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COMMUNICATION METHODS IN ORTHODONTIC INFORMED CONSENT AND THEIR EFFECTS: A SYSTEMATIC REVIEW

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ABBREVIATIONS

IC: Informed Consent

MIC: Modified Informed Consent

ICF: Informed Consent Form

AAO: American Association of Orthodontics

Tx: Treatment

Rsp: Responsibility(ies)

Rk: Risk(s)

Comp: Comprehension

Grp: Group(s)

MCQ: Multiple Choice Questions

Q: Question

ABSTRACT

Introduction: Informed consent (IC) is the fundaments in the dentist-patient relationship (1), a relationship to achieve better diagnosis, better treatment outcomes (6) and overall better satisfaction. IC is achieved in a process of dialog in which will be explained the full nature of the treatment, the purpose of the suggested procedure and the risks (4). Patients who are more appropriately informed and understand better tend to have better expectations of treatment outcomes.

Objective: The goal of this systematic review is to determine how an improved IC process can improve the orthodontist-patient relationship and treatment outcomes.

Material and Methods: A total of 9 randomised controlled trials have been selected through a bibliographic search via PubMed, Science Direct, Scopus and Scielo.

Results: Information leaflet is beneficial as a long-lasting accessible source of information (26), videotaped MIC (13) with humour (28) improved information retention after 6 weeks (28). Overall knowledge of risks are slightly low (6, 25, 26). Alternative IC format and "chunking" improved treatment recall in parents and treatment comprehension in patients (13). Rehearsal method improved both responsibility comprehension and recall, being greater to other domains (6).

Discussion: Concepts' complexity play an important role. Underwhelming results for custom risks recall might be due to patients' unawareness that they are specific to them and affected by positional effects (13). Self-assessment of understanding might lead to overestimation of knowledge (13,15) and results might be impacted by the use of close-ended questions (25, 26, 29). In orthodontists, the deficit in knowledge and overlooked importance of IC might suggest an inadequate information delivery (7). The lack of participant blinding may lead to anxiety, leading to worsened performance (6).

Conclusion: Leaflets don't show immediate benefits while visual formats reduce clinical chair time. Understanding of complex risks may be promoted by visual or audiovisual formats of MIC. Improved readability and information chunking is efficient in the treatment domain. Responsibilities seems the most understood due to simplicity.

KEYWORDS

“Informed consent”

“Informed consent document”

“Informed consent form”

“Modified informed consent”

“Comprehension”

“Recall”

“Readability”

“Understanding”

“Risks”

“Adverse Effects”

“Orthodontics”

1. Introduction

1.1 Informed consent (IC): Definition and origin

Informed consent (IC) in dental practice is considered to be the fundaments in the dentist-patient relationship prior to the beginning of a suggested treatment plan. Informed consent documents are used by dental practitioners in the goal to acquire legal consent from patients to carry out a treatment plan composing of dental procedures. In Orthodontics, the application of IC is a fundamental requirement in the orthodontist-patient relationship as specific orthodontic procedure usually do not fall within the patient's knowledge (1), implying that a comprehensive and educational interaction is needed for the patient, to be provided adequate and accurate information regardless how the information is communicated: IC is a basic principle of dental practice in which information is provided to the patient and knowledge is shared between the dentist and the patient, creating a shared-decision-based treatment plan (2). This is the 'collaborative deliberation' regarding treatment options between the orthodontist and patient (3).

It is achieved in a process of dialog in which the patient will be explained the full nature of the treatment, including their initial diagnosis, the purpose of the suggested procedure and what risks could arise during the treatment. In return, the patient must be able to achieve a balanced judgement by asking questions and considering the information received (4). The orthodontist will have to be concise, clear, direct, will need the desire to not overly alarm the patient or the parents and lastly hope they will accept the treatment plan (5).

When talked about "informed consent", it is precisely about patient's autonomy and justice, as IC is "the agreement expressed by the patient, manifested in writing and after obtaining information for carrying out a therapeutic diagnosis on his person" (1). This highlights the importance of the principle of autonomy, the patient deliberately deciding on their own to accept or refuse the offered treatment (2).

The importance of IC begins from allowing patients to be able to take an active role in the decision-making process regarding the orthodontic treatment plan (6). Patients could benefit from the IC by having their awareness raised, their concerns voiced, increased empowerment, enhanced dignity, increased motivation, increased satisfaction and reduced anxiety (4).

On the oral practitioner's side, one important goal of the use of IC is the fulfilment of legal obligation, to inform and communicate the patient to the best of their knowledge in regards to their diagnostic situation, which will allow to build and solidify an orthodontist-patient relationship based on trust (7).

During centuries, ethical principles guided general medical practice and their basics can be dated to the Hippocratic code of conduct, in fact IC was first evident in the Hippocratic Oath, stating that respects play an important role in the healthcare providers-patient relationship, pledging "first, do no harm". (8) It specifies the physical will help the ones in need thanks to his knowledge, experience and judgment, and never in the view of wrongdoing and injury. The Hippocratic tradition and the Judeo Christian ethic of care of the sick recognise the patients' vulnerability with respect to their illness, the physician's expertise and knowledge and the potential for conflict of interest. (9)

IC is a doctrine of research ethics involving human beings and has evolved into the present over following this journey : (10, 11)

- 1947 : The Nuremberg Code, in response to Nazi doctors who practiced unethical experimentation. It was the first international document of its kind to provide guidelines regarding research ethics, making voluntary consent a requirement in research studies. Voluntary consent was characterised by participants of the clinical studies to be able to give consent, being free from coercion and fully understand the balance between risks and benefits. Researchers were needed to minimise harm as

much as possible, ensuring risks do not outweigh benefits.

- 1964 : Declaration of Helsinki, adopting 12 principles for ethical consideration related to research, stating that " after ensuring that the potential subject has understood the information" the participant should freely give IC.
- 1979 : The Belmont Report, setting three new principles in the ethical conduct of research, in which it is needed to protect those with diminished autonomy such as impaired decision-making skills, to protect others from harm by maximising benefits and finally, fairly distributing the benefits and burdens of research. The Belmont Report ensures the identification of IC as a process essential to the principal of respect.
- 1982 : CIOMS guidelines, Ethical Guidelines for Research created by CIOMS and WHO to support the implementation of ethical principles of the Helsinki Declaration, identifying 26 separate items of information that must be provided to participants in order to obtain their IC.
- 1996 : International Conference on Harmonisation-GCP, to protect the rights of subjects involved in clinical trials but also protect their wellbeing.

1.2 Validity of IC and its requirements

Written consent is important prior to starting the treatment plan but in no case it substitutes obtaining a valid IC (12). The validity of IC begins with patient and/or their parents fully understanding what the treatment consists of, what risks may arise during the duration of the treatment, what benefits comes with every different treatment alternatives. If not adhered to, not giving a valid IC may have legal implications (13). A valid consent is a legal and ethical principal fundamental and necessary to protect the patients' wellbeing and the physician from claims of assault, negligence which could lead to charges and/or civil claims (3). It is a general legal and ethical principle reflecting the right of patients to decide what procedure is being carried out on their bodies and is an essential part of good practice (14).

Three different principles, known as the Consent Triangle (3) determine the validity of IC. These principles are the following :

- Volition: Voluntary decision-making, in which the patient makes their decision without any form coercion, persuasion or manipulation.
- Capacity: An individual is assumed to have the capacity and competence to make their own decision unless proven otherwise. For an individual aged 16 years and below, to be considered 'Gillick competent', the Orthodontist must determine that the information is clearly understood as well as being satisfied that the child has sufficient maturity to comprehend their involved and consequences of the suggested treatment plan. There is a staged process for decision-making, involving a first stage where the information is shared with the adolescent, a second stage where there is shared decision-making between parent and adolescent and a final one in which the adolescent is judged having the capacity for autonomous decision-making.
- Specificity: The information delivery constitutes sufficient information to achieve an informed decision.

Certain assumption for a consent to be valid are required. The orthodontist providing the information must have ample mastery and knowledge to explain the treatment plan, the procedure, to explain the potential risks of the treatment and what alternatives are available. The use of simplified dental terminology easier to understand by the patient will also increase the IC's validity, it is critical for patients and parents to understand the specific terminology used to describe orthodontic treatment, their diagnosis and the risks and complications that could arise anytime during the treatment (15). The consent process to be valid, should be an on-going progress and not a one-off event, once IC is given, it may be withdrawn any time (14).
The Department of Health in 2001 highlighted if insufficient information is provided and offered to the patient, too insufficient to reasonably make their decision, and in a form they cannot understand, their consent is considered invalid (16).

IC, based on The Health Care Consent Act, 1996 Ontario, must include the following features (10):

[1] The nature of the suggested treatment/procedure,

[2] The benefits the patient can expect,

[3] The adverse effects and potential material risks,

[4] Alternative treatment options,

[5] Consequences of treatment negligence,

[6] Answers to questions and doubts the patient might have,

[7] Total cost of the treatment.

It is imperative and crucial that orthodontists provide evidence-based information on pain characteristics that comes with orthodontic treatment and how to manage it, prior to the start of the treatment (10).

1.3 Different types of IC

IC comes in different forms and types, the BDA Ethics in Dentistry established the following definitions (12):

- Implied consent: Agreement indicated by the patient by lying down in the dental chair and allowing intra oral examination by opening the mouth
- Valid consent: Validity comes from a specific consent, informed and given by a patient, parent or a guardian
- Written consent: To be taken for major and long-lasting procedures

A different classification of IC in research studies is also available, in which we can find the following :

- Consent: An individual over 18 years old, competent to make a decision and give their consent.

- Parental consent/permission: The parent or guardian of a minor must sign a parent permission consent form, which should be signed by both parents in some cases. In others, it might be compulsory to waive the requirement to obtain parental permission
- Assent: A minor's affirmative agreement to participate in research studies. Assent must be obtained if the individual's age is ranging from 7 to 17 years old. It is imperative that the assent is written with an appropriate reading level, using simple terminology to ensure full understanding and comprehension.
- Verbal: Containing all the elements of written consent, verbal consent consists of the participant reading verbal all these elements and verbally agreeing to participate.
- Short form : It is used in cases where language barrier is present, an IRB's approved consent is verbally translated in the subject's mother tongue.

1.4 Introduction to Orthodontists-Patients relationship

Throughout history, the doctor-patient relationship developed itself as not a simple link between two individual but rather as a complex relationship established between the oral health practitioner and the patient, based in trust, in order to achieve a common goal which is shared decision-making. This is achievable with a bidirectional conversation, with a flow of information in which explanations are detailed in regards of the patient's disease (in this case malocclusion), the treatment needed and the possible unfavourable and favorable consequences (17).

This relationship constitutes the basis of quality medical practice, if it is well established, orthodontists will achieve better diagnosis, better treatment outcomes (6) and overall better satisfaction of the patients' needs (1). A solid relationship also leads to better cooperation and compliance (6), which is attainable thanks to greater communication (15). In the case of lack of cooperation , it may lead to disappointing treatment results, prolonged treatment time, more fees and in terms of poor oral

hygiene maintenance, greater severity of white spot lesions or caries. (18) It is highlighted that compliance is particularly important as, in Orthodontics, many treatment forces are applied outside of the dental practice and the patient will have to fulfil their responsibilities extra-office as their effort is practically equal to their treatment result (8).

In terms of communication, well informed patients tend to show less anxiety, may require less pain medication prescribed, show better compliance and gain more satisfaction from the treatment. They develop more reasonable expectations from the treatment and are less likely to file complaints and lawsuits which is of great relevance for American practicing orthodontists (19). Most communication is bidirectional with one party being the sender and the other, the receiver, but when we discuss methods of communication we talk about altered forms that do not necessarily involve direct oral communication or directly sending written language to a receiver. Orthodontic practices around the world tend to use three different types of communiqués on a daily basis which are intra-office, inter-office and extra-office communication methods. On one hand, intra-office communication consists of all the available in-office internal forms and documentation effectuating day-to-day operations, policies and procedures such as an informed consent form. On the other hand, inter-office englobe all communication methods between the orthodontist and other medical personnel who are caring for the patient, via regularly exchanged referral forms and sypnosis letters while extra-office focus on website content and financial agreements given to the patient (20). The relationship may be interrupted by an ethical question, a doubt on the right action to be taken when ethical responsibilities may conflict or when their meaning is uncertain (9).

1.5 Ethics and Moral

It is fundamental for oral health professionals to build a solid ethical foundation in their career as nowadays, patients demand more benefits and performance in their

demands, influenced by advertising marketing. These demands tend to be unrealistic and difficult to meet (17). The basic rights of patients cannot be ignored because their autonomy and responsibility is of high importance when it comes to take part or refuse their participation, their ability to take a decision regarding their own health is universally recognised as a right which puts emphasis on obtaining IC and justifies its need in clinical practice settings (10).

In Spain, IC has been evolving in recent years, the Spanish Legislation clarifies the aspects to be considered through the Law 41/2002 of November 14th, defining IC as "the free, voluntary and conscious agreement of a patient, manifested in the full use of his faculties after receiving adequate information". Article 9 of Organic Law 8/2015 of July 22 describes and reinforces the right of the minor to be heard and listened, modifying the protection system of minors where it specifies that "the minor has the right to be heard and heard without any discrimination based on age, disability, or any other circumstance". The minor has the right to receive the information allowing him to exercise this right in a comprehensive and adapted language, in accessible formats (17).

Orthodontists over the course of their career encounter ethical dilemmas in many different levels, important human values are at stake when treating patients: prevention of pain, restoring oral function for speech and eating, restoring the patient's physical appearance (21). The orthodontist is obliged morally to promote the patient's best interest and to protect them, their skillset and knowledge should allow them to minimise harm. The concept of dedicating to the patient's interest distinguishes a purely commercial venture to a profession as is expressed as beneficence and nonmaleficence (9).

An orthodontist needs to view a thorough and fundamental understanding of the principles relating to obtaining IC lawfully as a moral obligation (19), the tort of lack of IC is put in place when the orthodontist fails to communicate appropriately the material risks and dangers involved in the suggested procedure, if the unrevealed risks

that should have been communicated actually happen and are the cause of iatrogenic injury and if, an individual in the position of the patient would have decided to refuse treatment if the risk had priorly been disclosed before the start of treatment (6).

