

TWO METHODS OF OBTAINING INFORMED CONSENT IN A GENETIC EPIDEMIOLOGICAL STUDY: EFFECTS ON UNDERSTANDING

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ABSTRACT: THIS STUDY EVALUATED THE EFFECT ON participant understanding and participation rates of two different approaches to obtaining informed consent, using 2,192 actual research subjects in a genetic cohort study. One group received the routine approach consisting of written materials and an oral explanation. The other group received a more intense approach consisting of educational lectures and group meetings in addition to the routine approach. Subjects in the intense approach group were relatively more likely to read some or all of the explanatory material. Those in the intense group who did not read the material were more likely than those in the routine group to express uncertainty about their understanding of the research. Those in the intense group who read the material perceived that they had a higher level of understanding of the research and this was associated with a higher frequency of volunteering to participate. In contrast, subjects in the routine group were less likely to read the written material, but ironically more likely to assume that they understood what the research was about. These rather paradoxical findings raised questions about what motivates potential research subjects to become sufficiently engaged to seek actual understanding of the research before volunteering.

KEY WORDS: informed consent, warranted uncertainty, epidemiological research, comprehension, intervention

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THERE HAVE BEEN MANY STUDIES on the informed consent process in research that have documented deficiencies in participant understanding of basic elements of the protocols (Griffin, Struve, Collins, Liu, Nelson, & Bloomfield, 2006). Therefore, identifying methods that will improve people's understanding has been a major concern.

In order to enhance understanding, some have applied multimedia-assisted consent procedures; others have modified the consent forms (Meade, McKinney, & Barnas, 1994; Weston, Hannah, & Downes, 1997; Bjørn, Rossel, & Holm, 1999; Krouse, 2001; Benitez, Devaux, & Dausset, 2002; Campbell, Goldman, Boccia, & Skinner, 2004; Cowan, Calderon, Gennis, Macklin, Ortiz, & Wall, 2007). Data suggest, however, that these efforts have not consistently improved the retention of information (Flory & Emanuel, 2004). What should also be of concern is that most of these studies have attempted to measure only what people can *recall* of the disclosed information (Wendler, Prasad, & Wilfond, 2002; Criscione, Sugarman, Sanders, Pisetsky, & St. Clair, 2003). The basic flaw in these studies is that they wrongly assume that the *recall* of information is equivalent to *understanding* itself (Meisel & Roth, 1981; Taylor, Bezjak, & Fraser, 1998); therefore, it is still not certain what procedures reliably lead to improved understanding.

Another problem with the existing research is that much of it has used hypothetical scenarios (Davis, Holcombe, Berkel, Pramanik, & Divers, 1998; Bjørn, Rossel, & Holm, 1999; Wragg, Robinson, & Lilford, 2000; Kruse, Kjaergard, Krogsgaard, Gluud, Mortensen, Gottschau, Bjerg, & the INFO Trial Group, 2000). Hypothetical decision-making situations may significantly differ from those where one has to make a real choice. Real participants may be less prepared for the consent process compared with participants asked to consider hypothetical scenarios, because real participants, unlike scenario participants, often do not read the consent materials before signing the forms (Cassileth, Zupkis, Sutton-Smith, & March, 1980; Lavelle-Jones,

Byrne, & Cuschieri, 1993; Wise, 1993; Sharp, 2004). This point is, however, rarely discussed in the current literature of informed consent in research ethics.

The purpose of the present study is therefore, first, to study the participants' actual reading status of the consent materials and perceived understanding at entry, and second, to seek to identify a method to improve their reading of the consent materials and understanding of the research. We provided two different methods of disclosing information to potential participants in an ongoing genetic cohort study in Japan. We then measured their self-perceived understanding of the study as well as the effect of reading the provided explanatory documents. Third, as the study also raises an ethical concern regarding *understanding* of research in the informed consent process, we conclude the paper with a discussion of what *understanding* is likely to mean to actual research participants.

Methods

SETTING AND STUDY POPULATION

A population-based genetic cohort baseline-study was conducted in the two towns of Takashima and Makino in Takashima County, Shiga, Japan, in conjunction with the national annual health checkup program that is provided by law to the people in Japan. In the baseline-study, data on lifestyle, medical and family history of diseases, blood plasma and serum, and genetic samples were collected from the general population for the subsequent longitudinal assessment of the associations between lifestyle, genetic profiles, and the change of health conditions including an onset of disease, and death.

