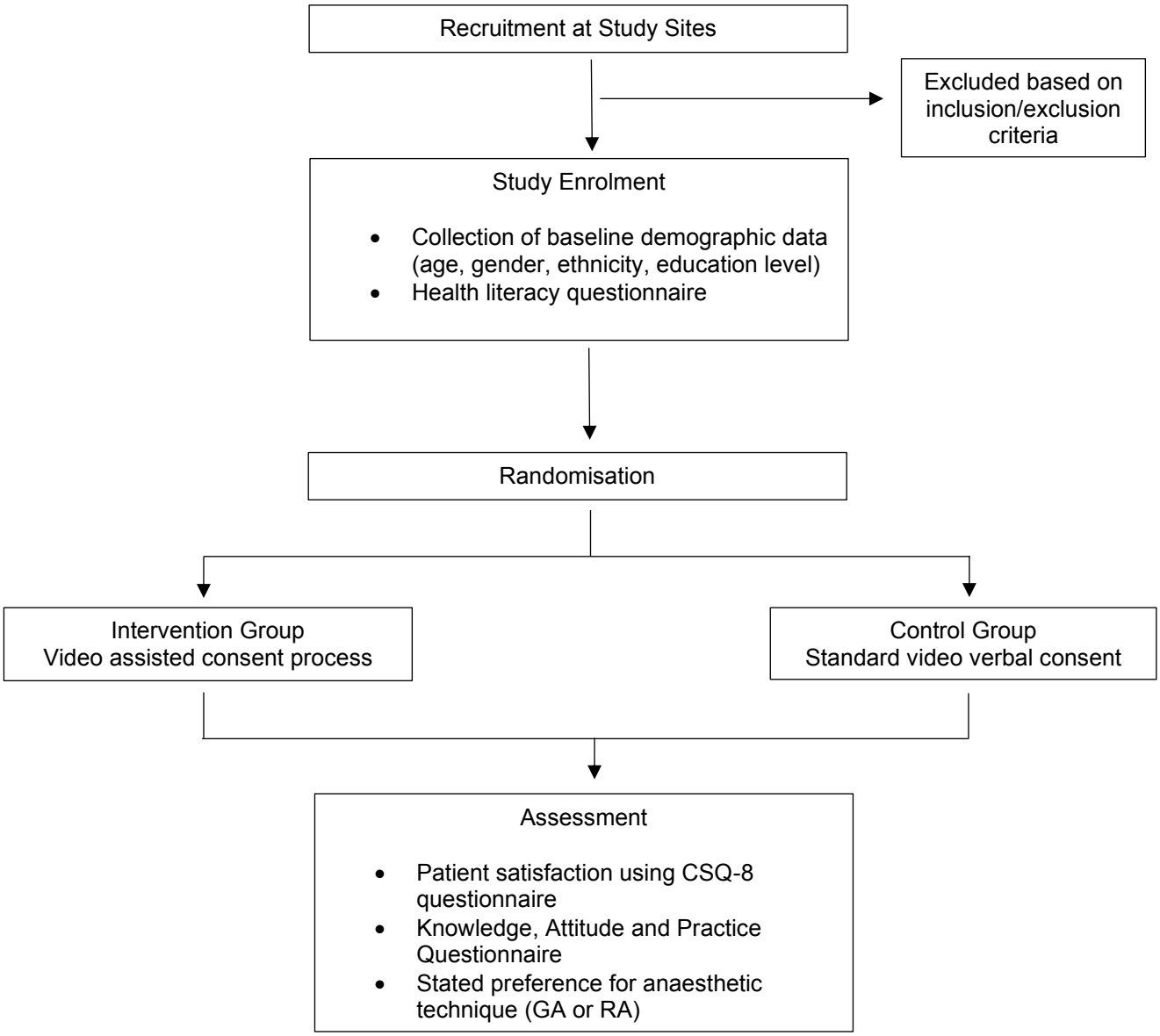
Exclusion criteria

- Patients <18 years or vulnerable groups
- Inability to communicate in English or language difficulty that requires an interpreter
- Severe vision or hearing loss if lack of other communication channels
- Private patients
- Prisoners
- Patients who reside outside the United Kingdom (home address)
- Opt-out patients on GP register

3.2. STUDY DESIGN

- Single centre prospective randomised-controlled trial
- Duration: 2 years

Figure 1 – Study Design Flow Chart



This is a prospective, randomised-controlled trial investigating the effects of using video media to aid the anaesthetic consent process.

