

Parental Comprehension of Standard and Simplified Information Consent Forms in a Pediatric Clinical Trial Simulation – A Randomized Controlled Study

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[See table of contents](#)

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Article abstract

Background: Informed consent forms (ICFs) are a mandatory prerequisite for participating in clinical trials. In pediatric studies, the ICF is generally signed by the child's parents. The ICFs designed for clinical trials are often lengthy and complex to understand. We conducted this study to determine if a simplified ICF would improve parental understanding compared to a standard ICF.

Methods: A single-centre, single-blind, randomized controlled trial featuring two fictitious ICFs took place in a tertiary Canadian mother and child university hospital. Parents of hospitalized children were assigned to read either a standard or simplified ICF. Parental comprehension was measured using the Modular Informed Consent Comprehension Assessment (MICCA) questionnaire. The primary outcome of this study was to assess the proportion of parents with a MICCA score of 75% or above. **Results:** One hundred and fifty participants answered the study questionnaires. The primary endpoint was reached by 55.7% of the participants who read the simplified ICF compared to 46.2% in the standard ICF group ($p=0.303$). The mean MICCA scores were 17.87 and 17.75 points, respectively ($p=0.847$). Themes that were poorly understood by both groups were the study procedures, the adverse effects, the other available treatment options as well as the main benefits and purpose of the study. **Conclusion:** This single centre, single-blind, randomized controlled study showed that the comprehension was similar between a simplified and a standard ICF. This suggests that using simplified ICFs does not improve nor impair parental comprehension. Therefore, a simplified ICF should be used as frequently as possible in pediatric research projects.



ARTICLE (PEER-REVIEWED)

Parental Comprehension of Standard and Simplified Information Consent Forms in a Pediatric Clinical Trial Simulation – A Randomized Controlled Study

Claudia Lord^{a,b}, Gabrielle Gauthier^{a,b}, Emma Legault^{a,b}, Irina Mitrea^{a,b}, Patrick Gogognon^c, Hélène Roy^{a,c}, Denis Lebel^{a,c}, Pascal Bédard^{a,c}, Marie-Élaine Métras^{a,b}

Résumé

Contexte : Les formulaires de consentement éclairé (FCE) sont une condition préalable obligatoire à la participation à des essais cliniques. Dans les études pédiatriques, le FCE est généralement signé par les parents de l'enfant. Les FCE conçus pour les essais cliniques sont souvent longs et complexes à comprendre. Nous avons mené cette étude afin de déterminer si un FCE simplifié améliorerait la compréhension des parents par rapport à un FCE standard. **Méthodes :** Un essai contrôlé randomisé, en simple aveugle, mené dans un seul centre et portant sur deux FCE fictifs, a été réalisé dans un hôpital universitaire tertiaire canadien spécialisé dans la santé maternelle et infantile. Les parents d'enfants hospitalisés ont été invités à lire soit un FCE standard, soit un FCE simplifié. La compréhension des parents a été évaluée à l'aide du questionnaire MICCA (Modular Informed Consent Comprehension Assessment). Le principal objectif de cette étude était d'évaluer la proportion de parents ayant obtenu un score MICCA de 75 % ou plus. **Résultats :** Cent cinquante participants ont répondu aux questionnaires de l'étude. Le critère d'évaluation principal a été atteint par 55,7 % des participants ayant lu le formulaire simplifié, contre 46,2 % dans le groupe ayant lu le formulaire standard ($p = 0,303$). Les scores MICCA moyens étaient respectivement de 17,87 et 17,75 points ($p=0,847$). Les thèmes mal compris par les deux groupes étaient les procédures de l'étude, les effets indésirables, les autres options thérapeutiques disponibles ainsi que les principaux avantages et l'objectif de l'étude. **Conclusion :** Cette étude randomisée contrôlée, monocentrique et en simple aveugle, a montré que la compréhension était similaire entre un formulaire de consentement éclairé simplifié et un formulaire standard. Cela suggère que l'utilisation de formulaires simplifiés n'améliore ni ne nuit à la compréhension des parents. Par conséquent, un formulaire simplifié devrait être utilisé aussi souvent que possible dans les projets de recherche pédiatrique.