The present study targeted the 2,279 people receiving a health checkup. A total of 84 checkup attendees, who were mentally or physically incompetent or refused the consent negotiation, were excluded from the whole study. There were also missing data for three attendees. Consequently, a total of 2,192 individuals (*potential participants*, in contrast to the people who ultimately decided to participate: 1,064 in Takashima, 1,128 in Makino) were considered to have completed the informed consent process for the genetic cohort study (response rate of 96.2%) (Figure 1).

METHODS OF PROVIDING INFORMATION

Information about the genetic research was provided to potential participants by either the routine approach or a more intense approach (Figure 2).

The potential participants in Takashima town received the routine approach, and those in Makino town received the intense approach.

Routine Approach. All those scheduled to appear for the annual health checkup during May 2003 in Takashima received a written notification and a written explanation of the research as part of the information sent to them about the national annual health checkup. While they were waiting to register for the annual checkup at the research site, all attendees received oral explanations about the research by the two PIs in small groups of 5–10 people. Then they proceeded to the initial stage of the annual health checkup, consisting of taking a medical history. Following that, those who were interested in participating in the study proceeded to see the research nurse associated with the cohort study. The nurse provided further information to each individual and gave each individual the informed consent sheet for the study. Those who consented to participate in the study proceeded to the blood drawing for research purposes, and then to the annual health checkup blood draw. Those who refused to participate in the cohort study proceeded directly to the annual health checkup blood draw.

Intense Approach. The intense approach included all the elements of the routine procedure described above, except that it was conducted in the town of Makino during June 2003, and a 2-hour community educational lecture and explanatory 60-minute meeting was conducted during the one-month time period preceding the annual health checkup. Community newsletters and posters advertising the lectures were widely circulated to the whole community by the municipal authority around 2 to 2.5 weeks before the posting of the explanatory documents about the study and the annual health checkup. It was also announced that the town mayor would attend and a famous actress, who is now a Ph.D. student of epidemiology and part of the staff of the cohort study, would act as a moderator of the lectures.

The lectures started at 7 p.m. with an opening address by the town mayor, addressing serious health-related problems of the town, such as a rapid aging population of the area, a seriously increasing number of patients suffering from diabetes mellitus and other lifestyle-related diseases, critically tight financial conditions of the social security costs of the town, and so forth. Subsequently, the head of the epidemiology department gave a 50-minute lecture on lifestyle-related diseases, genes, and evidence of genetic bases of diseases; then one of the two PIs explained the proposed genetic cohort study in detail, leaving sufficient time for a question-and-answer session with the audience. More than 300 people participated in the lectures. Separately from and right after the lectures, a 60-minute