1.6 Risks during Orthodontic treatment

Orthodontic treatment is no different from any other medical treatment as patients will be exposed to certain risks throughout their treatment plan. From an ethical point of view, the orthodontist must understand how these risks and adverse effects relate individually to each patient to ensure benefits of the treatment overweighs the risks. Failing to adequately identify and manage risks will lead to patient dissatisfaction and litigation (22).

The risks include periodontal damage, pain, root resorption, TMJ disorder, caries, speech problems and enamel damage. The orthodontist is required to accordingly plan the treatment taking into consideration their patients' susceptibility to these risks and they should appropriately inform them regarding these (22). Knowledge about these adverse effects are of extreme importance to the orthodontist and the patient's willing to receive treatment, obtaining their IC is as important as executing the treatment plan. The potential risks and identified factors will be discussed to the patient seeking treatment and those will imperatively be included in the ICF as well as the duration of the treatment (23). It is strictly unacceptable to simply quote or mention a risk during the consent process, the true significance of a risk is more efficiently explained by placing it in the appropriate context and describing its possible consequences on how it could affect the patient's wellbeing or quality of life (3). The orthodontic treatment is based on a risk-benefit analysis, in which risks should be minimised by employing risk management strategies (3, 8).

The risk of adverse effects during orthodontic treatment materialises through a synergy between the patient and the treatment, an adverse effect will be the result of the treatment challenge exceeding the patient's adaptability and resistance. Orthodontists must carefully manage their patients' expectations via IC as part of risk management, a

real risk of orthodontic therapy is patient disappointment with intended or accidental outcome in a medicolegal point of view. An adverse effect or risk may not be considered as negligence, but the failure to properly warn and discuss it prior to treatment or during the IC process, it considered to be negligence (22).

1.7 Importance of patient understanding and its consequences

One of the basic and fundamental requirements of IC is a complete explanation of the nature, the aim and risks of the suggested procedures in a language that the patient fully understands. The patients and parents should be able to consider the information and express doubts and incertitudes to the orthodontist in order to achieve a balanced judgment of whether they would like to proceed with the treatment plan or not (12).

Patients who are more appropriately informed tend to be better consumers of dental services with better expectations of treatment outcomes. In the case of Orthodontic treatment, patient understanding is of great importance as the procedures tend to involve long-term appliances, thus are long-lasting treatments: it is critical for children as parents must ensure their child's compliance, which starts from fully understanding what their responsibilities must be (24).

During the IC process, Orthodontists tend to employ very specific and scientific terminology which cannot be comprehended by the parents and/or the patients. The terms used are poorly understood, which requires the orthodontists to carefully improve their communication methods, which will increase validity of the IC. This is directly correlates to health literacy, which by definition, is "the ability to understand and use health related printed information in daily activities at home, at work, and in the community to achieve one's goals and to develop one's knowledge and potential" (25).

A lack of understanding is not always due to the communication mode employed by the Orthodontist. It can compromise the doctor-patient relationship,

essential to patient compliance during the treatment plan (51). This issue brings into question whether the current format of IC is appropriately efficient for its purpose and for its validity (15).

Critical elements that should be fully informed to the patient and fully understood during the IC process are the following (3):

- The nature and goal of all the suggested treatment options, what each treatment option could achieve and could not,
- The consequence of no treatment,
- Evidence-based benefits, risks and limitations of the treatment,
- Patient responsibilities, what type of commitment is required, retention post-treatment,
- Treatment cost and estimated treatment duration,
- Reminder their decision may be changed at any time and that they have a right to seek a second opinion.

Patients need to entirely understand prior to treatment the responsibilities Orthodontic treatment comes with. Patient responsibility is crucial when it comes to the correct use of appliances as Orthodontic appliances create specific forces provoking tooth movements to fix existing pathology and malocclusion. These movements may only efficiently be achieved if the appliances are worn as requested otherwise treatment outcomes and expectations won't be met. They should also be fully aware orthodontic treatment comes with meticulous oral hygiene, care of the appliance, routine dental visits and regularly rescheduled appointments with the Orthodontist (12).

1.8 Limits of IC

Obtaining adequate IC from the patient is nor an easy nor a quick task, it is complex and ethically flawed, requiring respect of the patients' rights, exemplary

communication and interaction involving critical information about the patient's current pathology and diagnosis, the available therapeutic options for the specific clinical case, including risks and adverse effects and benefits that come with the treatment. Major barriers come with the obtention of IC and its understanding by

patients. They tend to have a subjective impression that they are being well informed due to orthodontists' over-confidence in the intelligibility of the information they communicate to the patients for example (2).

One of the current leading problems of IC involves the lack of recall from both the parents and the patient, regarding why the treatment is needed, what procedures will be carried out, what risks may arise and what their responsibilities are during and after the treatment. The frequency of the poor recall and comprehension among patients demonstrates that the current methods of Orthodontic IC delivery are insufficient and flawed(6). The two current major limitations IC face are the large amount of information presented and given to the patients and the length of the IC process (25). Several approaches could improve the current orthodontic IC, these are newer methods that involve of creating a modified IC which reduce either the length of the presentation or the amount of information presented. The aim of the modified IC is to create a concise medical consent with lesser words, shorter and simpler sentences and easier readability which shouldn't negatively affect the patient's understanding (25).

During the IC process, some challenges may be encountered when it is being delivered to the patient (11):

- Language barrier: When a patient signs the IC form, we assume it is done with full understanding of its content, however it is complicated to evaluate their viewpoint since no method is currently able to measure their level of understanding. Misunderstanding tends to happen because of inadequately translated information in the case of foreign patients.

- Religious influence: In cases of research, religious beliefs may interfere on the patient's willingness to participate or not in research during the IC process, when they have to decide whether to accept or not the recommended orthodontic treatment.
- False expectations: Misunderstanding happens despite there not being any language barriers, as patients and participants tend to have flawed expectations of the treatment outcome.
- Patient's perceptions: Some type of patients believe conventional procedures are the best and refuse to believe in newer and improved procedures, giving IC in such patients results being a difficult task. Giving them too much information regarding side effects might scare them away easily.

Vulnerable people and groups: Potential problems in understanding may arise, obtaining IC from these patients can be complex and special care is needed in order to develop appropriate strategies to improve communication and understanding.

1.9 Justification :

Orthodontic treatment requires exemplary compliance and commitment on the patient's side and the IC needs to ensure full understanding of the procedure and responsibilities that come with it. It is important to underline the flaws present in the IC process when it comes to patient's and parents' understanding and how efficiently the information is being delivered to them by the Orthodontist. Communication methods employed by orthodontists should be evaluated in terms of efficacy, efficiency and chair time used to deliver the information in order to, for example, enhance patients' and parents' expectations in terms of iatrogenic complications during treatment.

On one hand, Orthodontists will benefit by understanding how they could improve information delivery by employing a modified IC which consists of new communicating methods and/or chunking and synthesising of information, prioritising important aspects and elements of the treatment plan. On the other hand, patients will benefit from improved comprehension and recall of their diagnosis, of the treatment being done, the risks and possible iatrogenic adverse effects that may arise

during the treatment and finally the responsibilities they will need to commit to during and after the treatment. They might be offered clinical attention of quality in terms of ethical aspects of improved IC, with clarity of the information and explanation.
Overall, this will improve compliance and cooperation, solidifying the orthodontist-patient relationship in the goal of achieving better results during the long-lasting treatment.

2. Hypothesis and objectives

2.1 Hypothesis

Patients and parents fully understand the type of treatment that will be carried out and what their diagnosis is. However it is less clear for them what adverse effects can arise from orthodontic treatment and the level of commitment orthodontic treatment requires from them during the treatment plan and afterwards.

2.2. Objectives

2.2.1 General objective

With the help of a systematic revision, determine how an improved IC process can improve the orthodontist-patient relationship and treatment outcomes.

2.2.2 Specific objectives

1. Analyse communication methods employed by Orthodontists
2. Evaluate patients' knowledge regarding risks during Orthodontic treatment
3. Analyse patients' recall and comprehension of treatment
4. Evaluate patients' awareness of their responsibilities during Orthodontic treatment

3. Material and Methods

3.1 Study design

A systematic review was carried out, a descriptive study through which publications from different databases and search engines were analysed, with a cross-sectional nature.

3.2 Formulation of the study question

In the first place, a research question was asked using the acronym PICO, which helps us to ask a directed clinical question and to search for information precisely.

- Patient/Problem: Patients in need of orthodontic treatment
- Intervention: Delivery of informed consent form
- Comparison: No groups of comparison / Groups of age / method-type
- Outcome: Efficient prioritised understanding and recall of the entirety of the informed consent process and of the treatment plan

The question is then : In patients in need of orthodontic treatment, is the informed consent process and treatment plan fully understood and recalled by the patient ?

3.3. Eligibility criteria

3.3.1 Inclusion criteria

In the aim of reducing the search's content, the following inclusion criteria have been applied :

(a) Studies between 2011 and 2021

(b) Studies assessing comprehension and/or recall of Informed Consent

(c) English-language and/or Spanish-language articles in peer-reviewed academic/ scientific journals

(d) Articles with available questionnaires used to examine the level of patients' understanding and comprehension.

3.3.2 Exclusion criteria

In the same goal as the inclusion criteria, exclusion criteria have also been applied, which eliminate:

(a) Studies comparing or evaluating methods of informed consent not related to IC comprehension and/or recall (defined in inclusion criteria),

(b) Studies that used intervention to improve patients' understanding,

(c) Studies that included patients and/or parents with cognitive deficiency

(d) Open letters, editorials, conflict of interest statement, conference abstracts, interviews, systematic reviews (only to be used in the Introduction); Controlled trials ; articles in which ethical approval cannot be applicable.

(e) Articles published prior to 2011.

3.4 Search strategy

To optimise and enhance the bibliographic research, a series of MESH keywords have been established, which are :

- "Informed consent"
- "Informed consent document"
- "Informed consent form"
- "Comprehension"

- "Recall"
- "Readability"
- "Understanding"
- "Risks"
- "Adverse Effects"
- "Orthodontics"

3.4.1 Initial bibliographic search

In late October, an electronic bibliographic search has been conducted on the following scientific databases: PubMed, Scielo, Scopus and Science Direct, using MeSH terms like "Informed consent", "Orthodontics", "Comprehension", "Recall", "Understanding", "Risks, identifying a total of 4622 articles on PubMed, a total of 11 articles on Scielo, 907 articles on Scopus and 1476 articles on Science Direct (Table 1).

3.4.2. Systematic search

In each of the databases, different combinations of the terms were assembled in order to obtain the best results.

After applying different filters; type of article, year of publication and Boolean markers, such as "AND" and "OR" , a total of 1403 articles were found in PubMed, a total of 4 articles on Scielo, 413 articles on Scopus and 820 articles on Science Direct (Tables 2, 3, 4 and 5)

After critical and cautious reading of the titles and abstract, different articles were discarded for not meeting the eligibility criteria and/or being duplicates, leaving 6 articles from PubMed, none from Scielo, 2 articles from Scopus and 1 articles from Science Direct (Tables 2, 3, 4 and 5).

Therefore, the selected studies were 9 articles to which a scale was passed to evaluate the methodological quality through CASPe, following PRISMA 2020 guidelines. Below are the tables with the terms and Boolean markers used in each search, the

filters applied, the articles obtained, those selected that are part of the study, as well as the date on which the search was carried out.

3.5 Articles obtained in the databases

Table 1. Initial search without filters applied.

DATABASE	SEARCH	RESULTS WITHOUT FILTERS	TOTAL
PUBMED (October 2021)	(((informed consent) OR (informed consent document) OR (informed consent form))) AND ((((orthodontics) OR (corrective orthodontics) OR (interceptive orthodontics) OR (preventive orthodontics))))	466	4622
	((informed consent) OR (consent form)) AND ((orthodontics) OR (braces))	533	
	((consent) OR (consent form)) AND ((brackets) OR (orthodontics))	773	
	((moral) OR (ethical)) AND ((orthodontics) OR (Orthodontic treatment))	959	
	((((((moral obligation) OR (ethical guideline) OR (moral guideline) OR (moral concerns) OR (ethical concerns))))) AND ((Orthodontics) OR (Orthodontic treatment))	65	
	((patient understanding) OR (patient comprehension)) AND ((Orthodontics) OR (Orthodontic treatment)	1808	
	(patient comprehension[MeSH Terms]) AND (orthodontics[MeSH Terms])	18	

Table 1. Continued

SCOPUS (December 2021)	(patient comprehension) AND (orthodontics) (patient understanding) AND (informed consent form) AND (orthodontics) (risks) AND (informed consent) AND (orthodontics) (Adverse effects) AND (informed consent) AND (orthodontics) (Recall) AND (informed consent) AND (orthodontics)	301 68 387 65 86	907
Science Direct (November 2021)	(patient comprehension) AND (orthodontics) (patient understanding) AND (informed consent form) AND (orthodontics) (risks [MeSH Terms]) AND (informed consent [MeSH Terms]) AND (orthodontics [MeSH Terms]) (recall) AND (informed consent) AND (orthodontics)	339 675 58 404	1476
SCIELO (October 2021)	" Consentimiento informado ortodoncia " " Patient understanding orthodontics " " Orthodontics ethics "	2 3 6	11

Table 2. PubMed systematic search.

Search equation	Filters	Results	Selected
(((informed consent) OR (informed consent document) OR (informed consent form))) AND ((((orthodontics) OR (corrective orthodontics) OR (interceptive orthodontics) OR (preventive orthodontics))))	Free full text 10 years	187	6
((informed consent) OR (consent form)) AND (orthodontics)	Free full text 10 years	231	
((consent) OR (consent form)) AND ((brackets) OR (orthodontics))	Free full text 10 years	54	
((moral) OR (ethical)) AND ((orthodontics) OR (Orthodontic treatment))	Free full text 10 years	389	
((((((moral obligation) OR (ethical guideline) OR (moral guideline) OR (moral concerns) OR (ethical concerns))))) AND ((Orthodontics) OR (Orthodontic treatment))	Free full text 10 years	23	
((patient understanding) OR (patient comprehension)) AND ((Orthodontics) OR (Orthodontic treatment))	Free full text 10 years	501	
(patient comprehension[MeSH Terms]) AND (orthodontics[MeSH Terms])	Free full text 10 years	18	

Table 3. Science Direct systematic search.