3.3. RECRUITMENT

Potential trial participants will be recruited from the general adult population (i.e. males and females aged over 18yrs) presenting to pre-operative orthopaedic surgical clinic within Imperial College Healthcare NHS Trust at St Mary's and Charing Cross Hospitals. Potential participants will be approached by members of the study team that may or may not be part of the primary care team. All potential participants will be invited to take part with the use of a participant information sheet (PIS), approved by a Research Ethics Committee, that describes the study. The participant will have time to read the PIS and to discuss their participation with others outside the research team (e.g. relatives or friends) if they wish. A

member of the research team will then answer any questions, confirm the participant's eligibility and take written informed consent if the participant decides to proceed. Details of all participants approached for the trial and reason(s) for non-participation (e.g. reason for being ineligible or patient refusal) will be documented. Also the non-participant does not need to give a reans for non-participation and if so will be documented as non-participation in the reason(s) for refusal.
All data will be anonymised.

3.4. PROTOCOL

Recruited participants will be randomised into two groups. The control group will undergo the standard video verbal consent process for both GA and RA for orthopaedic surgery. This will be delivered using a standardised video script that will be generated from existing certified material, as well as being reviewed by an experienced body of anaesthetists, in order to ensure that the length and content of information given is appropriate, unbiased, accurate and consistent. In order to account for adaptations to services in light of the coronavirus pandemic, and to further ensure standardisation, this verbal communication will be pre-recorded and shown to the participant. The intervention group will also be shown the same pre-recorded standard verbal consent, but following this will additionally be shown a specifically recorded video of the anaesthetic process for both GA and RA. This video will aim to communicate the same information as that found in the traditional verbal consent, using an actor undergoing an anaesthetic to provide context.

Following the consent process, participants from both groups will be asked to complete two questionnaires to enable assessment of participant satisfaction, retained knowledge and perceptions regarding anaesthesia from the consent process, and a stated preference for anaesthetic technique (i.e. GA or RA).

3.5. MEASUREMENTS

Following recruitment, baseline demographic data will be collected on each participant, including age, gender, ethnicity and education level.

Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions[28]. Health literacy may be an important confounding factor within this study; therefore, assessing health literacy will be a useful screening tool prior to conducting the study. Prior to randomisation, participants will be asked to complete the Newest Vital Sign-UK questionnaire *(see appendix 11.2)* to assess health literacy.

For measuring the primary outcome, participant satisfaction, the Client Satisfaction Questionnaire (CSQ-8) will be utilised, which measures the most salient items for the satisfaction with services *(see appendix 11.1).* This will be administered for the control group after receiving standard verbal consent, and the intervention group after receiving video assisted consent.

For measuring the secondary outcomes, a knowledge, attitudes and practices (KAP) questionnaire will be utilised *(see appendix 11.3).* As part of the questionnaire, the participant will be offered the choice of anaesthetic technique between GA and RA. This is to evaluate whether the proportions choosing GA or RA differ between control and intervention groups.

3.5.1. Summary of pre-randomisation actions

Event	Measurement/Action	Means	Timing	Time
Recruit participants	Inform participants	Participant Information Sheet	At time of recruitment	5-10 minutes
Consent participants	Informed written consent	Online consent form	At time of consent	5 minutes
Demographic data collection	Age, gender, ethnicity, education level	Online questionnaire	Once consented	2-3 minutes
Health Literacy Assessment	Newest Vital Sign-UK	Online questionnaire	Once consented	3-5 minutes

3.5.2. Summary of Study Outcome Measurement

Outcome	Data	Measurement Tool	Timing	Time
Primary Outcome	Participant satisfaction	Client Satisfaction questionnaire (CSQ-8)	Following intervention	3 minutes
Secondary Outcomes	Knowledge, attitudes and practices towards general and regional anaesthesia	KAP questionnaire	Following intervention	5-10 minutes
	Stated preference of anaesthetic technique	KAP questionnaire	Following intervention	<1 minute

3.6. WITHDRAWAL CRITERIA

Each participant has the right to withdraw at any time. If a participant withdraws, we will continue to analyse any data already collected, unless the participant expresses a wish for any associated data to be destroyed.

4. ADVERSE EVENTS

4.1. DEFINITIONS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*
- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

4.2. REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

4.2.1 Non serious AEs

All such events, whether expected or not, should be recorded- it should be specified if only some non-serious AEs will be recorded, any reporting should be consistent with the purpose of the trial end points.

4.2.2 Serious AEs

An SAE form should be completed and emailed to the Chief Investigator within 24 hours.