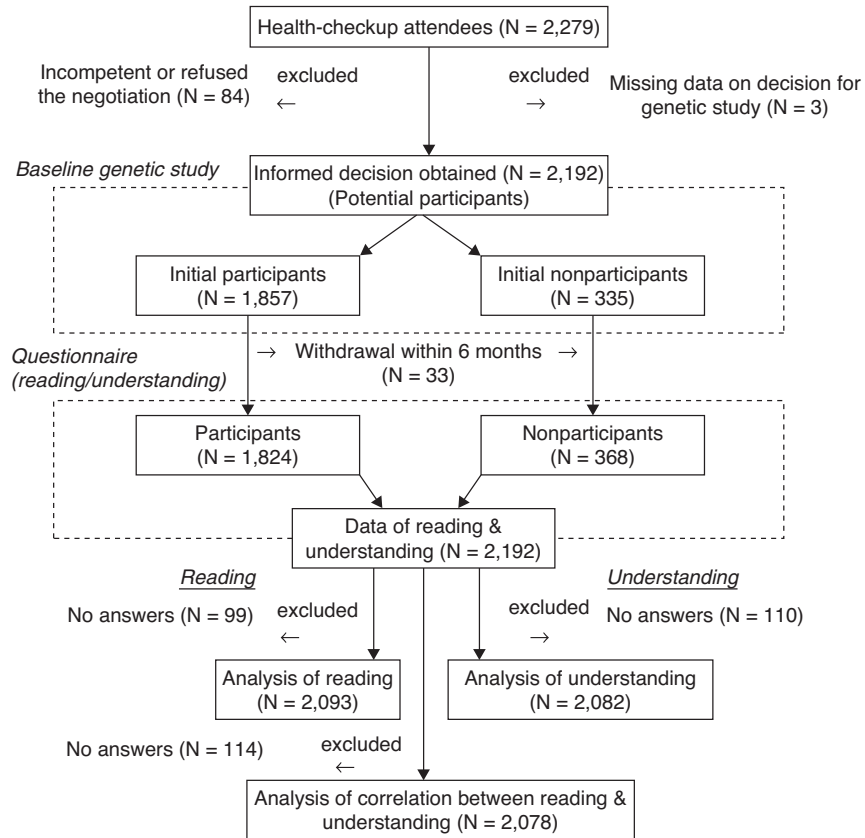


FIG. 1. Recruitment and process for the genetic study, the questionnaire study, and the analyses.

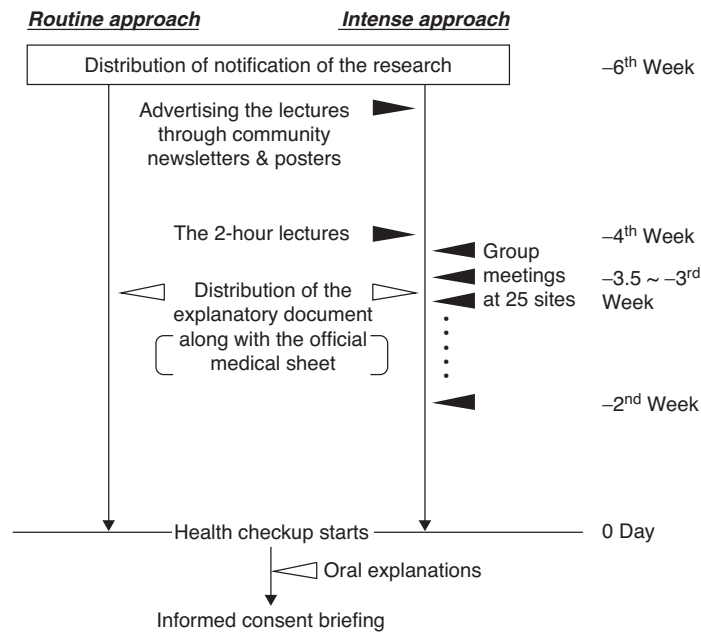


FIG. 2. Two methods of obtaining informed consent.

group meeting was also conducted by one of the two PIs for the scheduled health-checkup attendees 2 to 3.5 weeks before the checkup at each of 25 sites in conjunction with the municipal explanatory program of the health checkup. The session started with an explanation of the procedures of the annual health checkup. Then one of the PIs gave an overview of the meaning of the blood tests conducted during the health checkup, such as the test of total cholesterol level and basic elements of the proposed genetic cohort study. One-fourth to one-third of the scheduled individuals at each site participated in this group meeting.

EXPLANATORY DOCUMENT

The explanatory document, which all subjects received, contains information required by the national ethics guidelines for epidemiological and genetic research and information commonly found in informed consent documents. Participants are asked to sign this document before entering a genetic epidemiological study. The document explains the relationship between targeted diseases and genes, as well as the purposes, methods, duration, and potential risks and anticipated benefits of the study, voluntariness of the participation, confidentiality of materials, how materials are stored and destroyed, a policy for the disclosure of individual results and genetic counseling, the names and affiliations of the research members, and their contact information. It was about 15 pages long and consisted of 12,311 letters/characters of *Hiragana/Katakana/Kanji* in Japanese.

The vocabulary level of the explanatory document was graded at the second level of the Japanese-Language Proficiency Test, by using a Japanese-language reading tutorial system, "Reading Tutor," developed by Kawamura et al. (Kawamura, Kitamura, & Hobara, 2007; Kawamura, 1998). The grade 2 is at the level for those non-native Japanese speakers who have learned Japanese for about 600 hours and completed middle Japanese language courses: this is almost consistent with a level of those native Japanese who finish, at least, elementary education for 6 years with knowledge of about 1,000 *Kanji* characters and having a 6,000-word vocabulary or over. Grade 1 is more complex, being at the level for entering Japanese universities for non-native Japanese speakers with sufficient knowledge of around 2,000 *Kanji* characters and a 10,000-word vocabulary, which is almost equivalent to the level of a second- to third-grader of high school.