Mots-clés

formulaires de consentement éclairé, simplifiés, compréhension, pédiatrique, questionnaire validé

Abstract

Background: Informed consent forms (ICFs) are a mandatory prerequisite for participating in clinical trials. In pediatric studies, the ICF is generally signed by the child's parents. The ICFs designed for clinical trials are often lengthy and complex to understand. We conducted this study to determine if a simplified ICF would improve parental understanding compared to a standard ICF. **Methods:** A single-centre, single-blind, randomized controlled trial featuring two fictitious ICFs took place in a tertiary Canadian mother and child university hospital. Parents of hospitalized children were assigned to read either a standard or simplified ICF. Parental comprehension was measured using the Modular Informed Consent Comprehension Assessment (MICCA) questionnaire. The primary outcome of this study was to assess the proportion of parents with a MICCA score of 75% or above. **Results:** One hundred and fifty participants answered the study questionnaires. The primary endpoint was reached by 55.7% of the participants who read the simplified ICF compared to 46.2% in the standard ICF group ($p=0.303$). The mean MICCA scores were 17.87 and 17.75 points, respectively ($p=0.847$). Themes that were poorly understood by both groups were the study procedures, the adverse effects, the other available treatment options as well as the main benefits and purpose of the study. **Conclusion:** This single centre, single-blind, randomized controlled study showed that the comprehension was similar between a simplified and a standard ICF. This suggests that using simplified ICFs does not improve nor impair parental comprehension. Therefore, a simplified ICF should be used as frequently as possible in pediatric research projects.

Keywords

information consent forms, simplified, comprehension, pediatric, validated questionnaire

Affiliations

^a Department of Pharmacy, CHU Sainte-Justine, Montreal, Quebec, Canada

^b Faculty of Pharmacy, Université de Montréal, Montreal, Quebec, Canada

^c Research Ethics Board, CHU Sainte-Justine, Montreal, Quebec, Canada

Correspondance / Correspondence: Pascal Bédard, pascal.bedard.hsj@ssss.gouv.qc.ca

INTRODUCTION

The ethical process required to partake in clinical trials includes the informed and voluntary consent of the participants, a necessary prerequisite to ensure the respect of their autonomy and right to self-determination (1). A distinctive feature in the branch of pediatric research is that it is parents or legal guardians who generally consent on behalf of their children until they have the appropriate capacity to provide informed consent (1,2). In the Canadian province of Québec, consent must generally be given by a parent or guardian until the subject is 18 years old (3,4). However, a minor aged 14 and over who can understand the nature and consequences of the research should give written or at least verbal assent when possible. This assent is in addition to parental consent and does not replace it (3).

To allow parents to make the best decision on behalf of their child, it is important, from an ethical standpoint, that they have a good understanding of the study's risks and benefits (5). Informed consent forms (ICFs) are legal-required documents that contain information about the research project. They should be concise and understandable so that parents can make an informed choice about whether they want to include their child in a study (6,7). Unfortunately, and mostly due to legal constraints, ICFs are often very lengthy (around 20 to 30 pages) and hard to understand (8-12), containing many complex medical terms as well as mandatory legal notices (7,12). A systematic review and a meta-analysis recently revealed that the undue complexity and length of ICFs can lead the readers to misunderstand the information they seek to provide (13,14). The themes that are the least understood include the benefits of a study, randomization, and the risks and the side effects of drugs being administered (14). Another meta-analysis established that participants' comprehension of ICFs had not improved over the last three decades, even for basic concepts such as the use of placebo or freedom to withdraw from the study at any time (15).

Some researchers have thus tried to improve participants' comprehension by using different ICF simplification strategies. These included modifying the readability, the text formatting (bullet points, font, bold or italic accents), the visual aspect (including more diagrams, tables, pictures) and the length of the text (16,17). Studies comparing standard and simplified ICFs suggested that the simplification increased patient comprehension (13,16,18-20). However, the literature supporting this claim is heterogenous, mostly due to the use of non-validated questionnaires. Moreover, there is limited data specifically concerning the pediatric population, where decisions must be made by an adult on behalf of their child.