Search equation	Filters	Results	Selected
(patient comprehension) AND (orthodontics)	Free full text 10 years Medecine and Dentistry	147	1
(patient understanding) AND (informed consent form) AND (orthodontics)	Free full text 10 years Medecine and Dentistry	382	
(risks [MeSH Terms]) AND (informed consent [MeSH Terms]) AND (orthodontics [MeSH Terms])	Free full text 10 years Medecine and Dentistry	36	
(recall) AND (informed consent) AND (orthodontics)	Free full text 10 years Medecine and Dentistry	255	

Table 4. Scopus systematic search.

Search equation	Filters	Results	Selected	Total selected
(patient comprehension) AND (orthodontics)	Free full text 2011-2021 Medecine + Dentistry Source type : Journal Keyword : human & humans	147	7	2
(patient understanding) AND (informed consent form) AND (orthodontics)	Free full text 2011-2021 Medecine + Dentistry Source type : Journal Keyword : human & humans	30	3	
(risks) AND (informed consent) AND (orthodontics)	Free full text 2011-2021 Medecine + Dentistry Source type : Journal Keyword : human & humans	157	1	
(Adverse effects) AND (informed consent) AND (orthodontics)	Free full text 2011-2021 Medecine + Dentistry Source type : Journal Keyword : human & humans	35	0	
(Recall) AND (informed consent) AND (orthodontics)	Free full text 2011-2021 Medecine + Dentistry Source type : Journal Keyword : human & humans	44	7	

Table 5. Scielo systematic search.

Search equation	Filters	Results	Total selected
" Consentimiento informado ortodoncia "	2011-2021 Dentistry	0	0
" Patient understanding orthodontics "	2011-2021 Dentistry	1	
" Orthodontics ethics "	2011-2021 Dentistry	3	

3.6 Evaluation of the methodological quality of the articles

The selected articles for this systematic review were evaluated through the CASPe guide, Critical Reading Sheets, specifically the 2020 PRISMA checklist which we analyse the methodological quality, reliability and clinical evidence of scientific studies through a series of questions that must be answered.

It includes tools for the evaluation of seven different types of designs (diagnostic test studies, systematic reviews, clinical trials, cohort studies, case-control studies, economic evaluation studies and case series) and depending on the type of study, a series of questions were answered about the type of study design, study objectives, inclusion/exclusion criteria, results and conclusions, as well as conflicts of interest.

After answering the questions, it was subsequently determined whether the study had high, medium or low quality to proceed with its inclusion or exclusion. Depending on whether it presented a yes, partially or no in the method section, it was classified according to the quality it presented, as well as in the rest of the areas (research question, results, conclusions, conflicts of interest and external validity). in order to obtain the quality of each article.

After passing the various questions to the 9 articles and checking the quality, those that presented a high/medium quality were selected, so that the total number of articles included for the development of the objectives is 9 articles.

4. Results

4.1. Study selection

4.1.1. Flow Chart Diagram

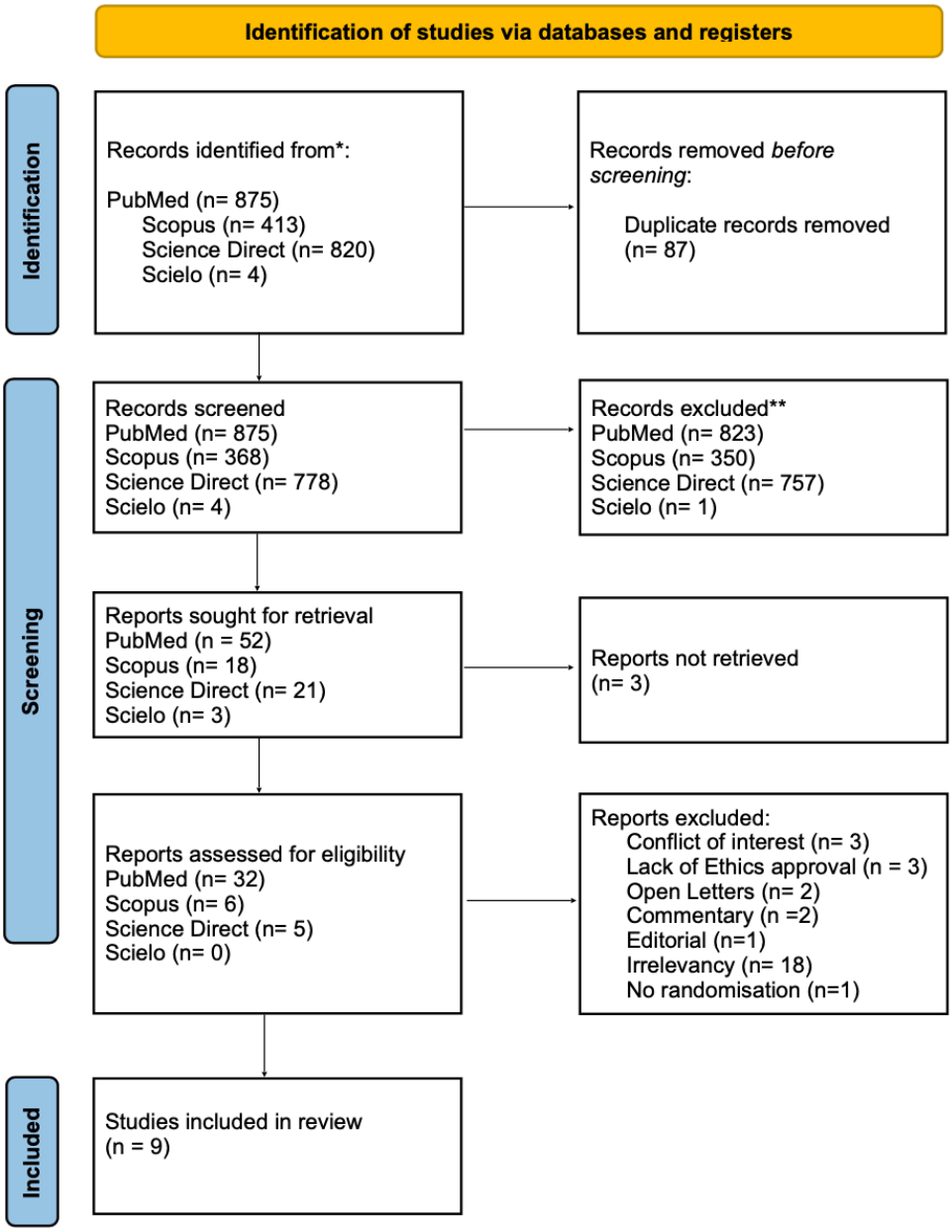

Fig 1. FlowChart of the Systematic Review, according to PRISMA 2020 guidelines.

A total of n= 2112 articles have been identified through bibliographic searches in databases PubMed, Scopus, Science Direct and Scielo from which n= 87. The results' titles have been screened, resulting in a total n= 94 reports sought for retrieval in which n= 3 couldn't be retrieved due to inaccessibility. The assessment for eligibility involved n= 32 articles from PubMed, n= 6 from Scopus and n=5 from Science Direct in which n= 5 were excluded from inappropriate format such as being Open Letters, Commentary and Editorial. In n= 3 conflict of interests were mentioned and n= 3 lacked of ethical approval in the IC process. A total of n= 18 have been excluded for irrelevancy, of particular disinterest for the systematic review being conducted. Lastly, n=1 was discarded for not being a Randomized Controlled Trial study.

4.2. Study Characteristics

4.2.1. General characteristics of the included studies

Table 1. General information of the included studies. Author, Sample Size (Age of patients), Groups, Clinical Parameters, Methods, Efficacy. IC: Informed Consent; MIC: Modified Informed Consent; MCQ: Multiple Choice Question.

AUTHOR	SAMPLE SIZE (AGE OF PATIENTS)	GROUPS	CLINICAL PARAMETERS	METHODS	EFFICACY
Skulski B et al. (6) 2021	90 pairs (11-18 years).	Groups A and B.	Short-term recall and comprehension.	MIC with visual printouts and slideshow presentation.	Slideshow presentation gathered better results.
Alagesan A et al. (7) 2015	25 pairs (18-35 years).	Orthodontists (n=25) and Patients (n=25).	Knowledge and awareness of informed consent.	Participant information sheet, a MCQ questionnaire and 3 Likert Format statements.	A majority of Orthodontists are aware of knowledge regarding IC.
Pawlak C et al. (13) 2014	69 pairs (12-18 years).	Group A (n=34), Group B (n=35), Group C and D from the Study of King EY et al (31) and Group E from the study of Carr K et al (25).	Recall and comprehension of the risks, benefits and alternatives.	Information "chunking" and MIC with a short videotaped presentation.	Improved readability with information "chunking" showing increased overall comprehension and recall but audiovisual MIC did not show benefits.
Nasr I et al. (16) 2011	80 (12-14 years).	Control group (n=40) and Intervention group (n=40).	Patient expectations.	MIC with additional information leaflet.	No significant differences nor immediate impact found.
Carr K et al. (25) 2012	80 pairs (12-18 years) + 30 subjects from the study of Kang EY et al (31).	Intervention groups A, B and C from Kang EY et al (31).	Understanding of risks and limitations of Orthodontic treatment.	MIC with customised slideshow with or without verbal review.	Improvement of overall comprehension, risk recall and comprehension, and of general risks and limitations.

Table 1. Continued

Sharma P et al. (26) 2016	61 pairs (10-15 years).	Control group (n=30) and Study group (n=31).	Recall of information during IC process.	Verbal information with or without written information.	Patients disposing of written consent showed better knowledge and recall.
Levine T et al. (28) 2020	38 (10.6-33.5 years).	Group H (n=20) and Group U (n=18).	Recall of information regarding Orthodontic treatment.	Viewing humorous video or live-action video without humor.	Informativeness showed no difference. Increase of replay value and memorability with humor.
Shqaidef A et al. (29) 2021	64 (12-18 years)	2 unnamed groups.	Recall and comprehension of information.	Delivery of BOS leaflet followed by verbal explanation and visualisation of a 3D animation.	3D animated video saved clinical and chair time but is equivalent to written and verbal information.
Desman A et al. (30) 2021	116 pairs (11-18 years)	Group A and B.	Long-term recall and comprehension of IC.	Visual printout images and audiovisual presentation.	No significant differences were found.

The main characteristics of the selected articles for the systematic review are shown in Table 1. A total of 1094 individuals have been studied undergoing an IC process, in which 441 are parents and 25 are Orthodontists. A range of different IC communicative methods and MIC formats have been employed such as information leaflets in studies of Nasr I et al. (16) and Shqaidef A et al. (29); visual printouts in studies of Skulski B et al. (6) and Desman A et al. (30), audiovisual media in studies of Pawlak C et al. (13), Levine T et al. (28), Shqaidef A et al. (29) and Desman A et al. (30) and finally slideshow presentations in studies of Skulski B et al. (6), Carr K et al. (25) and Desman A et al. (30) (Table 1).

4.3 Risk of bias

4.3.1 Risk of bias assessment of the included studies

AUTHOR	Q1 1. Clear focused research question	Q2 2. Randomisation of participants	Q3 3. All participants accounted	Q4 4. Blinded participants	Q5 5. Groups similar at the start	Q6 6. Equal level of care in groups	Q7 7. Effects reported comprehensively	Q8 8. Precision of the estimate	Q9 9. Benefits outweigh harms and costs	Q10 10. Results applied to your context	Q11 11. Experimental intervention provide greater value
Skulski B et al. (6)	+	+	+	-	+	?	+	+	-	+	+
Alagesan A et al. (7)	+	?	+	?	-	?	+	-	+	+	+
Pawlak C et al. (13)	+	+	+	+	+	+	+	+	+	+	+
Nasr I et al. (16)	+	+	+	+	+	?	+	+	-	+	+
Carr K et al. (25)	+	+	+	+	+	+	+	+	+	+	?
Sharma P et al. (26)	+	+	-	-	+	+	+	+	+	+	+
Levine T et al. (28)	+	+	-	+	+	?	+	?	+	+	+
Shqaidef A et al. (29)	+	+	-	-	+	?	+	+	+	?	?
Desman A et al. (30)	+	+	-	?	+	+	+	?	+	+	+

Fig. 2. Risk of bias assessment. According to CASPe guideline, PRISMA 2020 checklist: an updated guideline for reporting systematic reviews. +: low risk of bias; -: high risk of bias; ?: unclear risk of bias.

4.3.2. Reporting of biases

The evaluation of the risk of bias of the studies through the CASPe guideline according to the PRISMA 2020 checklist showed highly positive results in the

participants randomisation sequence as well as the clarity of the research question of each studies and how the effects have been reported. Ideally, low biases have been found for applying results in our context and experimental interventions possibly providing greater value to people in our care. Satisfactory bias can be reported for the benefits outweighting the harms and costs except for two studies in which visual printouts were used, the studies of Skulski B et al. (6) and Nasr I et al. (16).

However, significant high risk of bias have been found in studies of Sharma P et al (26), Levine T et al (28), Shqaidef A et al. (29) and Desman A et al. (30) in which participants have not committed to the entirety of the studies. High uncertainty of risk of bias have been specifically reported for Questions 3 and 4 in which an important number of studies faced participants drop-outs (26, 28, 29, 30) and participants were not blinded (6, 26, 29).

Results show the studies of Alagesan A et al. (7), Sharma P et al. (26), Shqaidef A et al (29) show moderate risk of bias (Fig 2).

4.4 Specific variables of the studies

Table 2. Results of the clinical parameters evaluated by each study. Comp: comprehension; Grp: Group; Tx: Treatment; Rk: Risk; Rsp; Responsibilities; Cust: Custom; Gen: General.