QUESTIONNAIRE

All 2,192 potential subjects were asked the following two short questions immediately after they signed the consent form or declined to participate: (1) "Have you read in advance the explanatory document describing the proposed genetic cohort study?" Answer categories included "I read all of the explanatory document"; "I read only parts of it"; or "I did not read it at all." (2) "Do you feel that you understand the purposes of the proposed genetic study and the methods by which it will be carried out?" The four answer categories included: "I feel that I understand the proposed research very well"; "I feel that I understand it well"; "I feel that I understand it to some degree"; or "I feel that I don't understand it at all."

STATISTICAL ANALYSIS

Demographic data, other than age and gender, were obtained through an associated questionnaire. "Participants" are those who enrolled in the study and participated for at least 6 months ($n = 1,824$). "Nonparticipants" are those who declined to participate at baseline ($n = 335$) or who initially participated but withdrew within 6 months ($n = 33$) (most withdrawals actually happened within a few days). The 99 people who did not answer the two questions noted above were excluded from analysis, so that the subsequent analysis was done with data for 2,093 people (Figure 1). The χ^2 -test, Mann-Whitney's U-test, the statistic for γ , and multivariable logistic regression analysis were applied for analysis with the SPSS package (version 14.0J).

Results

Sociodemographic characteristics. The cohort that received the routine approach ($n = 1,064$) was older ($p < .001$, χ^2 -test) and included more females ($p = .002$, χ^2 -test) than the cohort that received the intense approach ($n = 1,128$) (Table 1). Between the two cohorts, there was no difference in educational history, religious status, or marital status, but the former cohort had higher household income than the latter ($p < .001$, χ^2 -test).

Participation. The participation rate (those who enrolled at entry and remained in the study for at least 6 months) was 83.6% for the routine approach group and 82.7% for the intense approach group, with no statistical difference in participation rates by a chi-square test (for details, see Matsui, Kita, & Ueshima, 2005). A multivariate logistic regression adjusted for all

TABLE 1. Sociodemographic Characteristics of the Research Cohorts, Year 2003, Shiga.

	Routine Approach (N = 1,064)	Intense Approach (N = 1,128)
Age** (years)		
mean (SD)	62.1 (13.0)	58.1 (14.7)
Gender*		
male (%)	344 (32.3)	438 (38.8)
female (%)	720 (67.7)	690 (61.2)
Marriage [†]	(N = 761; RR 71.5%)	(N = 882; RR 78.2%)
(ever) married (%)	749 (98.1)	845 (95.8)
never married (%)	12 (1.9)	37 (4.2)
Religion [†]	(N = 754; RR 70.9%)	(N = 859; RR 76.2%)
Yes (%)	681 (90.3)	773 (90.0)
No (%)	73 (9.7)	86 (10.0)
Education [†] (%)	(N = 749; RR 70.4%)	(N = 853; RR 75.6%)
<= 6 years	37 (4.9)	41 (4.8)
<= 9 years	273 (36.4)	355 (41.6)
<= 12 years	246 (32.8)	262 (30.7)
<= 14 years	104 (13.9)	99 (11.6)
<= 16 years	87 (11.6)	95 (11.1)
<= 18 years	2 (0.3)	1 (0.1)
mean (SD)	11.4 (2.7)	11.1 (2.7)
Household income ^{†**} (million ¥)	(N = 734; RR 69.0%)	(N = 815; RR 72.3%)
mean (SD)	4.5 (3.0)	3.8 (2.8)

Abbreviations: SD, standard deviation; RR, response rate.

[†]'No answers' were excluded from the table and analysis.

* $p = 0.002$; ** $p < 0.001$.

sociodemographic factors noted above also showed no statistical difference in participation status between the two groups (odds ratio = .88; 95% confidence interval (CI) .62–1.26).

Reading. Overall, 664 potential participants (31.7%) reported reading all of the explanatory document in advance; 366 individuals (17.5%) reported reading only parts; and 1,063 individuals (50.8%) reported not reading it at all (Table 2).