The aim of this study is to determine whether a simplified ICF, compared to a standard ICF, improves comprehension in parents asked to consent to a clinical trial for their child using a validated questionnaire. We hypothesized that a simplified ICF featuring an improved layout and with less superfluous details would allow parents to better focus on the important items, thereby improving their comprehension of the essential key points for informed decision-making.

MATERIALS & METHODS

We conducted a single-blind, randomized controlled study featuring two different fictitious ICFs, a standard ICF and a simplified ICF, to determine parental understanding of research-related information. The study took place at the CHU Sainte-Justine, a 500-bed Canadian tertiary mother and child university hospital in Montreal, Quebec. The protocol and related documents received ethical approval from the institutional research ethics board.

Study population

Parents were included in the study if their child was aged between 7 days and 17 years old, and was hospitalized for a minimum of 48 hours on non-critical care units of the CHU Sainte-Justine. Participants had to be able to read in either French or English. For ethical concerns and to avoid bias, we excluded all parents who had type 1 diabetes or who had a child with this condition since our fictitious ICFs were focused on that disease. Only one of the child's parents could be enrolled and families could not be re-enrolled in the study if they were re-admitted at the hospital. Eligible parents were identified with support from the units' clinical pharmacists.

Study procedures

We randomly assigned parents to one of the two study groups (standard ICF vs simplified ICF) in a 1:1 ratio using a computerized multiple block randomization sequence. The randomization was performed by an online website ([Sealed Envelope](#)) in blocks of 4 or 6. Parents were blinded to the ICF they received. Participants had 24 hours to read their assigned ICF. No questions about the fictitious ICF were answered by the research team; participants were invited to write down any comments they had about their ICF. After 24 hours, an investigator collected the ICF and gave participants two questionnaires: one to assess their comprehension and another with supplementary demographic questions. The parents then had 2 hours to answer the questionnaires and they had no access to the ICF during that time. If needed, parents could be granted more time to complete these steps since we recognized that the hospital setting could be disruptive to the completion of the above tasks. Many precautions were taken during the recruitment, consent and participation phases to ensure that the parents would not be misled on their child's real diagnosis by the fictitious study we used. Precautions included clearly stating the nature of the study in the consent form, verbally informing participants at both the beginning and end of the study, and adding the watermark 'Fake Study' to the fictitious ICFs, as well as a cover page clearly indicating that the fictitious study did not apply to their child.

Informed consent forms

The fictitious ICFs were built around a fake medication called Insuperos, an oral treatment for type 1 diabetes. This study topic was chosen since there is a Modular Informed Consent Comprehension Assessment (MICCA) questionnaire specific to diabetes. In the province of Québec, standard joint legal clauses featured in the ICFs of research studies are negotiated at a government level to allow provincial standardization. The topics covered by the legal clauses are compensation, prejudice, confidentiality, participation and withdrawal, commercialization, contact information and signature. These clauses needed to be included in our fictitious ICFs, and their content could not be modified (21). The legal clauses amounted to 1570 words in French and 1421 words in English.

The standard informed consent form

Fifteen real-life ICFs were consulted as reference for the formatting and content of our standard ICF. Once the first draft was completed, the standard ICF was reviewed by different experts (clinical activities specialists, research ethics board members, pharmacists) to ensure that it would closely reflect a real-world informed consent form. The final version of the French standard ICF contains 8960 words (22 pages) whereas the English one has 8110 words (22 pages). Both versions feature two tables (Appendix 1). The LIX score, which measures readability, was 54 for the French version and 51 for the English version, corresponding approximately to a grade 11 to 12 reading level (22).

The simplified informed consent form

After the completion of the standard ICF, non-healthcare workers were consulted to target modifications for the simplified version and ensure that the content was clear and easily understandable by the general public. Senior members of the research team (many of whom serve in the hospital's research ethics board) also evaluated this version to ensure that all essential elements were preserved. We used simplification techniques suggested in several past guidelines and papers (16,17). Unnecessary repetitions of information were avoided, only elements essential to the comprehension of the study were included, and a simplified language was used. The following formatting techniques were used: more bullet point enumerations, italics, underlining, as well as bold characters for the important words and concepts. Supplementary diagrams were added.