<table>
<tr><th>AUTHOR</th><th colspan="6">CLINICAL PARAMETERS EVALUATED</th></tr>
<tr><td rowspan="2">Skulski B et al. (6)
2021</td><td colspan="3">Recall of Core, Custom & General Rk elements (n%)</td><td>Rsp Comp (n%)</td><td>Rk Comp (n%)</td><td>Tx Comp (n%)</td></tr>
<tr><td>Grp A Core (rehearsal)= 81
Grp B Core (slideshow)= 70</td><td>Grp A Cust (rehearsal)= 43
Grp B Cust (slideshow)= 37</td><td>Grp A Gen (rehearsal)= 46
Grp B Gen (slideshow)= 50</td><td>Grp A (rehearsal)= 77
Grp B (slideshow)= 70</td><td>Grp A (rehearsal)= 49
Grp B (slideshow)= 49</td><td>Grp A (rehearsal): 30
Grp B (slideshow): 41</td></tr>
<tr><td rowspan="2">Alagesan A et al. (7)
2015</td><td colspan="6">Comp of IC obtention (n% of correct answers)</td></tr>
<tr><td colspan="3">Orthodontists: n= 79,14</td><td colspan="3">Patients: n= 35.14</td></tr>
<tr><td rowspan="3">Pawlak C et al. (13)
2014</td><td colspan="2">Mean (SD)% of overall on-target Recall and Comp</td><td colspan="2">Mean (SD)% of on-target responses on consent domains</td><td colspan="2">Mean (SD)% of on-target responses for Recall and Comp of core, custom and general Rk</td></tr>
<tr><td>Patients</td><td>Parents</td><td>Patients</td><td>Parents</td><td>Patients</td><td>Parents</td></tr>
<tr><td>51.5% (SD, 20.3%) to 55% (SD, 14.7%) between Grp A and B.</td><td>66.0% (SD, 13.7%) to 71.5% (SD, 14.4%) between Grp A and B.</td><td>Tx Recall= 50.2 (20.4)
Rk Recall= 59.4 (22.3)
Rsp Recall= 60.7 (18.3)
Tx Comp= 47.0 (25.6)
Rk Comp= 38.4 (18.8)
Rsp Comp=69.8 (18.6)</td><td>Tx Recall= 70.1 (19.7)
Rk Recall= 65.7 (17.4)
Rsp Recall= 80.0 (15.8)
Tx Comp= 57.0 (18.6)
Rk Comp= 57.2 (18.7)
Rsp Comp= 87.8 (14.3)</td><td>Core Recall= 53.8 (18.5)
Cust Recall= 36.2 (36.1)
Gen Recall= 52.7 (15.2)
Core Comp= 69.4 (23)
Cust Comp= 31.1 (40.3)
Gen Comp= 41.3 (17.9)</td><td>Core Recall= 73.5 (17)
Cust Recall= 60.8 (32.1)
Gen Recall= 71.0 (11.7)
Core Comp= 84.5 (14.9)
Cust Comp= 37.2 (36.5)
Gen Comp= 61.0 (16.9)</td></tr>
<tr><td colspan="2">No significant differences found.</td></tr>
<tr><td rowspan="3">Nasr I et al. (16)
2011</td><td colspan="2">Difference between Male and Female (Control and Intervention groups combined)</td><td colspan="2">Before and after intervention scores for all the continuous variables (Control group vs. Intervention group)</td><td colspan="2">Before and after scores for the categorical variables</td></tr>
<tr><td colspan="2">P= 0.007; chi-squared (χ2).
No significant differences.</td><td colspan="2">P= 0.04; ANCOVA.
Significant differences.</td><td>Q8: χ2= 0.18
Q8: P= 0.67</td><td>Q9: χ2= 1.16
Q9: P= 0.28</td></tr>
<tr><td colspan="4"></td><td colspan="2">No statistically significant differences</td></tr>
</table>

Table 2. Continued

Carr K et al. (25) 2012	Mean (SD)% of overall on-target recall and comp		Mean (SD)% of on-target responses for consent domains		Mean (SD) % of on-target responses for general, core, and custom questions	
	Patients	Parents	Patients	Parents	Patients	Parents
	Grp A Recall= 58.8 (14.8) Grp B Recall= 57.4 (13.4) Grp C Recall= 52.6 (14.4) Grp A Comp= 52.9 (15.8) Grp B Comp= 53.6 (13.3) Grp C Comp= 44.2 (16.7)	Grp A Recall= 71.0 (13.9) Grp B Recall= 70.6 (13.9) Grp C Recall= 67.3 (16.8) Grp A Comp= 67.1 (13.3) Grp B Comp= 69.2 (15.2) Grp C Comp= 66.3 (16.6)	Tx Recall Grp A= 47.0 (19.3) Tx Recall Grp B= 48.9 (19.0) Tx Recall Grp C= 36.7 (22.9) Rk Recall Grp A= 68.6 (20.6) Rk Recall Grp B= 57.4 (18.5) Rk Recall Grp C= 51.3 (20.3) Rsp Recall Grp A= 67.4 (18.5) Rsp Recall Grp B= 68.6 (18.5) Rsp Recall Grp C= 70.7 (18.3) Tx Comp Grp A= 40.9 (24.5) Tx Comp Grp B= 39.0 (20.0) Tx Comp Grp C= 32.7 (23.8) Rk Comp Grp A= 41.6 (17.4) Rk Comp Grp B= 38.9 (18.5) Rk Comp Grp C= 28.1 (19.7) Rsp Comp Grp A= 72.3 (17.8) Rsp Comp Grp B= 78.2 (15.5) Rsp Comp Grp C= 68.2 (23.0)	Tx Recall Grp A= 60.8 (21.5) Tx Recall Grp B= 62.1 (27.0) Tx Recall Grp C= 62.3 (24.5) Rk Recall Grp A= 72.4 (17.4) Rk Recall Grp B= 69.6 (19.3) Rk Recall Grp C= 66.0 (22.0) Rsp Recall Grp A= 84.2 (15.7) Rsp Recall Grp B= 80.8 (15.9) Rsp Recall Grp C= 80.5 (17.8) Tx Comp Grp A= 52.4 (22.8) Tx Comp Grp B= 59.6 (26.4) Tx Comp Grp C= 56.4 (24.1) Rk Comp Grp A= 58.2 (19.9) Rk Comp Grp B= 57.5 (20.5) Rk Comp Grp C= 52.2 (21.1) Rsp Comp Grp A= 85.6 (15.6) Rsp Comp Grp B= 86.8 (13.1) Rsp Comp Grp C= 87.0 (18.3)	Grp A Gen Recall= 58.0 (15.5) Grp B Gen Recall= 51.8 (15.3) Grp C Gen Recall= 47.2 (14.5) Grp A Core Recall= 58.9 (20.8) Grp B Core Recall= 65.7 (17.9) Grp C Core Recall= 62.5 (20.9) Grp A Cust Recall= 55.0 (35.9) Grp B Cust Recall= 55.7 (33.3) Grp C Cust Recall= N/A Grp A Gen Comp= 39.8 (18.4) Grp B Gen Comp= 39.7 (19.0) Grp C Gen Comp= 32.5 (15.4) Grp A Core Comp= 68.5 (18.7) Grp B Core Comp= 70.6 (15.6) Grp C Core Comp= 60.7 (22.7) Grp A Cust Comp= 45.7 (38.6) Grp B Cust Comp= 46.3 (36.7) Grp C Cust Comp= N/A	Grp A Gen Recall= 70.2 (14.7) Grp B Gen Recall= 67.3 (16.1) Grp C Gen Recall= 65.9 (18.3) Grp A Core Recall= 71.1 (19.2) Grp B Core Recall= 75.5 (15.6) Grp C Core Recall= 68.9 (19.1) Grp A Cust Recall= 68.7 (37.1) Grp B Cust Recall= 70.9 (31.1) Grp C Cust Recall= N/A Grp A Gen Comp= 56.9 (17.6) Grp B Gen Comp= 57.5 (19.6) Grp C Gen Comp= 55.9 (19.4) Grp A Core Comp= 81.2 (16.6) Grp B Core Comp= 83.8 (13.3) Grp C Core Comp= 80.9 (18.1) Grp A Cust Comp= 56.0 (35.6) Grp B Cust Comp= 62.7 (39.0) Grp C Cust Comp= N/A
Sharma P et al. (26) 2016	Comp of Information given		Lack of Rk Recall		Resp & Tx Comp	
	Control Grp n(%)	Study Grp n(%)	Control Grp n(%)	Study Grp n(%)	Control Grp n(%)	Study Grp n(%)
	30 (100%)	31 (100%)	8 (26.7%)	1 (3.2%)	13 (43.3%) 23 (76.7%) 16. (53.3%)	22 (71.0%) 27 (87.1%) 25 (80.6%)
Levine T et al. (28) 2020	Mean (SD) responses for objective questions			Mean (SD) responses for subjective questions		
	Humorous video	Unhumorous video	P (Humorous vs Unhumorous)	Humorous video	Unhumorous video	P (Humorous vs Unhumorous)
	T1= 90.50 (0.126) T2= 89.55 (0.119) P= 0.335	T1= 86.58 (0.127) T2= 77.78 (0.186) P= 0.042* *Significant mean difference	T1= 0.075 T2= 0.001* P= N/A *Significant mean difference	Replay Value: 6.636 (2.361) Memorability: 8.591 (1.141) Recall: 6.750 (2.124)	Replay Value: 4.857 (0.793) Memorability: 5.571 (2.014) Recall: 5.778 (1.768)	Replay Value: P= 0.002* Memorability: P=<0.0001* Recall: P= 0.1363 *Significant mean difference

4.4.1. Communication methods employed by Orthodontists

In the different studies included, various methods have been employed for information delivery whether it's through direct communication or by the use of MIC, in which information is delivered to the patient through a range of methods different to basic written or verbal communication. It was found that written information as a leaflet is beneficial to patients as a long-lasting accessible source of information in the study of Sharma P et al. (26) improving both comprehension and recall, however neither the verbal or verbal supplemented with written information methods seemed successful in regards to risks during treatment requiring constant re-informing by the Orthodontist (26). Similarly, in the study of Shqaidef A et al. (29) in which information leaflets were also used supplemented or not by a 3D animated video, the conventional group with written information scored higher with 79.1 ± 18.4 with no statistically significant difference (P = 0.492) (29) with no drastic change one year later. Additional verbal review by the clinician to a MIC is also analysed in the study of Carr K et al. (25).

Results show that for parents and patients,

with or without the clinician's supplemented verbal explanation, overall comprehension and recall in the treatment domains were alike as well as in the 18 IC elements. Despite no significant differences, the need of additional verbal reviewing for the domain should be emphasised in the risk domain for children (25).

Communication methods by Orthodontists can also be indirect, through the format of a multimedia recording as presented in the studies of Pawlak C et al. (13) and Levine T et al. (28). No significant differences were shown with the use of a videotaped MIC in patients or parents (13) but if the nature of communication is altered with humour (28), with no changes in the informative aspect, information retention after 6 weeks can be enhanced (28) (Table 2).

4.4.2. Patients' risks knowledge during Orthodontic treatment

As previously mentioned, overall knowledge of risks ascertained to be slightly underwhelming in the studies of Carr K et al. (25) and Sharma P et al. (26). In the study of Skulski B et al. (6), insignificant results and improvements were found when trying to improve recall of Core, Custom and General risks elements and comprehension of possible risks during treatment as both groups A and B (rehearsal and slideshow groups respectively) showed very similar response rate (6, Table 2). A recurring pattern of prominent response rate is noticeable in the first pieces of information presented to the patients and parents (6). Recall and comprehension for both core and general risks elements were improved for patients and parents thanks to information chunking as seen in the article of Pawlak C et al. (13) while custom risks are unsatisfactory. Results in Table X show they are the lowest values, 36.2 (36.1)% and 31.1 (40.3)% for patients, 60.8 (32.1)% and 37.2 (36.5)% for parents (13, Table 2). The study of Carr K et al. (25) showed predominantly low on-target responses percentages for recall in patients, with 58% and parents with 71% but also in comprehension, respectively 53% and 68% in patients and parents. Nonetheless, among the patients, group A patients dominantly scored in the risk recall domain as seen in Table 2, thanks to reinforced verbal

information due to the previously noticed low scores (25). Regarding the use of information leaflets as a MIC in the study of Sharma P et al. (26) , only 1 patient, accounting for 3.2% of the Study group, enquired for further risks explanation compared to 8 patients (26.7%) from the control group (26.7%) showing the study group was better informed of the possibility of risks and emergency occurrences (26, Table 2) however neither methods in the study were greatly successful as they both require clinicians to reinforce information delivery at relevant times during the treatment (26).

The implementation of a 3D animation as seen in the study of Shqaidef A et al. (29) yielded a larger number of correct answers at T0 compared to conventional methods, nevertheless risks recall remaining generally poor, diminishing 1 year later at T1. An example is root resorption patients fail to comprehend thus fail to recall its importance yet lightly bettered by the visual nature of the 3D animation (29). Desman et al. (30) did not get hold of significant differences in the average scores between both rehearsal and best practices groups for patients and parents as values are almost identical in Table X. At 6 months, the same can be stated for the follow up (30).

4.4.3. Patients' recall and comprehension of treatment

Alagesan A et al. (7) tested general knowledge about IC delivery in both orthodontists and patients. Interestingly, orthodontists accounted for 79.14% of correct answers compared to patients with only 35.14%, showcasing lack of knowledge in Orthodontists and the obligation to fortify information delivery in patients in hopes to improve overtime the recall. On one hand, it was found in the study of Pawlak C et al. (13) treatment recall in patients showed a result of 50.2 (20.4)% being the lowest amongst recall of risks and responsibility, which were respectively of 59.4 (22.3)% and 60.7 (18.3)%. On the other hand, treatment recall in parents was superior, with a result of 70.1 (19.7)% (Table 2). It was mentioned that the alternative IC format improved treatment recall in parents as well as information "chunking" in a readable form

whereas it improved treatment comprehension in patients. Sharma P et al. (26) called upon the use of information leaflets in his study group in which greater results were observed for Treatment recall such as 22 (71.0%) and 25 (80.6%), compared to control group with 13 (43.3%) and 16 (53.3%) respectively (Table 2). Specifically, the study group was more up-to-date with duration of treatment as verbal information given about treatment should be supplemented with written information (26). In the study of Levine et al. (28) assessing the efficacy of a humorous audiovisual format in terms of treatment comprehension and recall, better results were found with the use of humour such as 90.50 (0.126) at T1, 89.55 (0.119) at T2 and P= 0.335 (28, Table 2) for objective questions regarding Orthodontic treatment. The same trend was noticed in subjective questions with 6.750 (2.124) for treatment recall, compared to 5.778 (1.768) without humour (28, Table 2) Desman A et al. (30) found that despite the rehearsal method seemed to have shown overall improvements (P <0.05), results were slightly underwhelming specifically for treatment recall in both parents and patients. Parents scored higher than the patients with the rehearsal method at both baseline and 6 months follow-up: from 52 (24) at baseline to 43 (16) after 6 months for parents and respectively 36 (21) to 26 (18) for patients. (30)

4.4.4. Patients' awareness of their responsibilities during treatment

In the study of Skulski B et al. (6), the rehearsal method showcased improvement in both responsibility comprehension and recall but is also shown in Table 2 as being overall greater compared to risk and treatment domains (6). Similar outcomes were found with Skulski B et al. (6) in which patient responsibility recall was significant improved while comprehension still being superior as seen in Table X in both patients and parents (13). The same trend repeats in the study of Carr K et al. (25) in which responsibility domain on-target responses are the highest, while comprehension is greater than recall (Table 2). Overall, domains of responsibility scored best compared to other domains in both patients and parents. Nasr I et al. (16) analysed differences in responses between the genders and has found that

there were no statistical significant differences except one finding that males believed responsibilities before the intervention were going to be more demanding (P50.007; chi-squared test) (16). The domain of responsibilities also scored higher in both the study of Sharma P et al. (26) and Desman A et al. (30) with the use of supplemented written information (26) and the use of visual printouts and audiovisual material (30).