The group of potential participants that received the intense approach was more likely than the group that received the routine approach to have read all or part of the explanatory document in advance ($p = .013$, U-test). Actual participants were more likely to have read the

explanatory document in advance ($p < .001$, U-test) than nonparticipants (Table 3). Among actual participants, the group that received the intense approach was more likely than the routine approach group to read all or part of the explanatory document ($p = .002$, U-test). On the other hand, among nonparticipants the different type of explanatory approach had no significant impact on their reading status.

Understanding. Overall, 444 potential participants (21.3%) reported that they understood the proposed research "very well"; 1,292 individuals (62.1%) reported "well"; 281 individuals (13.5%) reported "to some degree"; and 65 individuals (3.1%) reported "not at all" (Table 4).

TABLE 2. Effect of Intervention on Reading Status.

Reading Explanation	Overall (N = 2,093)	Routine Approach (N = 998)	Intense Approach (N = 1,095)
All (%)	664 (31.7)	313 (31.4)	351 (32.1)
Only parts (%)	366 (17.5)	137 (13.7)	229 (20.9)
Not at all (%)	1,063 (50.8)	548 (54.9)	515 (47.0)

A total of 99 'no answers' were excluded from the table and analysis.

TABLE 3. Reading Status of Participants and Nonparticipants.

Reading Explanation	Participants			Nonparticipants		
	Overall (N = 1,792)	Routine (N = 866)	Intense (N = 926)	Overall (N = 301)	Routine (N = 132)	Intense (N = 169)
All (%)	584 (32.6)	275 (31.8)	309 (33.4)	80 (26.6)	38 (28.8)	42 (24.9)
Only parts (%)	335 (18.7)	123 (14.2)	212 (22.9)	31 (10.3)	14 (10.6)	17 (10.1)
Not at all (%)	873 (48.7)	468 (54.0)	405 (43.7)	190 (63.1)	80 (60.6)	110 (65.1)

A total of 32 and 67 'no answers' among participants and nonparticipants respectively were excluded from the table and analysis.

Ironically, the subjects who received the routine approach and presumably had less information about the study rated their understanding higher than those who received the intense approach ($p < .001$, U-test). Presumably their confidence in their knowledge was not warranted by their level of actual knowledge.

Participants tended to evaluate their understanding as higher than that of nonparticipants ($p < .001$, U-test). Among both participants and nonparticipants, the group that received the routine approach reported their understanding as higher ($p < .001$ and $p = .018$, respectively, U-test) than the group that received the intense approach (Table 5).

Multivariable logistic regression analysis with adjustment for the sociodemographic data and the types of intervention demonstrated that those who evaluated their understanding more highly were more likely to be a participant than those who evaluated their understanding as lower (odds ratio 19.79, 95%CI 8.01 to 48.89, in the "very well" group; odds ratio 16.74, 95%CI 7.57 to 37.02, in the "well" group; and odds ratio 3.02, 95%CI 1.34 to 6.83, in the "to some degree" group).

CORRELATION BETWEEN READING AND UNDERSTANDING

Overall, those who read more of the document were more likely to report a better understanding ($\gamma = .43$; $p < .001$) than those who read less (Table 6).

The results of the analysis by participation were consistent with this ($\gamma = .46$ and $\gamma = .42$; all $p < .001$). In both groups, those individuals who read more of the document were more likely to report a better understanding ($\gamma = .66$ and $\gamma = .37$ respectively; all $p < .001$).

More than 80% of participants who had *not* read the document at all still evaluated their understanding as "well" or "very well," irrespective of the types of the intervention (Table 6). Similarly, among the nonparticipants who had *not* read the document, one third who received the routine approach and more than half of those who received the intense approach reported their understanding as "well" or "very well."

Discussion

Our study demonstrates that the reality of informed consent in epidemiological studies appears to be remote from the ideal of informed consent discussed in most of the simulated or clinical settings: our data show that half of the potential participants did not read the explanatory document before signing the consent form. In spite of this, many of them felt that they understood the proposed research quite well. These findings indicate that potential participants might not be interested in reading lengthy informed consent documents and are prepared to participate based on an apparently superficial understanding of the research,

TABLE 4. Effect of Intervention on Understanding.