The final version of the French simplified ICF contains 4914 words (17 pages) whereas the English version has 4459 words (17 pages). Both feature one table and five diagrams (Appendix 2). The LIX score was 52 for the French version and 50 for the English version, which is also equivalent to a grade 11 to 12 reading level (22).

Study instruments

Parental comprehension of their allocated ICF was assessed using a validated questionnaire, the diabetes-specific MICCA (23). This questionnaire was specifically chosen because it was built according to the ethical principles of different countries (including Canada) and its multiple-choice format allowed for an objective evaluation. The MICCA questionnaire is composed of 25 questions, 13 general interest and 12 that are trial-specific. Of these, 14 are true or false, 5 are simple multiple choices with only one possible answer, and 6 are complex multiple choices with more than one possible answer. Each question is worth 1 point (no partial points for the complex multiple choices), for a maximum score of 25. The MICCA also includes 7 supplementary questions about the participant's demographics (Appendix 3). As the MICCA was only available and validated in English, we translated it to French using forward and back translation (to ensure accuracy).

A subset of six questions regarding medication-specific outcomes were analyzed separately. Because there were only a few medication-specific questions, exceptionally partial points were awarded. The maximum total score was 6.

Additional information about the participants was collected with a supplementary questionnaire developed by our research team (Appendix 4). We asked participants about the time they needed to read the ICF and if they would consent to the fictitious study if it was real. Supplementary demographic questions were also included, and parents were invited to write any comments they had about the ICF.

Study outcomes

The primary outcome was the difference in the proportion of parents who obtained a MICCA score of 75% (19/25) or above, between the standard and the simplified groups. This score has been arbitrarily set and used in previous studies as a reflection of good comprehension (24). The secondary outcomes were the difference of mean score between the two groups for the whole questionnaire, the differences of proportion and mean score between the two groups for the medication-specific questions (6 questions, see Appendix 3) as well as the collection of the written comments in each group.

Data analysis

In an Ethiopian study that used the MICCA questionnaire, only 5% of participants who read an ICF obtained a score above 75% (24). Considering the results of that study as well as the differences between their and our study populations, we estimated that 15% of parents reading the standard ICF would score above 75%. Thus, using G*Power 3.1, we calculated that a sample size of 150 parents would allow us to detect a 20% difference between our two independent proportions of the primary endpoint ($p_1=0.15$ and $p_2=0.35$), with a power of 80% and significance level of 5%. We added a 10% margin for expected losses to follow up; consequently, our target sample size was 164 parents (82 in each study group).

The distribution of the results was assumed to be normal considering the sample size. For the primary outcome, the Fisher exact test was used to calculate the difference between the proportion of participants that obtained a score of 75% or above (19/25). To assess the robustness of our estimate, we conducted a sensitivity analysis with proportions of participants that obtained a MICCA score of 65% and 85%.

For the secondary outcomes, the difference in proportions was calculated with a Fischer exact test and the mean understanding differences were calculated with a Student T test.