4.5 Data extraction

Due to the heterogeneity presented in the results of the included studies, since most assess and measure the variables in different ways, it is not possible to do a meta-analysis with the gathered data from the results.

5. Discussion

The obtention of IC is a complex task in which the information should be communicated and presented appropriately to the patient to ensure solid comprehension and achieve necessary compliance for treatment. The studies of Skulski B et al. (6), Carr K et al. (25), Sharma P et al. (26) and Desman A et al. (30) all found greater comprehension of responsibilities that come with Orthodontic treatment in both patients and parents while in the same studies deficient comprehension was seen in the risk domain. The complexity of the concepts presented play an important role in these findings as a weighty part of responsibilities are common-sense notions regarding oral hygiene, frequent appointments, retainer wearing while in the risk domains, a wide variety of concepts range from sensitivity and pain, to root resorption and ankylosis which were found to have statistically poor reliability (6, 25). While understanding the possible risks that could arise during treatment was slightly poor, only the recall of core risks and general risks were improved in the study of Pawlak C et al. (13) whereas Skulski et al. (6) found none to be improved. Reasons for the lack of improvement in custom risks recall could be the patient's lack of awareness that the risks presented in that section are customised, individualised and specific to them, as well as core risks who were presented first and general risks last, gathered better on-target responses due to positional effects such as primacy effect and the recency effect (13). Primacy effect was also noticeable with Skulski B et al. (6) in the first concepts presented to patients and parents. A reason why Skulski B et al. (6) did not find the same recall improvements as Pawlak C et al. (13) could be the fact that further efforts should be put in the conversion of short-term memory into long-term by accentuating the rehearsal method, the importance of long-term memory being the enhancement of IC validity as <6 weeks recall is considered invalid in the IC process (26). The rehearsal method has great potential in getting the patients and/or parents to "parrot" the recall information but wouldn't affect in anyway its understanding. The "information chunking" method, supplemented by improved readability and additional audiovisual material was beneficial in the study of Pawlak C et al. (13) as participants

might have not been fatigued with an overwhelming delivery and presentation of information however results could be significantly bettered if patients were aware that information has been “chunked”. Another limitation to this study is the instability of literacy levels in the groups and different ethnic distributions. To improve the lack of custom risks recall, due to its importance, it could be placed in the beginning in order to benefit from the primacy effect (13).

Overall Carr K et al. (25) and Sharma P et al. (26) found improvements in risk recall despite the lacking of understanding at first. The same idea of repeating information by patients and parents could be correlated to the complexity of the questions presented in the first place. Direct recall questions could allow patients and/or parents to “parrot” appropriately responses positively affecting recall evaluation

while difficulties of doing so can be encountered in scenario-based questions. To avoid questions cueing answers, Shqaidef A et al. (29) used open-ended questions to avoid patients and/or parents to guess answers when evaluating recall.

Regarding the basic aspects of IC as well as its fundamentals and generalities concerning its delivery to patients, Alagesan A et al. (7) compares knowledge in both orthodontists and patients only to find that as much as orthodontists are erudite regarding IC concepts compared to patients, their knowledge are far from being perfected as only half understand the necessity of obtaining IC. The reason for underwhelming scores in both groups can simply be the fact that first of all, orthodontists fail to spread the adequate amount of information to patients regarding IC and secondly, orthodontists oversee the importance of IC and judge its necessity only for treatment approval or do not carry out a progressive and extended IC process from fear of refusal from the patient (7). These findings might be due to a lack of education in college about IC, the deficit in knowledge and overlooked importance might suggest that after all, orthodontists might not share the most adequate information to patients regarding risks, limitations, benefits and other IC elements but might not reach full potential in assuring patient’s full awareness of orthodontic treatment expectations impacting patient’s compliance during the treatment, thus the

results and duration of the treatment. Further knowledge reinforcement and general focus should be applied on orthodontists before trying to understand how to maximise patients' comprehension and recall because in the speciality of orthodontics, obtaining a valid and true IC is an ethical and legal requirement by law (7).

In the study of Desman A et al. (30) in which the purpose was to compare 6-month recall between a written rehearsal method and the current best practices methods, positive results have been gathered in the recall subdomains than for comprehension however, no significant differences have been found in both groups overall (30). As previously seen, despite disposing of the biggest pool of participants in this systematic review with a high distribution of ethnicities and a high dropout rate of 33.6% (30), it is unclear whether participants have been blinded or not which could affect the results. This could imply that, being aware of the research they're paticipating in, anxiety levels could be slightly higher than the average leading to worsened performance or poorer on-target responses. Interestingly, this comes to view with Skulski et al. (6) who substantiates that increased anxiety in patients decreases patients' on-target responses. Another study facing the problem of participants not being blinded in the research is the one from Sharma P et al. (26) which increases bias and additionally compromises the power the study. Their sample size did not reach the minimum size requirements alongside the few dropouts the study faced, validity of the study decreases however the homogeneity in the sample with respect to demographic variables is found to be advantageous despite the merest sample size. In comparison, Desman A et al. (30) is unsuccessful in the homogeneity of the sample with restricted generalisability as non-White ethnic groups are poorly present in the study. He believes anxiety affects less non-whites compared to white non-hispanics however the correlation between anxiety and race is unclear and insignificant in his study (30). Reoccurrence of defective sample size is also noticeable in the study of Nasr I et al. (16) in which he detects a medium effect size while a smaller effect size with a larger sample size would be more appropriate (16). Because of this, inconsequent results are found when comparing groups using information leaflets as immediate benefits are not

imparted in terms of knowledge. Nevertheless Nasr I et al. (16) suggests that verbal discussion between the clinician and the patient can be reinforced through the use of leaflets which guarantees a written record of mentioned key points throughout the IC process with the possibility of referring back, thus ensuring aid in recall (16).

A major issue when it comes to patients and parents recall is the common problem faced in the studies of Pawlak C et al. (13) and Carr K et al. (25) in which results were self-assessed. In the case of Carr K et al. (25), self-assessment of understanding might be subjective, patients and parents are unable to objectively evaluate their own knowledge and comprehension of concepts which could alter the meaning of the recall results. Identically with Pawlak C et al. (13), patients and parents might overestimate their understanding however in the study of Levine T et al. (28), even though the follow-up has been carried out electronically without being able to evaluate if the participants answered purely from memory, objective measurements in the study show that the self-assessment wasn't subjective after all (28). The study of Levine T et al. (28) seems promising in the sense of the use of humour improves memorability of the presented content but also the replay value of the audiovisual media which makes the IC informative but also rewatchable. The study was appropriately randomised with subjects recruited from both public and private settings, improving generalisability of current findings however a greater sample size could allow for a smaller effect size giving the possibility to examine demographic effects (28). This study could not compare its results to other authors' as it is the first of its kind. Similarly, no standard to compare has also been found in the studies of Alagesan A et al. (7) and Shqaidef A et al. (29). One of the benefits of the visual method Shqaidef A et al. (29) employed is that the visual nature of the video simplifies the recall of the concepts shown but also may reduce clinical time. In fact, the 3D animation allows information reinforcement for the patient as it can be watched in different occasions, especially prior to the dental appointment so the clinician can directly assess comprehension and recall.

Desman A et al (30) reduces the reading level of his IC to one similar of seventh grade for both his rehearsal and best practices approach, which enhances readability and processability in order to obtain more satisfactory results in immediate comprehension and recall. Pawlak C et al. (13) besides assessing information positioning, improves readability compared to the standard AAO form, gathering positive results (13). Another author, Carr K et al. (25) finds the same improvements through improved readability and processability which outperforms the standard reported levels by the commonly used AAO forms. Health literacy is an important factor to take into consideration during the IC process, as a low health literacy indicates poor decision-making from the patient. Unfortunately, health literacy may be affected by evaluated parents who have other family member(s) who underwent orthodontic treatment in the past thus aiding their comprehension and recall regarding basic key elements of risks and responsibilities such as discomfort and pain, attendance to revisions and the wear of retainers.

Lack of evidence online is noticeable as very few systematic reviews and/or meta-analyses about this topic have been published in the last 10 years, especially in the field of Orthodontics.

Aljabaa A et al. (32), in a systematic review composed of 4 randomised controlled trials dating between 1998-2011, investigates interventions in the aim to improve adherence to treatment whose outcomes include treatment recall and awareness of responsibilities amongst others, being related to our present systematic review. Verbal and written information given to anxious patients improved appointment attendance and periodontal hygiene overall however no significant results or differences have been found (32). Aljabaa A et al. (32) faces issues regarding the blinding of participants and sample sizes which lowers the quality of the outdated randomised controlled trials used. Appropriate information, subjectively-speaking, might increase patients' awareness of responsibilities coming with a long-lasting orthodontic treatment. In our

case, without statistically significant results, patients performance on comprehension

and recall in various domains and subdomains seemed to have been negatively impacted (6, 26, 30).

Tam N et al. (33) evaluate patients' understanding with the use of open-ended and close-ended questions with the help of a meta-analysis composed of 135 papers. On one hand, he finds the use of close-ended questions obtaining higher scores of understanding which could be led to overestimation of understanding. On the other hand, open-ended questions seem to emulate more accurately understanding (33). In our systematic review, similar findings have been found as Carr K et al. (25) and Sharma P et al. (26) found recall improvements thanks to close-ended questions which participants were able to "parrot" back while Shqaidef A et al. (29) specifically put to use only open-ended questions to appropriately evaluate comprehension and recall. The same argument is present in the systematic review of Moreira N et al. (34) in which assessment methods used would somehow indicate the participants what the answer is, implying the use of close-ended questions (25, 26, 34) but also that self-assessment of recall is overestimated by the participants, similarly speculated in the studies of Pawlak C et al. (13) and Carr K et al. (25).

6. Conclusion

It is of great importance that the IC process is carried out by the Orthodontist, directly to the patient. A vast variety of methods can be used as a MIC or simply to supplement additional information, visually, verbally or in a written format. Written information leaflets are an acceptable source of information without immediate benefits, that the patient can keep throughout the long-lasting treatment with the possibility of referring back to it at anytime and reinforce instructional conversations with the clinician. Visual formats are efficient in reducing clinical chair time but are always required to be followed by verbal reviewing from the clinician as the video alone isn't sufficient. Advantages are encountered when the video's nature and format encourages the patient to rewatch it, as a greater replay value increases long-term memory. A MIC should be as personalised as possible, with the information properly positioned to unsure important elements are firstly focused on. These should be able to improve, to a certain extent, the Orthodontist-patient relationship and patient's compliance however Orthodontists should further be evaluated when it comes to their knowledge regarding IC and awareness of its importance.

Any treatment comes with adverse effects, side effects or simply risks that the patient should thoroughly be aware of, to increase treatment satisfaction and compliance. In general the knowledge of risks have been underwhelming while the recollection have sometimes been satisfying. Educating patients on orthodontic treatment's risks is challenging as concepts range from very basic to more elaborated ones such as root resorption and ankylosis. Understanding of complex risks may be promoted by visual or audiovisual formats of MIC while recall is progressively improved by verbal reviewing and rehearsing. It should be highlighted that patients must be aware in case custom risks are specifically targeted to them, to improve their understanding and recall.

Improved readability and information chunking is found to be efficient for the improvement of treatment recall elements in parents and comprehension in patients. Overall in patients, recall should be stressed as it is the worst compared to the risk and responsibilities domains, greatest efficacy in improving it was found with the use of humorous video. Treatment knowledge is fundamental as it is part of the patient's rights to be adequately informed, through IC. Unfortunately orthodontists aren't all fully aware of the importance of the IC process nor fully master how to appropriately deliver the IC to patients, thus appropriately educating them.

The domain of responsibilities seems the most understood amongst parents and patients, because of the simplicity of the information presented compared to other domains. Comprehension and recall are efficiently improved with the use of supplemented written information and verbal reviewing but also with the use of audiovisual material and visual printouts. Patients, especially parents, seem to be aware of responsibilities that come with orthodontic treatment but emphasis should be applied on its recall.

The authors do not declare any conflict of interests.