All SAEs should be reported to the North West London REC where in the opinion of the Chief Investigator, the event was:

- 'related', ie resulted from the administration of any of the research procedures; and
- 'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator must also notify the Sponsor of all related and unexpected SAEs.

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

Contact details for reporting SAEs
RGIT@imperial.ac.uk
CI email (and contact details below)
Please send SAE forms to: Boyne Bellew (boyne.bellew@nhs.net)
Tel: 07710787321 (Mon to Fri 09.00 – 17.00)

5. ASSESSMENT AND FOLLOW-UP

Baseline demographic data will be collected for all study patients. These will include age, gender, ethnicity and educational level.

Assessment will be carried out using the following tools:

- CSQ-8 satisfaction questionnaire (appendix 12.1)
- Newest Vital Sign (NVS)-UK (appendix 12.2)
- Knowledge, Attitudes and Practice questionnaire (appendix 12.3), based on information contained in the consent process

Each participant, with their consent, will be informed of the outcome of the trial and any subsequent publication. There is no requirement for follow-up after the investigative period.

There is unlikely to be any losses as the participant will undertake the 2 questionnaires and state their theoretical choice of anaesthesia immediately after undergoing either the traditional verbal consent process and/ or the video-assisted consent process. The only possible loss would be if the participants abruptly withdraws consent to participate if called away for clinical or personal reasons.

The end of the trial will be when the trial database is complete and locked for analysis.

6. STATISTICS AND DATA ANALYSIS

Two hundred and six patients in total will be randomised using an online randomisation tool. https://www.graphpad.com/quickcalcs/randomize1.cfm

Patient satisfaction, the primary endpoint measured by CSQ-8, is expected to be approximately 30 in both arms. VAC and SVC will be considered equivalent if the VAC satisfaction score is no more than 1.5 points lower than the SVC score. With 103 subjects in the Control Group (SVC) and 103 subjects in Experimental Group (VAC), there is an 85% chance that the observed difference (SVC-VAC) in satisfaction scores will be significantly less than 1.5 at the 5% level, if the true means are 30 in both groups. The standard deviation has been assumed to be 4.

After the first 50 participants have been entered into the trial a feasibility analysis will be undertaken. Three outcomes of particular interest will be the accrual rate, the proportion accepting their randomisation and the proportion evaluable (completing all questionnaires). With 50 participants it will be possible to estimate the proportions in the latter two groups with 95% confidence intervals of at most ±15%. A record will be kept of the number of participants approached and their reasons for declining to enter the study. With 50 participants it should be possible to identify and remedy any minor issues that are impediments to recruitment. It may be necessary to plan to increase accrual if withdrawals or the number of non-evaluable participants is greater than expected.

The primary analysis will be by intention to treat (ITT). It is planned to make comparisons between groups for normally distributed variables with independent samples t-test or ANOVA, variables that are not normally distributed will be analysed with Mann–Whitney U-tests. The Chi-squared or Fisher's exact test will be used to compare proportions and Pearson Product or Spearman Rank statistics will be used to assess correlation. Multiple regression exploratory analyses may be employed to estimate multiple effects simultaneously.

Data and all appropriate documentation will be stored for a minimum of 5 years after the completion of the study, including the follow-up period.

7. REGULATORY ISSUES

7.1. ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the North West London Research Ethics Committee (REC) and Health Regulator Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting

participants into the study or any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

7.2. CONSENT

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so should be recorded. In these cases the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

7.3. CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

Data will be pseudonymised.

7.4. INDEMNITY

Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Resolution for NHS Trusts in England, which apply to this study.

7.5. SPONSOR

Imperial College Healthcare NHS Trust will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

7.6. FUNDING

Imperial Health Charity are funding this study (via the Innovate Grant)

7.7. AUDITS

The study may be subject to audit by Imperial College London/ Imperial College Healthcare NHS Trust under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Frame Work for Health and Social Care Research.

8. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through a Trial Management Group. This will be chaired by the Chief Investigator and will include all members of the named research team

9. PUBLICATION POLICY

Results will be published in a peer-reviewed journal and presented at relevant national and international conferences.