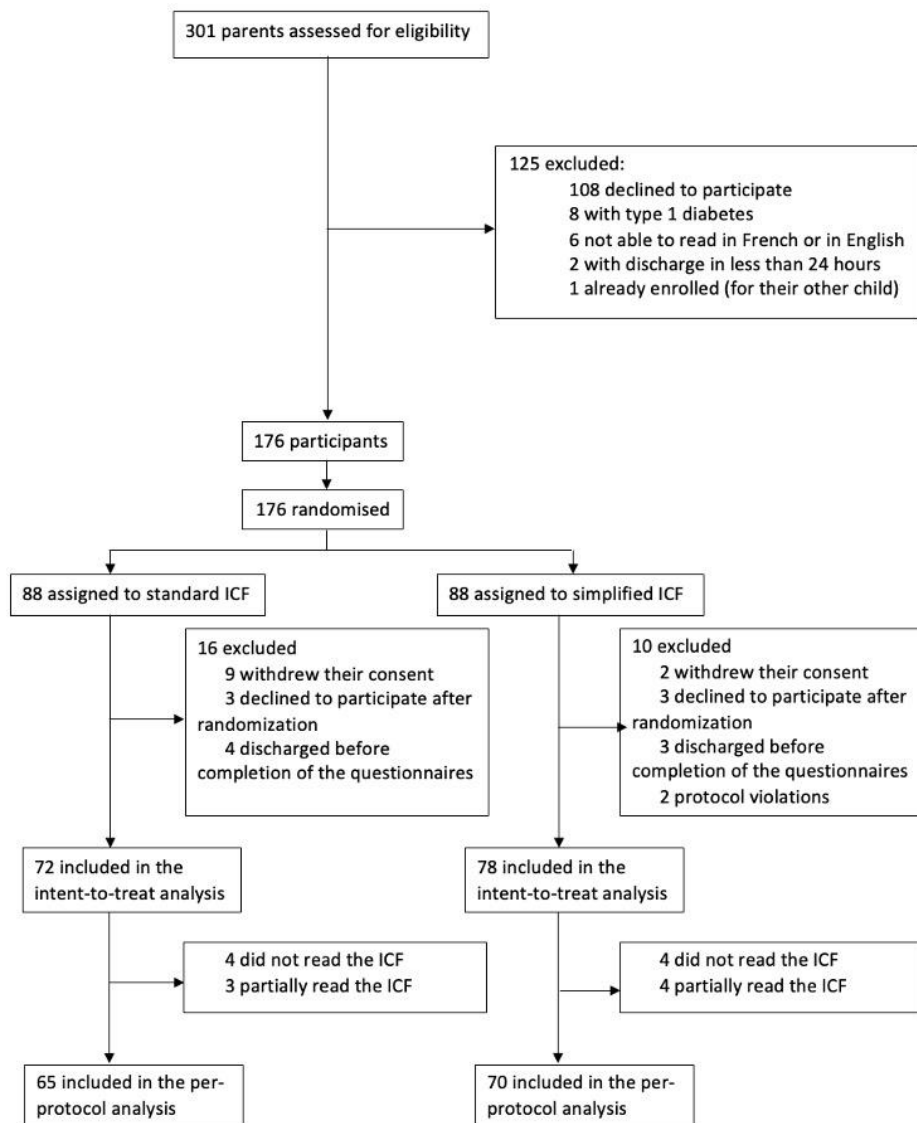
The statistical significance was set at $\alpha = 0.05$ for all tests. Statistical analyses were performed using IBM SPSS version 27 (Armonk, NY). All the analyses for the total MICCA score and the medication-specific questions were conducted using the modified intent-to-treat and the per-protocol analysis. The modified intent-to-treat analysis included all the participants who answered the questionnaires, even if they did not read the ICF or read it only partially. The per-protocol analysis included only participants who read the ICF completely and answered the questionnaires.

The parents' reading notes and comments were grouped in common themes, to enhance our understanding of their subjective reading experience.

RESULTS

Between March and July 2023, 176 parents of children hospitalised at CHU Sainte-Justine were included in this study. The sample size was increased to compensate higher than anticipated losses to follow-up. Of the 150 who completed the questionnaires, 135 participants read the ICF completely ($n=65$ for standard ICF and $n=70$ for simplified ICF) (Figure 1).

Figure 1: Study schematic



Most of the participants were mothers, younger than 40 years old, spoke French and had an educational status higher than high school. Less than 20% of participants were healthcare workers (Table 1).