Understanding	Overall (N = 2,082)	Routine Approach (N = 987)	Intense Approach (N = 1,095)
Very well (%)	444 (21.3)	252 (25.5)	192 (17.5)
Well (%)	1,292 (62.1)	589 (59.7)	703 (64.2)
To some degree (%)	281 (13.5)	117 (11.9)	164 (15.0)
Not at all (%)	65 (3.1)	29 (2.9)	36 (3.3)

A total of 110 'no answers' were excluded from the table and analysis.

TABLE 5. Understanding of Participants and Nonparticipants.

Understanding	Participants			Nonparticipants		
	Overall (N = 1,786)	Routine (N = 860)	Intense (N = 926)	Overall (N = 296)	Routine (N = 127)	Intense (N = 169)
Very well (%)	413 (23.1)	231 (26.9)	182 (19.7)	31 (10.5)	21 (16.5)	10 (5.9)
Well (%)	1,167 (65.3)	525 (61.0)	642 (69.3)	125 (42.2)	64 (50.4)	61 (36.1)
To some degree (%)	181 (10.1)	87 (10.1)	94 (10.2)	100 (33.8)	30 (23.6)	70 (41.4)
Not at all (%)	25 (1.4)	17 (2.0)	8 (0.9)	40 (13.5)	12 (9.4)	28 (16.6)

A total of 38 and 72 'no answers' among participants and nonparticipants respectively were excluded from the table and analysis.

that is, mainly through the verbal explanation. This implies that modification of informed consent documents, readability assessment of the consent forms or introduction of various multimedia techniques might therefore not be appropriate means of improving the informed consent process.

Our results also show that, contrary to what we might expect, a more intense approach for providing information may actually lead to a lower degree of self-perceived understanding. We have measured self-perceived understanding, which is different from actual understanding, so our results do not necessarily show that the more intense approach leads to a lower level of actual understanding. On the other hand, unlike most other previous studies, we have studied participants who are being approached for entry into a real study rather than a simulated study and have measured their perceived understanding at the time of entry into the study, rather than how much they can *recall* some time after study entry. Our results also support the general conclusion from previous studies that adding explanatory material itself may not lead to a higher degree of perceived understanding (Davis et al., 1998; Campbell et al., 2004).

Interestingly, our data show three important relationships between the method of providing information, reading of the explanatory material, degree of

understanding, and participation rates. First, the intense approach is more likely than the routine approach to lead potential participants to read the explanatory document. Second, those who read the explanatory documents rate their own understanding of the research higher than those who do not. Third, those individuals who evaluate their understanding to be higher are more likely to be a research participant.

What we have found, therefore, is that a more intense approach leads to lower self-perceived understanding overall and makes no difference in terms of participation rates. On the other hand, a more intense approach seems to motivate the potential participants to read the explanatory documents, which appears to lead to a higher degree of self-perceived understanding and an enhanced participation rate. One plausible explanation for these findings is that those who receive the more intensive information realize that there is a lot they do not know about the research, and therefore they evaluate their self-perceived understanding as lower; some of them are, however, motivated to read more, and among those who do, their self-perceived understanding is higher, and this increased sense of understanding also enhances their participation. Another way of looking at this might be that the routine approach group, who did not receive elaborate instruction in and detailed discussion of the

TABLE 6. Correlation Between Reading and Understanding.

Reading	Understanding				Total
	Very Well	Well	To Some Degree	Not at All	
All	242 (36.4)	376 (56.6)	43 (6.5)	3 (0.5)	664 (100.0%)
Only parts	50 (13.7)	264 (72.5)	49 (13.5)	1 (0.3)	364 (100.0%)
Not at all	152 (14.5)	649 (61.8)	188 (17.9)	61 (5.8)	1,050 (100.0%)

A total of 114 'no answers' were excluded from the table and analysis.

proposed research prior to consent, apparently assumed that they understood the research, but this confidence in their understanding and their subsequent consent were based on a false assumption, and therefore their confidence was unwarranted. In contrast, the relative lack confidence of the intense group in their own understanding was more warranted because they have recognized the complexity of the research and their lack of understanding before they signed the consent form.