10. REFERENCES

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11. APPENDICES

11.1. CLIENT SATISFACTION QUESTIONNAIRE (CSQ-8)

The Client Satisfaction Questionnaire (CSQ) instruments are self-report questionnaires constructed to measure satisfaction with services received by individuals[29].
The CSQ-8 is an 8-item questionnaire that measures the most salient items for the measurement of satisfaction with services:

Questionnaire Item	Scoring			
	4	3	2	1
How would you rate the quality of the service you received?	Excellent	Good	Fair	Poor
Did you get the kind of service you wanted?	Yes definitely	Yes generally	No not at all	No definitely not
To what extent has our service met your needs?	Almost all met	Most met	Only a few met	None met
If a friend were in need of similar help would you recommend our service?	Yes definitely	Yes I think so	No I do not think so	Definitely not
How satisfied are you with the amount of help you received?	Very satisfied	Mostly satisfied	Indifferent	Quite dissatisfied
Have the services you received helped you to deal more effectively with your problems?	Yes a great deal	Yes somewhat	No did not help	No made it worse
In an overall sense, how satisfied are you with the service you have received?	Very satisfied	Mostly satisfied	Indifferent	Quite dissatisfied
If you were seeking help again, would you come back to our service?	Yes definitely	Yes I think so	No I do not think so	No definitely not

11.2. HEALTH LITERACY ASSESSMENT

Health literacy is defined as 'the cognitive and social skills that determine the motivation and ability of individuals to gain access to, understand and use information in ways that promote and maintain good health'[28].

Health literacy may be an important confounding factor within this study. The Newest Vital Sign (NVS)-UK is a simple, accurate and validated predictor of health literacy skills that has been shown to take on average 3 minutes to complete, and can be administered by both clinical and non-clinical personnel[30].

NVS consists of a food nutrition label with six associated questions giving scores from 0 to 6

Product Description: Ice Cream	
Serving Size:	100ml
Servings per container:	4
NUTRITIONAL INFORMATION	
TYPICAL VALUES	***Per 100ml***
Energy	**1050 kJ**
	250 kcal (calories)
Protein	**4 g**
Carbohydrate	**30 g**
of which sugars	23 g
Fat	**13 g**
of which saturates	9 g
of which monounsaturates	0 g
of which polyunsaturates	3 g
of which trans fats	1 g
Fibre	**0 g**
Sodium	**0.05 g**

Ingredients: Cream, Skimmed Milk, Sugar, Whole Egg, Stabilisers (Guar Gum), Peanut Oil, Vanilla Extract (0.05%).

Question	**Correct response**
1. How many calories (kcal) will you eat if you eat the whole container?	1,000 KCAL or 1,000 CALORIES
2. If you are advised to eat no more than 60 grams of carbohydrate for dessert, what is the maximum amount of ice cream you could have?	Two servings (or anything up to 2 servings) OR Half the container (or any amount up to half the container) OR 200 ml (or any amount up to 200 ml).
3. Imagine that your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, some of which comes from one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be eating each day?	33 g
4. If you usually eat 2500 calories each day, what percentage of your daily calorie (kcal) intake will you get if you eat one serving of ice cream?	1/10 (one tenth) OR 10%
Imagine that you are allergic to the following substances: penicillin, peanuts, latex gloves, and bee stings.	
5. Is it safe for you to eat this ice cream?	No
If 'No' to Q5:	
6. Why not?	Because it contains peanut oil/peanuts/nuts OR Because you might have an allergic reaction
ASK IF answer to Q6 is 'Because you might have an allergic reaction':	
7. Why would you have an allergic reaction?	Because it contains peanut oil/peanuts/nuts

11.3. KNOWLEDGE AND PERCEPTION QUESTIONNAIRE

SECTION1: PREVIOUS EXPERIENCE

1. Have you been anaesthetised before? Yes ___ No ___
   1.1 If so, what type (or types) of anaesthesia?

General anaesthesia ___
Spinal or epidural (lower half of the body) ___
Nerve block (for example only arm, hand or foot anaesthesia) ____
Local anaesthesia ____

2. If you have been anaesthetised, have you experienced any complication related to anaesthesia?
Yes ___ What?
_____
___
No ___
I have never been anaesthetised ____

3. Do you know anyone who has experienced complications related to regional anaesthesia?
Yes ___ What?
_____
____
No ___

SECTION 2: KNOWLEDGE OF ANAESTHESIA

4. How many options do you have for your anaesthetic for your operation?
0 ___ 1 ___ 2 ___ More than 2 ___ Don't Know ___

5. Having which type of anaesthetic will mean that you are awake for your surgery?
General ___ Regional ___ Both ___ Don't Know ___

6. Which type of anaesthetic is associated with the following statements:
A cannula is inserted into your hand General ___ Regional ___ Both ___ Don't Know ___
Monitors are applied to your body General ___ Regional ___ Both ___ Don't Know ___
A tube is inserted into your throat General ___ Regional ___ Both ___ Don't Know ___
You can listen to your own music General ___ Regional ___ Both ___ Don't Know ___
You will have a heavy, numb arm General ___ Regional ___ Both ___ Don't Know ___