Table 1: Baseline characteristics of the intent-to-treat population

	Standard ICF (n=72) (%)	Simplified ICF (n=78) (%)
Age (years)		
< 40	48 (66.7)	56 (71.8)
≥ 40	22 (30.6)	18 (23.1)
Unknown	2 (2.8)	4 (5.1)
Sex		
Female	54 (75.0)	52 (66.7)
Male	16 (22.2)	22 (28.2)
Unknown	2 (2.8)	4 (5.1)
Preferred language for communication		
French	67 (93.1)	64 (82.1)
English	3 (4.2)	11 (14.1)
Other	2 (2.8)	2 (2.6)
Unknown	0	1 (1.3)
Highest educational level reached		
Primary school	1 (1.4)	0
Secondary school	5 (6.9)	9 (11.5)
Technical/vocational education	26 (36.1)	21 (26.9)
Some university education	5 (6.9)	7 (9.0)
Undergraduate degree	20 (27.8)	20 (25.6)
Higher graduate degree	12 (16.7)	16 (20.5)
Unknown	3 (4.2)	5 (6.4)
Healthcare worker		
Yes	14 (19.4)	14 (17.9)
No	58 (80.6)	62 (79.5)
Unknown	0	2 (2.6)
Participation to a clinical trial in the past		
Yes	9 (12.5)	17 (21.8)
No	60 (83.3)	57 (73.1)
Unknown	3 (4.2)	4 (5.1)

Upon analysis of the primary endpoint using the per-protocol model, 55.7% of participants in the simplified group obtained a total MICCA score ≥ 75%, compared to 46.2% in the standard ICF group (p=0.303) (Table 2). The pre-determined sensitivity analyses provided similar results (Table 3). There was no difference in the mean comprehension score between the 2 groups: 17.87 in the simplified group vs 17.75 in the standard group (p=0.512).

Table 2: Total and medication-specific MICCA scores, per-protocol analysis

		Standard ICF (n=65)	Simplified ICF (n=70)	RR	95% CI	P value*
Total score	Proportion of participants with a score of ≥ 75%	46.2%	55.7%	0.681	(0.346 to 1.343)	0.303
	Mean score (/25)	17.75 +/- 3.41	17.87 +/- 3.62		(-1.317 to 1.082)	0.847
Medication-specific questions	Proportion of participants with a score of ≥ 75%	30.8%	31.4%	0.970	(0.468 to 2.011)	1.000
	Mean score (/6)	3.485 +/- 1.25	3.414 +/- 1.24		(-0.354 to 0.494)	0.743

*Fisher exact for the difference between proportions and Student T test for the mean difference

When analyzing the comprehension of the medication-specific questions, the mean scores and the proportion of scores ≥ 75% were also similar between the 2 study groups (Table 2). Likewise, all these results were not statistically significant in the modified intent-to-treat model (Appendix 5).

Table 3: Sensitivity analysis for the total and the medication-specific MICCA scores, per-protocol analysis

		Standard ICF (n=65)	Simplified ICF (n=70)	RR	95% CI	P value*
Total score	Proportion of participants with a score of ≥ 65%	67.7%	74.3%	0.725	(0.344 to 1.530)	0.450
	Proportion of participants with a score of ≥ 85%	7.7%	11.4%	0.646	(0.200 to 2.086)	0.565
Medication-specific questions	Proportion of participants with a score of ≥ 65%	41.5%	44.3%	0.894	(0.452 to 1.769)	0.862
	Participation of participants with a score of ≥ 85%	10.8%	2.9%	4.103	(0.820 to 20.530)	0.088

*Fisher exact for the difference between proportions

In a post-hoc analysis, we compared the reported reading time between the two groups. The percentage of participants who took ≤ 1 hour to read their ICF was 60.0% for the standard group vs 73.9% for the simplified group ($p=0.100$). The themes of the questions that were failed by more than 50% of the participants in both groups were the study procedures, the adverse effects, the other available treatment options, as well as the main benefits and purposes of the study (Appendix 6).

When compiling the comments and suggestions made by the parents who read the simplified ICF, some participants identified the layout, with the bold words and point forms, as positive and useful. Others also commented that the simplified tables and figures helped make the text lighter. In the standard ICF group, some parents would have appreciated having this kind of layout and/or more tables. A point that stood out in the standard ICF was that parents found there were too many repetitions. In both groups, some parents reported that the ICF was too long and that the section about the risks associated with the procedures was too detailed and unnecessary.