Our results also demonstrate the importance of the contextual factors for achieving participant understanding of research in the consent process. The intense disclosure approach should perhaps not only be regarded as an extra medium for the conveying of information. Rather, the intense approach—giving community educational lectures and group meetings for discussion—could have functioned as an interface for human communication to cultivate a partnership of *trust* between research subjects and researchers: This trusting partnership could have subsequently led to an enhanced document reading. Consequently, the sense of trust in the research as well as in the researchers created by the intense approach could lead to at least some of them wanting to read the background documents, leading to a higher evaluation of their *understanding* of the research.

This study has several limitations. First, the individuals' self-perceived understanding may not be equivalent to true understanding. This is, however, a methodological challenge for all studies of understanding since there is no standard way of measuring actual understanding. The most commonly used measure, recall, may also be significantly different from actual understanding (Meisel & Roth, 1981). Furthermore, previous data have shown that there is a correlation between the respondents' own assessment of the comprehensibility of the form and their actual comprehension as measured as "recall" (Bjørn et al., 1999), so that the self-perceived understanding correlates with true understanding in the same way as recall. Second, our previous data indicated that participation rates after 6 months observed in the cohorts with the routine and the intense approach did not differ from each other (Matsui et al., 2005), so that an effect of the intense approach on the participation status is still uncertain. However, the underlying genetic epidemiological study is a cohort study with a long-term follow-up that will involve re-approaching participants every 4 to 5 years to collect new biological samples and sensitive personal information such as whether participants have had an onset of

or died from the targeted diseases. Therefore, in the long term, the potential effects of the intense approach on participation, as well as perceived understanding, may be revealed, possibly in relation to long-term retention rates. Third, our findings may be unique to the Japanese population and may not be directly applicable to other cultural settings. Fourth, a part of differences observed between the two approaches may possibly be attributed to the difference in the human nature of people in the two research areas. Fifth, the penetration of the intense approach was unmeasured and highly likely to be incomplete. Only up to half of the potential participants actually participated in the meetings as a part of the intense approach. However, it was highly likely that most of potential participants were aware of the meetings, through the extensive announcement of the meetings. Also, discussion among the town people as a result of the announcement of the meetings would have taken place. All of this activity likely motivated everyone to read the explanatory material once it arrived in the mail. Sixth, there is a possible bias in response by social desirability, i.e., reporting more reading and better understanding than was the actual case. Given that social desirability bias exists, however, it would apply to both groups equally and therefore its effect on data should be little.

Conclusion and Best Practices

This study demonstrates that many individuals in a real genetic research study decide to enroll without reading the explanatory materials. If we are concerned about participants' understanding of a proposed research before they decide to enroll, efforts to improve the informed consent forms or improve readability may therefore not be the best way to increase understanding. Efforts to make the informed consent process more elaborate and detailed may also be a waste of time and cost if the goal is to increase participant understanding of the research.

However, we found that among those participants who actually read the information material, there is an increase both in self-perceived understanding and participation rates. Efforts to improve the informed consent process should perhaps therefore better be directed towards getting people to read the information material for the study. We demonstrated that our more intense approach did lead to a higher degree of reading of the provided material, and this in turn might increase understanding, because of the link between reading of the material and understanding.

It may not be the specific interventions that we provided that increased reading, but it could instead possibly be the result of a stronger relationship building process. Investigators should therefore be aware of this possible effect and plan to spend additional time and effort to building a relationship while providing information in the course of conducting genetic research.

Research Agenda

One main methodological challenge in studies of informed consent is how to measure true understanding. We have measured self-perceived understanding, and we have found that self-perceived understanding is actually lower in the group receiving more information, even though the more intense approach seems to motivate people to read the explanatory material and that in turn improves self-perceived understanding. In order to identify what practices actually improve understanding, we therefore need to develop better methods for assessing true understanding in the context of research.

Educational Implications

The reality of informed consent in an actual research setting is that people decide to enroll in research with only a fairly superficial understanding of the research. Our work implies that people participate in research not necessarily because they are fully informed about the research. Rather, they enroll in research because they get something from the informed consent process about the research that is somehow relevant and valued to each individual. Alternatively, perhaps they decided to participate before receiving any information. If we believe that understanding of the research is essential, and that getting people to read explanatory material is of key importance, then we need to implement procedures that will achieve this. There is some indication that a more intensive human interaction in the informed consent process has potential to achieve this. A key to successful research in terms of practice as well as ethics is that researchers acknowledge this importance of human interaction and make appropriate plans to spend the necessary time and cost this involves.

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