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Annexe 1. PRISMA 2020 Checklist for Systematic Reviews

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Main page
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Page 2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Pages 4-15
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Page 18
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Pages 19-20
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Pages 22-23
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Pages 24-25
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Pages 27-28
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Pages 27-28
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Page 26
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Pages 28-29
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Pages 30-31
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	

Annexe 1. Continued

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Pages 27-28
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Pages 27-28
Study characteristics	17	Cite each included study and present its characteristics.	Pages 28-29
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Pages 29-31
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Pages 31-32
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Pages 32-36
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Pages 32-36
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Pages 32-36
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Pages 32-36
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Pages 32-36
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Pages 37-43
	23b	Discuss any limitations of the evidence included in the review.	Pages 37-43
	23c	Discuss any limitations of the review processes used.	Pages 37-43
	23d	Discuss implications of the results for practice, policy, and future research.	Pages 37-43
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	
Competing interests	26	Declare any competing interests of review authors.	Page 44
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Page 45

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: http://www.prisma-statement.org/

Annexe 2. Article format

Journal section: Journal of Clinical and Experimental Dentistry - eISSN 1989-5488
Section: Orthodontics

COMMUNICATION METHODS IN ORTHODONTIC INFORMED CONSENT AND THEIR EFFECTS: A SYSTEMATIC REVIEW

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Abstract:

Introduction: Informed consent (IC) is the fundaments in the dentist-patient relationship (1), a relationship to achieve better diagnosis, better treatment outcomes (6) and overall better satisfaction. IC is achieved in a process of dialog in which will be explained the full nature of the treatment, the purpose of the suggested procedure and the risks (4). Patients who are more appropriately informed and understand better tend to have better expectations of treatment outcomes.
Objective: The goal of this systematic review is to determine how an improved IC process can improve the orthodontist-patient relationship and treatment outcomes.
Material and Methods: A total of 9 randomised controlled trials have been selected through a bibliographic search via PubMed, Science Direct, Scopus and Scielo.
Results: Information leaflet is beneficial as a long-lasting accessible source of information (26), videotaped MIC (13) with humour (28) improved information retention after 6 weeks (28). Overall knowledge of risks are slightly low (6, 25, 26). Alternative IC format and "chunking" improved treatment recall in parents and treatment comprehension in patients (13). Rehearsal method improved both responsibility comprehension and recall, being greater to other domains (6).
Discussion: Concepts' complexity play an important role. Underwhelming results for custom risks recall might be due to patients' unawareness that they are specific to them and affected by positional effects (13). Self-assessment of understanding might lead to overestimation of knowledge (13,15) and results might be impacted by the use of close-ended questions (25, 26, 29). In orthodontists, the deficit in knowledge and overlooked importance of IC might suggest an inadequate information delivery (7). The lack of participant blinding may lead to anxiety, leading to worsened performance (6).

***Keywords**: "Informed consent", "Informed consent document", "Informed consent form", "Modified informed consent", "Comprehension", "Recall", "Readability", "Understanding", "Risks", "Adverse Effects", "Orthodontics"*

Introduction:

Informed consent (IC) is the fundaments in the dentist-patient relationship prior to treatment. In Orthodontics, the application of IC is a fundamental requirement in the orthodontist-patient relationship as specific orthodontic procedure usually do not fall within the patient's knowledge (1), implying that a comprehensive and educational interaction is needed for the patient, to be provided adequate and accurate information: IC is a basic principle of dental practice in which information is provided to the patient and knowledge is shared between the dentist and the patient, creating a shared-decision-based treatment plan (2). On the oral practitioner's side, one important goal of the use of IC is the fulfilment of legal obligation, to inform and communicate the patient to the best of their knowledge in regards to their diagnostic situation, which will allow to build and solidify an orthodontist-patient relationship based on trust (7).

Written consent is important prior to starting the treatment plan but in no case it substitutes obtaining a valid IC (12). The validity of IC begins with patient and/or their parents fully understanding what the treatment consists of, what risks may arise during the duration of the treatment, what benefits comes with every different treatment alternatives. If not adhered to, not giving a valid IC may have legal implications (13). The use of simplified dental terminology easier to understand by the patient will also increase the IC's validity, it is critical for patients and parents to understand the specific terminology used to describe orthodontic treatment, their diagnosis and the risks and complications that could arise anytime during the treatment (15). The consent process to be valid, should be an on-going progress and not a one-off event, once IC is given, it may be withdrawn any time (14).

The orthodontist-patient relationship constitutes the basis of quality medical practice. A well established one, can achieve better diagnosis, better treatment outcomes (6) and overall better satisfaction of the patients' needs (1). A solid relationship also leads to better cooperation and compliance (6), which is attainable thanks to greater communication (15).
An orthodontist needs to view a thorough and fundamental understanding of the principles relating to obtaining IC lawfully as a moral obligation (19).

The tort of lack of IC is put in place when the orthodontist fails to communicate appropriately the material risks and dangers involved in the suggested procedure (6). Failing to adequately identify and manage risks will lead to patient dissatisfaction and litigation (22). Knowledge about these are of extreme importance to the orthodontist and the patient's willing to receive treatment, obtaining their IC is as important as executing the treatment plan (23). The orthodontic treatment is based on a risk-benefit analysis, in which risks should be minimised by employing risk management strategies (3, 8).

Patients who are more appropriately informed tend have better expectations of treatment outcomes. Patient understanding is of great importance as Orthodontic procedures tend to involve long-term appliances: it is critical to ensure patient compliance, which starts from fully understanding what their responsibilities must be (24). A lack of understanding is not always due to the communication mode employed by the Orthodontist. It can compromise the doctor-patient relationship, essential to patient compliance during the treatment plan (51). This issue brings into question whether the current format of IC is appropriately efficient for its purpose and for its validity (15).

The aim of this study is included in the following PICO question: In patients in need of orthodontic treatment, is the informed consent process and treatment plan fully understood and recalled by the patient ? To answer this question, a systematic review of randomised controlled trials was conducted in order to to determine how an improved IC process can improve the orthodontist-patient relationship and treatment outcomes.

Material and Methods:

The preparation of the systematic review follows the PRISMA 2020 guidelines.
- Eligibility criteria: In the aim of reducing the search's content, inclusion criteria are such as we prioritise studies between 2011 and 2011, assessing comprehension and/or recall of IC in English and or Spanish-language articles in peer-reviewed academicor scientific journals, with available methods/questionnaires used to examine the level of understanding and comprehension.

- Search strategy:

An electronic search of articles has been carried out in scientific databases such as PubMed, Science Direct, Scopus and Scielo, using a range of keywords such as “Informed consent”, “Informed consent document”, “Informed consent form”, “Modified informed consent”, “Recall” “Comprehension”, “Readability”, “Risks” “Understanding”, “Adverse Effects”, and “Orthodontics”.

- Study selection:

The study selection has been proceeded by the inclusion and exclusion criteria we had previously set.

- RIsk assessment of bias

Risk assessment of bias was reported according to the CASPe guideline, PRISMA 2020 checklist. The individual evaluation of the articles were carried out based on 11 questions specific to randomised controlled trials which included whether there is a clear focused research question (Q1), if participants were randomised (Q2), all accounted at the end (Q3), blinded (Q4), if groups were similar at the start (Q5) and received equal care (Q6). It also assessed if the effects were reported comprehensively (Q7), the precision of the estimate (Q8), if benefits overweight harms and costs (Q9) and whether or not results can be applied in our context (Q10) and assess if the experimental intervention provides greater value (Q11).

- Statistical analysis

A meta-analysis will be implemented depending on the homogeneity of the results from our included studies.

Results:

-Study selection and description

A total of 43 articles were obtained, 32 being from PubMed, 6 from Socpus, 5 from Science Direct and none from Scielo, awaiting for assessment for eligibility. As shown in Figure 1, n= 5 were excluded from inappropriate format such as being Open Letters, Commentary and Editorial. In n= 3 conflict of interests were mentioned and n= 3 lacked of ethical approval in the IC process. A total of n= 18 have been excluded for irrelevancy, of particular disinterest for the systematic review being conducted. Lastly, n=1 was discarded for not being a Randomized Controlled Trial study.

- General characteristics of the studies

The main characteristics of the selected articles for the systematic review are shown in Table 1. A total of 1094 individuals have been studied undergoing an IC process, in which 441 are parents and 25 are Orthodontists. A range of different IC communicative methods and MIC formats have been employed such as information leaflets in studies of Nasr I et al (16) and Shqaidef A et al. (29); visual printouts in studies of Skulski B et al (6) and Desman A et al (30), audiovisual media in studies of Pawlak C et al (13), Levine T et al (28), Shqaidef A et al (29) and Desman A et al (30) and finally slideshow presentations in studies of Skulski B et al (6), Carr K et al (25) and Desman A et al (30) (Table 1).

- Risk assessment of bias

In Figure 2, highly positive results are found in the participants randomisation sequence as well as the clarity of the research question of each studies and how the effects have been reported. Ideally, low biases have been found for applying results in our context and experimental interventions possibly providing greater value to people in our care. Satisfactory bias can be reported for the benefits outweighting the harms and costs except for two studies in which visual printouts were used, the studies of Skulski B et al (6) and Nasr I et al (16).However, significant high risk of bias have been found in studies of Sharma P et al (26), Levine T et al (28), Shqaidef A et al (29) and Desman A et al (30) in which participants have not committed to the entirety of the studies. High uncertainty of risk of bias have been specifically reported for Questions 3 and 4 in which an important number of studies faced participants drop-outs (26, 28, 29, 30) and participants were not blinded (6, 26, 29).

Results show the studies of Alagesan A et al (7), Sharma P et al (26), Shqaidef A et al (29) show moderate risk of bias (Fig 2).

-Main characteristics of the studies

The main characteristics of the included studies are shown in Table 1.

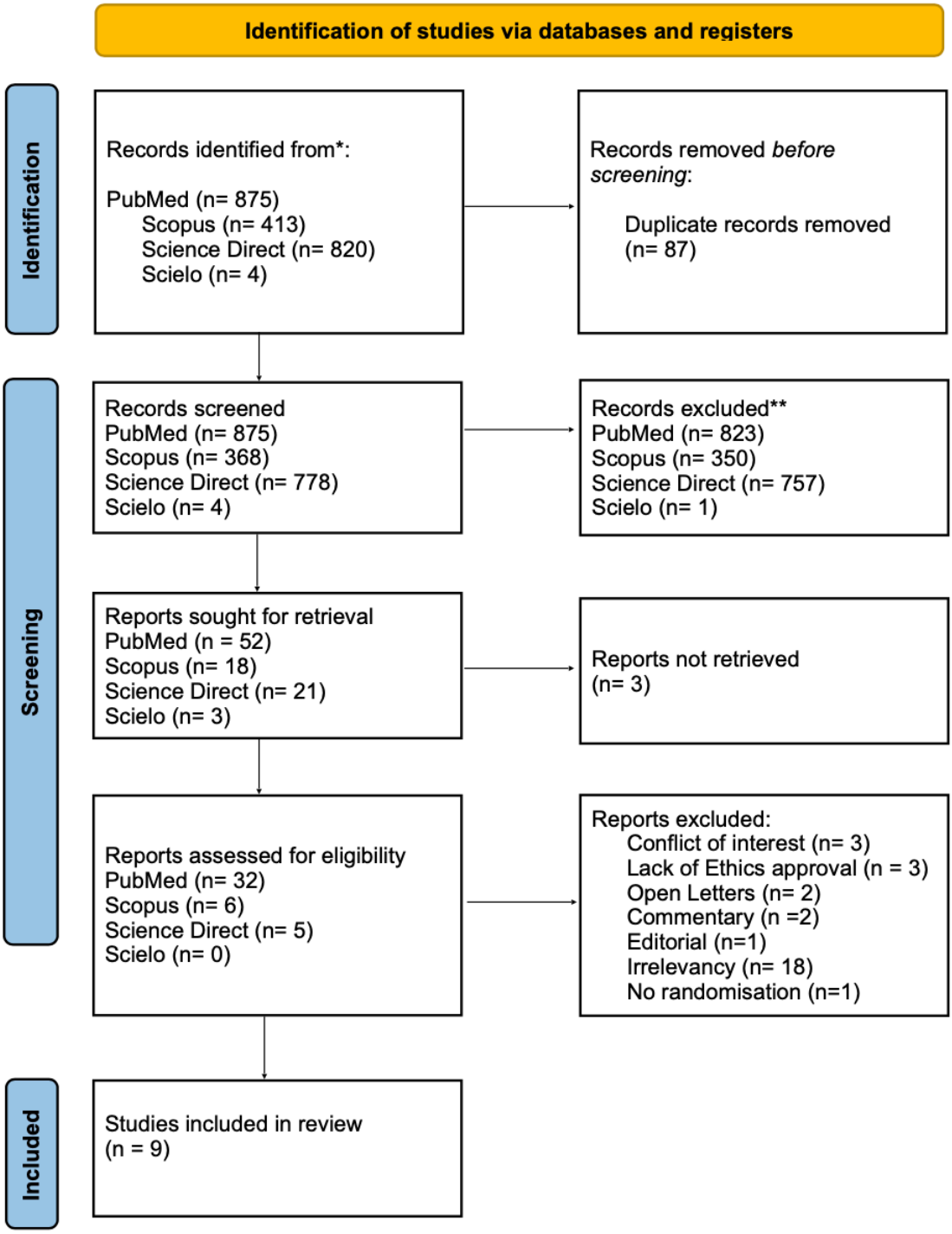

Figure 1. FlowChart of the Systematic Review, according to PRISMA 2020 guidelines.

AUTHOR	SAMPLE SIZE (AGE OF PATIENTS)	GROUPS	CLINICAL PARAMETERS	METHODS	EFFICACY
Skulski B et al. (6) 2021	90 pairs (11-18 years).	Groups A and B.	Short-term recall and comprehension.	MIC with visual printouts and slideshow presentation.	Slideshow presentation gathered better results.
Alagesan A et al. (7) 2015	25 pairs (18-35 years).	Orthodontists (n=25) and Patients (n=25).	Knowledge and awareness of informed consent.	Participant information sheet, a MCQ questionnaire and 3 Likert Format statements.	A majority of Orthodontists are aware of knowledge regarding IC.
Pawlak C et al. (13) 2014	69 pairs (12-18 years).	Group A (n=34), Group B (n=35), Group C and D from the Study of King EY et al (31) and Group E from the study of Carr K et al (25).	Recall and comprehension of the risks, benefits and alternatives.	Information "chunking" and MIC with a short videotaped presentation.	Improved readability with information "chunking" showing increased overall comprehension and recall but audiovisual MIC did not show benefits.
Nasr I et al. (16) 2011	80 (12-14 years).	Control group (n=40) and Intervention group (n=40).	Patient expectations.	MIC with additional information leaflet.	No significant differences nor immediate impact found.
Carr K et al. (25) 2012	80 pairs (12-18 years) + 30 subjects from the study of Kang EY et al (31).	Intervention groups A, B and C from Kang EY et al (31).	Understanding of risks and limitations of Orthodontic treatment.	MIC with customised slideshow with or without verbal review.	Improvement of overall comprehension, risk recall and comprehension, and of general risks and limitations.
Sharma P et al. (26) 2016	61 pairs (10-15 years).	Control group (n=30) and Study group (n=31).	Recall of information during IC process.	Verbal information with or without written information.	Patients disposing of written consent showed better knowledge and recall.
Levine T et al. (28) 2020	38 (10.6-33.5 years).	Group H (n=20) and Group U (n=18).	Recall of information regarding Orthodontic treatment.	Viewing humorous video or live-action video without humor.	Informativeness showed no difference. Increase of replay value and memorability with humor.
Shqaidef A et al. (29) 2021	64 (12-18 years)	2 unnamed groups.	Recall and comprehension of information.	Delivery of BOS leaflet followed by verbal explanation and visualisation of a 3D animation.	3D animated video saved clinical and chair time but is equivalent to written and verbal information.
Desman A et al. (30) 2021	116 pairs (11-18 years)	Group A and B.	Long-term recall and comprehension of IC.	Visual printout images and audiovisual presentation.	No significant differences were found.