A few parents made suggestions to help simplify future ICFs. They suggested adding a lexicon to define complicated words as well as providing complementary audiovisual explanations. They also suggested shortening the ICFs as much as possible and adding appendixes with supplementary information for parents who want more details.

DISCUSSION

To our knowledge, this is the first North American study to evaluate parental comprehension of a simplified ICF in a pediatric clinical trial simulation using a validated questionnaire. Our findings show that the comprehension of the simplified ICF was similar to that of the standard ICF. The absence of meaningful difference in comprehension applied to both the global questionnaire and the medication-specific themes. A shorter, more understandable document that does not compromise the quality of the informed consent process represents a valuable and positive result. Further, participants gave more positive feedback about the simplified ICF and more negative comments about the standard ICF, suggesting an enhanced perceived overall experience with the simplified ICF.

Our results differ from several studies which found that a simplified ICF was better understood than a standard ICF (16,20,24). It is important to consider certain key factors when comparing our study to others. First, most of the other studies in this field did not use a validated questionnaire, like we did, which makes it harder to compare and interpret the discrepancies between the results (25). Second, there is no standardized method for simplification of an ICF. However, some researchers did explore which methods could improve ICF comprehension. A combination of at least three different simplification techniques seems to be necessary to detect a difference in comprehension (16,17). Several of these recommended changes were used to create our simplified ICF, including four formatting techniques and three supplementary non-formatting changes, as well as additional diagrams. Finally, both our study groups achieved high comprehension scores in comparison to previous studies. For instance, a study using the MICCA questionnaire in Ethiopia showed that only 4.3% of the participants reached a comprehension score of more than 75% in the standard ICF group, compared to 46.2% in our study (24). The disparity in education levels is a contributing factor and likely plays a significant role, as approximately 50% of our study population had completed university studies, surpassing the 37% seen in the general Quebec population (26). Such a high score in the control group limits the chances to find statistically significant interventions in highly educated populations. Nonetheless, concerns remain for parents who do not achieve high comprehension scores.

Targeting parental interests and concerns may be a valid strategy. A study that evaluated parents' point of view on the important parts of an ICF showed that they considered the health benefits and the adverse effects of the drugs to be of the highest interest (27). In contrast to this, the results of a systematic review suggested that only a small minority of patients really understand the following elements of a research study: the concept of placebo, randomization, safety issues, risks and side effects (14). Similarly, in our study, 6 questions were failed by more than 50% of participants in both groups. These questions focused on study procedures, adverse effects, other available treatment options, and the main benefits and purposes of the study. Considering that these themes are the cornerstone of research projects, and are important for fully informed consent, greater efforts should be invested in making ICFs more accessible to the public — our results help target these areas for future improvement.

Our study shows that a simplified ICF is insufficient to achieve an optimal comprehension in all parents, even in a highly educated population. This highlights the importance of offering more guidance to potential participants in their reading of the ICF. A research team member who provides parents with supplementary explanations and answers their questions seems to be a key factor to promoting greater comprehension (28). Audiovisual or interactive content is another interesting avenue to improve the comprehension of study participants (13).

There were several limitations to our single centre study. First, comprehension was evaluated in a simulated study. Thus, parents may not have been as emotionally involved as those who would read an ICF to enroll their children in a real study. This issue is also described in other studies on this topic (13). Even though it would come with its own challenges, testing a simplified ICF in an active study would help to overcome this problem. Second, children and parents who had type 1 diabetes were excluded for ethical reasons. This could affect the level of comprehension in our study population because participants had less knowledge about the medical terms and procedures associated with that disease. Third, we did not respond to any questions the parents might have had reading the ICF, nor did we provide supplementary information on study-related

concepts. In a real clinical trial, the research team can answer any questions that arise. These limitations restrict our study's external validity, but they allowed us to focus exclusively on the ICFs.