7. When having **general anaesthesia**, how common is it to experience each one of the following events?

How common is it to:	Very rare	Rare	Uncommon	Common	Very Common
Experience nausea or vomiting	1	2	3	4	5
Have a sore throat	1	2	3	4	5

Suffer confusion, disorientation or memory loss	1	2	3	4	5
Experience pain whilst having the anaesthetic	1	2	3	4	5
Feel anything during surgery	1	2	3	4	5
Have damage caused to your teeth	1	2	3	4	5
Have permanent nerve damage	1	2	3	4	5
Suffer a life-threatening event	1	2	3	4	5
Be aware of your surroundings during surgery	1	2	3	4	5

8. When having **regional anaesthesia (nerve block)**, how common is it to experience each one of the following events?

How common is it to:	Very rare	Rare	Uncommon	Common	Very Common
Experience nausea or vomiting	1	2	3	4	5
Have a sore throat	1	2	3	4	5
Suffer confusion, disorientation or memory loss	1	2	3	4	5
Experience pain whilst having the anaesthetic	1	2	3	4	5
Feel anything during surgery	1	2	3	4	5
Have damage caused to your teeth	1	2	3	4	5
Have permanent nerve damage	1	2	3	4	5
Suffer a life-threatening event	1	2	3	4	5
Be aware of your surroundings during surgery	1	2	3	4	5

9. For the following statements, choose **general anaesthesia** or **regional anaesthesia** as the best option:

It is easier to manage postoperative pain. General ___ Regional ___ Don't Know ___
You will need less painkillers after your operation. General ___ Regional ___ Don't Know ___
You will be able to eat and drink straight away. General ___ Regional ___ Don't Know ___
You will be able to go home more quickly. General ___ Regional ___ Don't Know ____
You will feel like your normal self more quickly. General ___ Regional ___ Don't Know ____

SECTION 3: ATTITUDES TO ANAESTHESIA

10. How anxious do you feel about having an anaesthetic?
Very calm ___ Calm ___ Slightly anxious ___ Anxious ___ Very anxious ___

11. Do you consider **general anaesthesia** as a:
Very safe procedure ___ Safe procedure ___ Risky procedure ___ Very risky procedure ___

12. Do you consider **regional anaesthesia (nerve block)** as a:
Very safe procedure ___ Safe procedure ___ Risky procedure ___ Very risky procedure ___
13. How do you feel about the possibility of being awake during the surgery?
Very calm ___ Calm ___ Slightly anxious ___ Anxious ___ Very anxious ___

14. Imagine that you are having a **general anaesthetic.** How afraid are you about each of the following events?

How afraid are you of:	Very unafraid	Unafraid	Neither afraid or unafraid	Afraid	Very Afraid
Experiencing nausea or vomiting	1	2	3	4	5
Having a sore throat	1	2	3	4	5
Suffering confusion, disorientation or memory loss	1	2	3	4	5
Experiencing pain whilst having the anaesthetic	1	2	3	4	5
Feeling anything during surgery	1	2	3	4	5
Having damage caused to your teeth	1	2	3	4	5
Having permanent nerve damage	1	2	3	4	5
Suffering a life-threatening event	1	2	3	4	5
Being aware of your surroundings during surgery	1	2	3	4	5

15. Imagine that you are having **regional anaesthesia.** How afraid are you about each of the following events?

How afraid are you of:	Very unafraid	Unafraid	Neither afraid or unafraid	Afraid	Very Afraid
Experiencing nausea or vomiting	1	2	3	4	5
Having a sore throat	1	2	3	4	5
Suffering confusion, disorientation or memory loss	1	2	3	4	5
Experiencing pain whilst having the anaesthetic	1	2	3	4	5
Being in pain or feeling anything during surgery	1	2	3	4	5
Having damage caused to your teeth	1	2	3	4	5
Having permanent nerve damage	1	2	3	4	5

Suffering a life-threatening event	1	2	3	4	5
Being aware of your surroundings during surgery	1	2	3	4	5

SECTION 4: PRACTICES TOWARDS ANAESTHESIA

16. Which option for anaesthesia would you choose for your surgery?
General anaesthesia ___ Regional anaesthesia ___

16.1 Why?
_____
_____

17 If your anaesthetist advised you to have a regional anaesthetic technique, would you accept it?
Yes ___ No ___