Table 1. General information of the included studies. Author, Sample Size (Age of patients), Groups, Clinical Parameters, Methods, Efficacy. IC: Informed Consent; MIC: Modified Informed Consent; MCQ:

AUTHOR	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11
Skulski B et al. (6)	+	+	+	-	+	?	+	+	-	+	+
Alagesan A et al. (7)	+	?	+	?	-	?	+	-	+	+	+
Pawlak C et al. (13)	+	+	+	+	+	+	+	+	+	+	+
Nasr I et al. (16)	+	+	+	+	+	?	+	+	-	+	+
Carr K et al. (25)	+	+	+	+	+	+	+	+	+	+	?
Sharma P et al. (26)	+	+	-	-	+	+	+	+	+	+	+
Levine T et al. (28)	+	+	-	+	+	?	+	?	+	+	+
Shqaidef A et al. (29)	+	+	-	-	+	?	+	+	+	?	?
Desman A et al. (30)	+	+	-	?	+	+	+	?	+	+	+

Figure. 2. Risk of bias assessment. According to CASPe guideline, PRISMA 2020 checklist: an updated guideline for reporting systematic reviews. +: low risk of bias; -: high risk of bias; ?: unclear risk of bias.

AUTHOR	CLINICAL PARAMETERS EVALUATED					
Skulski B et al. (6) 2021	Recall of Core, Custom & General Rk elements (n%)			Rsp Comp (n%)	Rk Comp (n%)	Tx Comp (n%)
	Grp A Core (rehearsal)= 81 Grp B Core (slideshow)= 70	Grp A Cust (rehearsal)= 43 Grp B Cust (slideshow)= 37	Grp A Gen (rehearsal)= 46 Grp B Gen (slideshow)= 50	Grp A (rehearsal)= 77 Grp B (slideshow)= 70	Grp A (rehearsal)= 49 Grp B (slideshow)= 49	Grp A (rehearsal): 30 Grp B (slideshow): 41
Alagesan A et al. (7) 2015	Comp of IC obtention (n% of correct answers)					
	Orthodontists: n= 79,14			Patients: n= 35.14		
Pawlak C et al. (13) 2014	Mean (SD)% of overall on-target Recall and Comp		Mean (SD)% of on-target responses on consent domains		Mean (SD)% of on-target responses for Recall and Comp of core, custom and general Rk	
	Patients	Parents	Patients	Parents	Patients	Parents
	51.5% (SD, 20.3%) to 55% (SD, 14.7%) between Grp A and B.	66.0% (SD, 13.7%) to 71.5% (SD, 14.4%) between Grp A and B.	Tx Recall= 50.2 (20.4) Rk Recall= 59.4 (22.3) Rsp Recall= 60.7 (18.3) Tx Comp= 47.0 (25.6) Rk Comp= 38.4 (18.8) Rsp Comp=69.8 (18.6)	Tx Recall= 70.1 (19.7) Rk Recall= 65.7 (17.4) Rsp Recall= 80.0 (15.8) Tx Comp= 57.0 (18.6) Rk Comp= 57.2 (18.7) Rsp Comp= 87.8 (14.3)	Core Recall= 53.8 (18.5) Cust Recall= 36.2 (36.1) Gen Recall= 52.7 (15.2) Core Comp= 69.4 (23) Cust Comp= 31.1 (40.3) Gen Comp= 41.3 (17.9)	Core Recall= 73.5 (17) Cust Recall= 60.8 (32.1) Gen Recall= 71.0 (11.7) Core Comp= 84.5 (14.9) Cust Comp= 37.2 (36.5) Gen Comp= 61.0 (16.9)
	No significant differences found.					
Nasr I et al. (16) 2011	Difference between Male and Female (Control and Intervention groups combined)		Before and after intervention scores for all the continuous variables (Control group vs. Intervention group)		Before and after scores for the categorical variables	
	P= 0.007; chi-squared (χ2). No significant differences.		P= 0.04; ANCOVA. Significant differences.		Q8: χ2= 0.18 Q8: P= 0.67	Q9: χ2= 1.16 Q9: P= 0.28
					No statistically significant differences	
Carr K et al. (25) 2012	Mean (SD)% of overall on-target recall and comp		Mean (SD)% of on-target responses for consent domains		Mean (SD) % of on-target responses for general, core, and custom questions	
	Patients	Parents	Patients	Parents	Patients	Parents
	Grp A Recall= 58.8 (14.8) Grp B Recall= 57.4 (13.4) Grp C Recall= 52.6 (14.4) Grp A Comp= 52.9 (15.8) Grp B Comp= 53.6 (13.3) Grp C Comp= 44.2 (16.7)	Grp A Recall= 71.0 (13.9) Grp B Recall= 70.6 (13.9) Grp C Recall= 67.3 (16.8) Grp A Comp= 67.1 (13.3) Grp B Comp= 69.2 (15.2) Grp C Comp= 66.3 (16.6)	Tx Recall Grp A= 47.0 (19.3) Tx Recall Grp B= 48.9 (19.0) Tx Recall Grp C= 36.7 (22.9) Rk Recall Grp A= 68.6 (20.6) Rk Recall Grp B= 57.4 (18.5) Rk Recall Grp C= 51.3 (20.3) Rsp Recall Grp A= 67.4 (18.5) Rsp Recall Grp B= 68.6 (18.5) Rsp Recall Grp C= 70.7 (18.3) Tx Comp Grp A= 40.9 (24.5) Tx Comp Grp B= 39.0 (20.0) Tx Comp Grp C= 32.7 (23.8) Rk Comp Grp A= 41.6 (17.4) Rk Comp Grp B= 38.9 (18.5) Rk Comp Grp C= 28.1 (19.7) Rsp Comp Grp A= 72.3 (17.8) Rsp Comp Grp B= 78.2 (15.5) Rsp Comp Grp C= 68.2 (23.0)	Tx Recall Grp A= 60.8 (21.5) Tx Recall Grp B= 62.1 (27.0) Tx Recall Grp C= 62.3 (24.5) Rk Recall Grp A= 72.4 (17.4) Rk Recall Grp B= 69.6 (19.3) Rk Recall Grp C= 66.0 (22.0) Rsp Recall Grp A= 84.2 (15.7) Rsp Recall Grp B= 80.8 (15.9) Rsp Recall Grp C= 80.5 (17.8) Tx Comp Grp A= 52.4 (22.8) Tx Comp Grp B= 59.6 (26.4) Tx Comp Grp C= 56.4 (24.1) Rk Comp Grp A= 58.2 (19.9) Rk Comp Grp B= 57.5 (20.5) Rk Comp Grp C= 52.2 (21.1) Rsp Comp Grp A= 85.6 (15.6) Rsp Comp Grp B= 86.8 (13.1) Rsp Comp Grp C= 87.0 (18.3)	Grp A Gen Recall= 58.0 (15.5) Grp B Gen Recall= 51.8 (15.3) Grp C Gen Recall= 47.2 (14.5) Grp A Core Recall= 58.9 (20.8) Grp B Core Recall= 65.7 (17.9) Grp C Core Recall= 62.5 (20.9) Grp A Cust Recall= 55.0 (35.9) Grp B Cust Recall= 55.7 (33.3) Grp C Cust Recall= N/A Grp A Gen Comp= 39.8 (18.4) Grp B Gen Comp= 39.7 (19.0) Grp C Gen Comp= 32.5 (15.4) Grp A Core Comp= 68.5 (18.7) Grp B Core Comp= 70.6 (15.6) Grp C Core Comp= 60.7 (22.7) Grp A Cust Comp= 45.7 (38.6) Grp B Cust Comp= 46.3 (36.7) Grp C Cust Comp= N/A	Grp A Gen Recall= 70.2 (14.7) Grp B Gen Recall= 67.3 (16.1) Grp C Gen Recall= 65.9 (18.3) Grp A Core Recall= 71.1 (19.2) Grp B Core Recall= 75.5 (15.6) Grp C Core Recall= 68.9 (19.1) Grp A Cust Recall= 68.7 (37.1) Grp B Cust Recall= 70.9 (31.1) Grp C Cust Recall= N/A Grp A Gen Comp= 56.9 (17.6) Grp B Gen Comp= 57.5 (19.6) Grp C Gen Comp= 55.9 (19.4) Grp A Core Comp= 81.2 (16.6) Grp B Core Comp= 83.8 (13.3) Grp C Core Comp= 80.9 (18.1) Grp A Cust Comp= 56.0 (35.6) Grp B Cust Comp= 62.7 (39.0) Grp C Cust Comp= N/A
Sharma P et al. (26) 2016	Comp of Information given		Lack of Rk Recall		Resp & Tx Comp	
	Control Grp n(%)	Study Grp n(%)	Control Grp n(%)	Study Grp n(%)	Control Grp n(%)	Study Grp n(%)
	30 (100%)	31 (100%)	8 (26.7%)	1 (3.2%)	13 (43.3%) 23 (76.7%) 16. (53.3%)	22 (71.0%) 27 (87.1%) 25 (80.6%)
Levine T et al. (28) 2020	Mean (SD) responses for objective questions			Mean (SD) responses for subjective questions		
	Humorous video	Unhumorous video	P (Humorous vs Unhumorous)	Humorous video	Unhumorous video	P (Humorous vs Unhumorous)
	T1= 90.50 (0.126) T2= 89.55 (0.119) P= 0.335	T1= 86.58 (0.127) T2= 77.78 (0.186) P= 0.042* *Significant mean difference	T1= 0.075 T2= 0.001* P= N/A *Significant mean difference	Replay Value: 6.636 (2.361) Memorability: 8.591 (1.141) Recall: 6.750 (2.124)	Replay Value: 4.857 (0.793) Memorability: 5.571 (2.014) Recall: 5.778 (1.768)	Replay Value: P= 0.002* Memorability: P=<0.0001* Recall: P= 0.1363 *Significant mean difference

Table 2. Results of the clinical parameters evaluated by each study. Comp: comprehension; Grp: Group; Tx: Treatment; Rk: Risk; Rsp; Responsibilities; Cust: Custom; Gen: General.

- Communication methods

It was found that written information as a leaflet is beneficial to patients as a long-lasting accessible source of information in the study of Sharma P et al. (26) improving both comprehension and recall, however neither the verbal or verbal supplemented with written information methods seemed successful in regards to risks during treatment requiring constant re-informing by the Orthodontist (26).

Similarly, in the study of Shqaidef A et al. (29) in which information leaflets were also used supplemented or not by a 3D animated video, the conventional group with written information scored higher with 79.1 ± 18.4 with no statistically significant difference (P = 0.492) (29) with no drastic change one year later. Additional verbal review by the clinician to a MIC is also analysed in the study of Carr K et al. (25). Results show that for parents and

patients, with or without the clinician's supplemented verbal explanation, overall comprehension and recall in the treatment domains were alike as well as in the 18 IC elements. Despite no significant differences, the need of additional verbal reviewing for the domain should be emphasised in the risk domain for children (25).

Communication methods by Orthodontists can also be indirect, through the format of a multimedia recording as presented in the studies of Pawlak C et al. (13) and Levine T et al. (28). No significant differences were shown with the use of a videotaped MIC in patients or parents (13) but if the nature of communication is altered with humour (28), with no changes in the informative aspect, information retention after 6 weeks can be enhanced (28) (Table 2).

- Patients' risks knowledge

As previously mentioned, overall knowledge of risks ascertained to be slightly underwhelming in the studies of Carr K et al. (25) and Sharma P et al. (26). In the study of Skulski B et al. (6), insignificant results and improvements were found when trying to improve recall of Core, Custom and General risks elements and comprehension of possible risks during treatment as both groups A and B (rehearsal and slideshow groups respectively) showed very similar response rate (6, Table 2). A recurring pattern of prominent response rate is noticeable in the first pieces of information presented to the patients and parents (6). Recall and comprehension for both core and general risks elements were improved for patients and parents thanks to information chunking as seen in the article of Pawlak C et al. (13) while custom risks are unsatisfactory. Results in Table X show they are the lowest values, 36.2 (36.1)% and 31.1 (40.3)% for patients, 60.8 (32.1)% and 37.2 (36.5)% for parents (13, Table 2). The study of Carr K et al. (25) showed predominantly low on-target responses percentages for recall in patients, with 58% and parents with 71% but also in comprehension, respectively 53% and 68% in patients and parents. Nonetheless, among the patients, group A patients dominantly scored in the risk recall domain as seen in Table 2, thanks to reinforced verbal information due to the previously noticed low scores (25). Regarding the use of information leaflets as a MIC in the study of Sharma P et al (26) , only 1 patient, accounting for 3.2% of the Study group, enquired for further risks explanation compared to 8 patients (26.7%) from the control group (26.7%) showing the study group was better informed of the possibility of risks and emergency occurrences (26, Table 2)

however neither methods in the study were greatly successful as they both require clinicians to reinforce information delivery at relevant times during the treatment (26).

The implementation of a 3D animation as seen in the study of Shqaidef A et al. (29) yielded a larger number of correct answers at T0 compared to conventional methods, nevertheless risks recall remaining generally poor, diminishing 1 year later at T1. An example is root resorption patients fail to comprehend thus fail to recall its importance yet lightly bettered by the visual nature of the 3D animation (29). Desman et al. (30) did not get hold of significant differences in the average scores between both rehearsal and best practices groups for patients and parents as values are almost identical in Table X. At 6 months, the same can be stated for the follow up (30).