Furthermore, our simplified ICF's text, while shorter than the standard version, was equivalent to a 11-12th grade level text, which is not comprehensible to a significant part of the North American population (29,30). We tried to shorten the simplified ICF as much as possible, as Tait et al. reported that longer ICFs were correlated with poorer verbatim understanding of risks and benefits (16). However, our province's legal requirements were an obstacle in the shortening of our form. A revision of the standardized legal clauses could allow for more intelligible text. Finally, our study did not consider the children's comprehension since they were hospitalized and the timing for a simulated research project was not appropriate. Their inclusion could be a significant point of interest for further studies since children who are able to understand a clinical study need to give their assent in order to participate.

CONCLUSIONS

Our single centre, single-blind, randomized controlled study showed that comprehension was similar between simplified and standard ICFs. Both groups were highly educated and achieved higher comprehension scores than what was previously described. This suggests that using simplified ICFs in pediatric research projects does not improve nor impair parental comprehension. A simplified ICF may enhance the parent's overall experience, due to its shorter length, use of bullet points and improved layout. Out of respect for participants and their families, a simplified ICF should therefore be used in research projects as frequently as possible. Other interventions, such as the use of audiovisual or interactive supplementary content, are also interesting avenues for supporting parental comprehension of clinical studies.

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Conflits d'intérêts

Aucun à déclarer

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Conflicts of Interest

None to declare

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APPENDIX 1: STANDARD FICTITIOUS ICF – ENGLISH VERSION

Available at [external link](#)

APPENDIX 2: SIMPLIFIED FICTITIOUS ICF – ENGLISH VERSION

Available at [external link](#)

APPENDIX 3: DIABETES-SPECIFIC MICCA - ENGLISH VERSION

Available at [external link](#)

APPENDIX 4: SUPPLEMENTARY QUESTIONNAIRE MADE BY THE RESEARCH TEAM IN ENGLISH

Contact pascal.bedard.hsj@ssss.gouv.qc.ca if you want to obtain the French version

Supplementary questionnaire

1. Approximately how much time did you spend reading the fictitious information and consent form:
 - 0 to 1 hours
 - > 1 to 2 hours
 - > 2 to 3 hours
 - > 3 to 4 hours
 - More than 4 hours

2. If the information and consent form you just read was not for a fake study, assuming your child had type 1 diabetes, would you accept that your child participate in the research project?

REMINDER: THIS IS A FAKE STUDY. Your child does not have type 1 diabetes and will not take the Insuperos treatment or subcutaneous insulin. THIS IS A SIMULATION.

- Yes
 - No
3. Are you a healthcare worker?
 - Yes
 - No

 4. What is your preferred language for communication:
 - French
 - English
 - Spanish
 - Mandarin
 - Arab
 - Other (specify): _____

5. Do you have any comments about the fictitious information and consent form you read? (free text)

APPENDIX 5: TOTAL AND MEDICATION-SPECIFIC MICCA SCORES, INTENT-TO-TREAT ANALYSIS

		Standard ICF (n=72)	Simplified ICF (n=78)	RR	95% CI	P value*
Total score	Proportion of participants with a score of 75% or more	41.7%	51.3%	0.679	(0.356 to 1.294)	0.256
	Mean score	17.21 +/- 3.741	17.36 +/- 3.987		(-1.401 to 1.100)	0.812
Medication-specific questions	Proportion of participants with a score of 75% or more	27.8%	30.8 %	0.865	(0.428 to 1.752)	0.722
	Mean score	3.347 +/- 1.310	3.269 +/- 1.367		(-0.355 to 0.511)	0.722

* Fisher exact for the difference between proportions and Student T test for the mean difference

APPENDIX 6: QUESTIONS THAT WERE FAILED BY MORE THAN 50% OF THE PARTICIPANTS IN BOTH GROUPS IN A PER-PROTOCOL ANALYSIS

Questions	Percentage of participants who failed the question
8. I will be told about new findings from the clinical trials so I can decide whether to continue to take part.	54.1%
20. Which describes the main purpose(s) of the clinical trial?	68.1%
21. Which procedure(s) will you be asked to take part in?	81.5%
23. Which side effect(s) might occur?	77.8%
24. Which describes the main benefit(s) of taking part in the clinical trial?	71.7%
25. Which describes the other treatment option(s) available to you?	59.8%