- Patients' recall and comprehension of treatment

Alagesan A et al. (7) tested general knowledge about IC delivery in both orthodontists and patients. Interestingly, orthodontists accounted for 79.14% of correct answers compared to patients with only 35.14%, showcasing lack of knowledge in Orthodontists and the obligation to fortify information delivery in patients in hopes to improve overtime the recall. On one hand, it was found in the study of Pawlak C et al. (13) treatment recall in patients showed a result of 50.2 (20.4)% being the lowest amongst recall of risks and responsibility, which were respectively of 59.4 (22.3)% and 60.7 (18.3)%. On the other hand, treatment recall in parents was superior, with a result of 70.1 (19.7)% (Table 2). It was mentioned that the alternative IC format improved treatment recall in parents as well as information "chunking" in a readable form whereas it improved treatment comprehension in patients. Sharma P et al. (26) called upon the use of information leaflets in his study group in which greater results were observed for treatment recall such as 22 (71.0%) and 25 (80.6%), compare to control group with 13 (43.3%) and 16 (53.3%) respectively (Table 2). Specifically, the study group was more up-to-date with duration of treatment as verbal information given about treatment should be supplemented with written information (26). In the study of Levine et al. (28) assessing the efficacy of a humorous audiovisual format in terms of treatment comprehension and recall, better results were found with the use of humour such as 90.50 (0.126) at T1, 89.55 (0.119) at T2 and P= 0.335 (28, Table 2) for objective questions regarding

Orthodontic treatment. The same trend was noticed in subjective questions with 6.750 (2.124) for treatment recall, compared to 5.778 (1.768) without humour (28, Table 2) Desman A et al. (30) found that despite the rehearsal method seemed to have shown overall improvements (P <0.05), results were slightly underwhelming specifically for treatment recall in both parents and patients. Parents scored higher than the patients with the rehearsal method at both baseline and 6 months follow-up: from 52 (24) at baseline to 43 (16) after 6 months for parents and respectively 36 (21) to 26 (18) for patients. (30).

- Patient's awareness of responsibilities during treatment

In the study of Skulski B et al. (6), the rehearsal method showcased improvement in both responsibility comprehension and recall but is also shown in Table X as being overall greater compared to risk and treatment domains (6). Similar outcomes were found with Skulski B et al. (6) in which patient responsibility recall was significant improved while comprehension still being superior as seen in Table X in both patients and parents (13). The same trend repeats in the study of Carr K et al (25) in which responsibility domain on-target responses are the highest, while comprehension is greater than recall (Table 2). Overall, domains of responsibility scored best compared to other domains in both patients and parents. Nasr I et al. (16) analysed differences in responses between the genders and has found that there were no statistical significant differences except one finding that males believed responsibilities before the intervention were going to be more demanding (P50.007; chi-squared test) (16). The domain of responsibilities also scored higher in both the studies of Sharma P et al (26) and Desman A et al. (30) with the use of supplemented written information (26) and the use of visual printouts and audiovisual material (30).

- Data extraction

Due to the heterogeneity presented in the results of the included studies, since most assess and measure the variables in different ways, it is not possible to do a meta-analysis with the gathered data from the results.

Discussion:

The obtention of IC is a complex task in which the information should be communicated and presented appropriately to the patient to ensure solid comprehension and achieve necessary compliance for treatment. The studies of Skulski B et al. (6), Carr K et al. (25), Sharma P et al. (26) and Desman A et al. (30) all found greater comprehension of responsibilities that come with Orthodontic treatment in both patients and parents while in the same studies deficient comprehension was seen in the risk domain. The complexity of the concepts presented play an important role in these findings as a weighty part of responsibilities are common-sense notions regarding oral hygiene, frequent appointments, retainer wearing while in the risk domains, a wide variety of concepts range from sensitivity and pain, to root resorption and ankylosis which were found to have statistically poor reliability (6, 25). While understanding the possible risks that could arise during treatment was slightly poor, only the recall of core risks and general risks were improved in the study of Pawlak C et al. (13) whereas Skulski et al. (6) found none to be improved. Reasons for the lack of improvement in custom risks recall could be the patient's lack of awareness that the risks presented in that section are customised, individualised and specific to them, as well as core risks who were presented first and general risks last, gathered better on-target responses due to positional effects such as primacy effect and the recency effect (13). Primacy effect was also noticeable with Skulski B et al (6) in the first concepts presented to patients and parents. A reason why Skulski B et al. (6) did not find the same recall improvements as Pawlak C et al. (13) could be the fact that further efforts should be put in the conversion of short-term memory into long-term by accentuating the rehearsal method, the importance of long-term memory being the enhancement of IC validity as <6 weeks recall is considered invalid in the IC process (26). The rehearsal method has great potential in getting the patients and/or parents to "parrot" the recall information but wouldn't affect in anyway its understanding. The "information chunking" method, supplemented by improved readability and additional audiovisual material was beneficial in the study of Pawlak C et al. (13) as participants might have not been fatigued with an overwhelming delivery and presentation of information however results could be significantly bettered if

patients were aware that information has been "chunked". Another limitation to this study is the instability of literacy levels in the groups and different ethnic distributions. To improve the lack of custom risks recall, due to its importance, it could be placed in the beginning in order to benefit from the primacy effect (13). Overall Carr K et al. (25) and Sharma P et al. (26) found improvements in risk recall despite the lacking of understanding at first. The same idea of repeating information by patients and parents could be correlated to the complexity of the questions presented in the first place. Direct recall questions could allow patients and/or parents to "parrot" appropriately responses positively affecting recall evaluation while difficulties of doing so can be encountered in scenario-based questions. To avoid questions cueing answers, Shqaidef A et al. (29) used open-ended questions to avoid patients and/or parents to guess answers when evaluating recall.

Regarding the basic aspects of IC as well as its fundamentals and generalities concerning its delivery to patients, Alagesan A et al. (7) compares knowledge in both orthodontists and patients only to find that as much as orthodontists are erudite regarding IC concepts compared to patients, their knowledge are far from being perfected as only half understand the necessity of obtaining informed consent. The reason for underwhelming scores in both groups can simply be the fact that first of all, orthodontists fail to spread the adequate amount of information to patients regarding IC and secondly, orthodontists oversee the importance of IC and judge its necessity only for treatment approval or do not carry out a progressive and extended IC process from fear of refusal from the patient (7). These findings might be due to a lack of education in college about IC, the deficit in knowledge and overlooked importance might suggest that after all, orthodontists might not share the most adequate information to patients regarding risks, limitations, benefits and other IC elements but might not reach full potential in assuring patient's full awareness of orthodontic treatment expectations impacting patient's compliance during the treatment, thus the results and duration of the treatment. Further knowledge reinforcement and general focus should be applied on orthodontists before trying to understand how to maximise patients' comprehension and recall because in the speciality of orthodontics, obtaining a valid and true IC is an ethical and legal requirement by law (7).

In the study of Desman A et al. (30) in which the purpose was to compare 6-month recall between a written rehearsal method and the current best practices methods, positive results have been gathered in the recall subdomains than for comprehension however, no significant differences have been found in both groups overall (30). As previously seen, despite disposing of the biggest pool of participants in this systematic review with a high distribution of ethnicities and a high dropout rate of 33.6% (30), it is unclear whether participants have been blinded or not which could affect the results. This could imply that, being aware of the research they're paticipating in, anxiety levels could be slightly higher than the average leading to worsened performance or poorer on-target responses. Interestingly, this comes to view with Skulski et al. (6) who substantiates that increased anxiety in patients decreases patients' on-target responses. Another study facing the problem of participants not being blinded in the research is the one from Sharma P et al. (26) which increases bias and additionally compromises the power the study. Their sample size did not reach the minimum size requirements alongside the few dropouts the study faced, validity of the study decreases however the homogeneity in the sample with respect to demographic variables is found to be advantageous despite the merest sample size. In comparison, Desman A et al. (30) is unsuccessful in the homogeneity of the sample with restricted generalisability as non-White ethnic groups are poorly present in the study. He believes anxiety affects less non-whites compared to white non-hispanics however the correlation between anxiety and race is unclear and insignificant in his study (30). Reoccurrence of defective sample size is also noticeable in the study of Nasr I et al. (16) in which he detects a medium effect size while a smaller effect size with a larger sample size would be more appropriate (16). Because of this, inconsequent results are found when comparing groups using information leaflets as immediate benefits are not imparted in terms of knowledge. Nevertheless Nasr I et al. (16) suggests that verbal discussion between the clinician and the patient can be reinforced through the use of leaflets which guarantees a written record of mentioned key points throughout the IC process with the possibility of referring back, thus ensuring aid in recall (16).

A major issue when it comes to patients and parents recall is the common problem faced in the studies of Pawlak C et al. (13) and Carr K et al. (25) in which results were self-assessed. In the case of Carr K et al. (25), self-assessment of understanding might be subjective, patients and parents are unable to objectively evaluate their own knowledge and comprehension of concepts which could alter the meaning of the recall results. Identically with Pawlak C et al. (13), patients and parents might overestimate their understanding however in the study of Levine T et al. (28), even though the follow-up has been carried out electronically without being able to evaluate if the participants answered purely from memory, objective measurements in the study show that the self-assessment wasn't subjective after all (28). The study of Levine T et al. (28) seems promising in the sense of the use of humour improves memorability of the presented content but also the replay value of the audiovisual media which makes the IC informative but also rewatchable. The study was appropriately randomised with subjects recruited from both public and private settings, improving generalisability of current findings however a greater sample size could allow for a smaller effect size giving the possibility to examine demographic effects (28). This study could not compare its results to other authors' as it is the first of its kind. Similarly, no standard to compare has also been found in the studies of Alagesan A et al. (7) and Shqaidef A et al. (29). One of the benefits of the visual method Shqaidef A et al. (29) employed is that the visual nature of the video simplifies the recall of the concepts shown but also may reduce clinical time. In fact, the 3D animation allows information reinforcement for the patient as it can be watched in different occasions, especially prior to the dental appointment so the clinician can directly assess comprehension and recall.

Desman A et al. (30) reduces the reading level of his IC to one similar of seventh grade for both his rehearsal and best practices approach, which enhances readability and processability in order to obtain more satisfactory results in immediate comprehension and recall. Pawlak C et al. (13) besides assessing information positioning, improves readability compared to the standard AAO form, gathering positive results (13). Another author, Carr K et al. (25) finds the same improvements through improved readability and processability which outperforms the standard reported levels by the commonly used AAO forms. Health literacy is an important factor to take into consideration during the IC process, as a low health literacy indicates poor decision-making from the patient. Unfortunately, health literacy may be affected by evaluated parents who have other family member(s) who underwent orthodontic treatment in the past thus aiding their comprehension and recall regarding basic key elements of risks and responsibilities such as discomfort and pain, attendance to revisions and the wear of retainers.

Lack of evidence is noticeable as very few systematic reviews and/or meta-analyses about this topic have been published in the last 10 years, especially in the field of Orthodontics. Aljabaa A et al. (32), in a systematic review composed of 4 randomised controlled trials dating between 1998-2011, investigates interventions in the aim to improve adherence to treatment whose outcomes include treatment recall and awareness of responsibilities amongst others, being related to our present systematic review. Verbal and written information given to anxious patients improved appointment attendance and periodontal hygiene overall however no significant results or differences have been found (32). Aljabaa A et al. (32) faces issues regarding the blinding of participants and sample sizes which lowers the quality of the outdated randomised controlled trials used. Appropriate information, subjectively-speaking, might increase patients' awareness of responsibilities coming with a long-lasting orthodontic treatment. In our case, without statistically significant results, patients performance on comprehension and recall in various domains and subdomains seemed to have been negatively impacted (6, 26, 30).
Tam N et al. (33) evaluate patients' understanding with the use of open-ended and close-ended questions with the help of a meta-analysis composed of 135 papers. On one hand, he finds the use of close-ended questions obtaining higher scores of understanding which could be led to overestimation of understanding. On the other hand, open-ended questions seem to emulate more accurately understanding (33). In our systematic review, similar findings have been found as Carr K et al. (25) and Sharma P et al. (26) found recall improvements thanks to close-ended questions which participants were able to "parrot" back while Shqaidef A et al. (29) specifically put to use only open-ended questions to appropriately evaluate comprehension and recall. The same argument

is present in the systematic review of Moreira N et al. (34) in which assessment methods used would somehow indicate the participants what the answer is, implying the use of close-ended questions (25, 26, 34) but also that self-assessment of recall is overestimated by the participants, similarly speculated in the studies of Pawlak C et al. (13) and Carr K et al. (25).

Conclusion:

A vast variety of methods can be used as a MIC or simply to supplement additional information, visually, verbally or in a written format. Written information leaflets are an acceptable source of information without immediate benefits, that the patient can refer back to anytime anytime and reinforce instructional conversations with the clinician. Visual formats are efficient in reducing clinical chair time but are always required to be followed by verbal reviewing from the clinician as the video alone isn't sufficient. Advantages are encountered when the video's nature and format encourages the patient to rewatch it, as a greater replay value increases long-term memory. A MIC should be as personalised as possible, with the information properly positioned to unsure important elements are firstly focused on. These should be able to improve, to a certain extent, the Orthodontist-patient relationship and patient's compliance however Orthodontists should further be evaluated when it comes to their knowledge regarding IC and awareness of its importance.
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The patient should thoroughly be aware of risks. In general the knowledge of risks have been underwhelming while the recollection have sometimes been satisfying. Educating patients on orthodontic treatment's risks is challenging as concepts range from very basic to more elaborated ones such as root resorption and ankylosis. Understanding of complex risks may be promoted by visual or audiovisual formats of MIC while recall is progressively improved by verbal reviewing and rehearsing. It should be highlighted that patients must be aware in case custom risks are specifically targeted to them, to improve their understanding and recall.

Improved readability and information chunking is found to be efficient for the improvement of treatment recall elements in parents and comprehension in patients. Overall in patients, recall should be stressed as it is the worst compared to the risk and responsibilities domains, greatest efficacy in improving it was found with the use of humorous video. Orthodontists aren't all fully aware of the importance of the IC process nor fully master how to appropriately deliver the IC to patients, thus appropriately educating them.

Responsibilities domain seem the most understood because of the simplicity of the information presented. Comprehension and recall are efficiently improved with the use of supplemented written information and verbal reviewing but also with the use of audiovisual material and visual printouts. Parents seem to be aware of responsibilities that come with orthodontic treatment but emphasis should be applied on its recall.

Conflicts of interest:

All authors declare that they do not have any conflicts of interest.

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