Received: 11 August 2017 | Revised: 14 July 2018 | Accepted: 19 August 2018

DOI: 10.1111/ecc.12937

ORIGINAL ARTICLE

WILEY European Journal of Cancer Care

Quality of online information about phase I clinical cancer trials in Sweden, Denmark and Norway

Tove E. Godskesen[1,2] | Josepine Fernow[2] | Stefan Eriksson[2]

[1]Department of Health Care Sciences, Ersta Sköndal Bräcke University College, Stockholm, Sweden

[2]Centre for Research Ethics & Bioethics, Uppsala University, Uppsala, Sweden

Correspondence
Tove E. Godskesen, Department of Health Care Sciences, Ersta Sköndal Bräcke University College, Stockholm, Sweden.
Emails: tove.godskesen@esh.se, tove.godskesen@crb.uu.se

Abstract

Patients increasingly search for online information about clinical trials. Little is known about the quality and readability of the information in these databases. Therefore, the aim of this study was to assess the quality and readability of online information available to the public on phase I clinical cancer trials in Sweden, Denmark and Norway. A qualitative content analysis was made of 19 online trial descriptions from three public websites in Sweden, Denmark and Norway, and the readability of the documents was tested. Both the quality of the content and the readability scores were best for the Danish information. The Swedish texts were very short and were the least readable. Overall, the quality of the information was highly variable and nearly all the documents were misleading in part. Furthermore, the descriptions provided almost no information about possible adverse effects or disadvantages of study participation. This study highlights a communication problem and proposes new ways of presenting studies that are less suggestive of positive outcomes, arguing that we should be more careful to include information about adverse effects, and that the use of simple measures like readability testing can be useful as an indicator of text quality.

KEYWORDS

cancer, comprehension, ethics, informed consent, Internet, phase I clinical trials

1 | BACKGROUND/AIMS

Patients are increasingly searching for online information on clinical trials (Dolinsky, Wei, Hampshire, & Metz, 2006). This trend is especially obvious in the Nordic countries: a survey of seven European countries showed that more patients searched for health information online in Norway and Denmark than in other countries (Andreassen et al., 2007). However, little is known about the quality and readability of this online trial information. In the Nordic countries, the Nordic Trial Alliance (NTA) is working to implement EU Regulation No. 536/2014, which aims to decrease bureaucracy and accelerate the speed and efficacy of pharmaceutical clinical trials, thus stimulating and improving conditions for the Nordic pharmaceutical industry. Several public English language platforms are now available for patients, medical staff, academic communities and industries. The most recognised platform for clinical trials is the US-based ClinicalTrials.gov, which was initiated by the US government to serve as a public registry and results database for both publicly and privately supported clinical studies. The similar Clinical Trials Register for medicinal products has been launched in the EU. However, these platforms primarily aim to inform professionals about clinical trials and, in response to the perceived need, the national authorities of Sweden, Denmark and Norway have all initiated public platforms to help patients find information about clinical trials in the last three years. Although there are other potential users of this information, patients are the main focus, for both the platforms and this study.

1.1 | Phase I clinical cancer trials

In cancer trials, the drug is tested in patients with advanced cancer, to find a tolerable dose. The drug is tested in patients with cancer, not in healthy volunteers, because of the potentially serious adverse

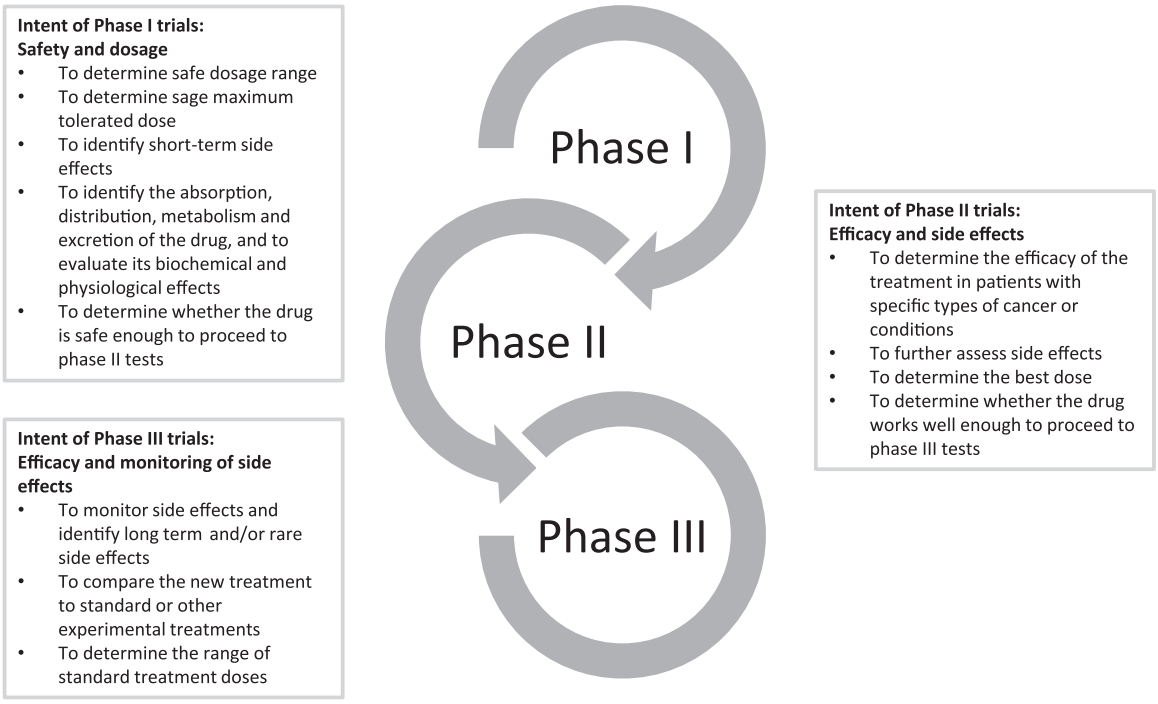

FIGURE 1 The development of anticancer drugs

effects of these drugs. Phase I studies almost always enrol patients with *any* type of cancer, but usually cancer that is inoperable, refractory or metastatic and that has failed available standard treatments (Arkenau et al., 2008).

Classic phase I trials are safety trials and dose escalation studies, which aim to assess how much of the drug can be safely given without the development of too many or too severe adverse effects and to determine the recommended phase II dose. In dose escalation studies, each cohort of patients is given increasing doses of the investigational drug with the aim of learning about its associated toxicities and adverse effects and to determine the maximum tolerated dose (Emanuel, 2008). Preliminary efficacy is sometimes a secondary endpoint (Figure 1).

1.2 | The therapeutic misconception

A significant body of evidence shows that many participants in phase I clinical trials believe they will experience a substantial therapeutic benefit by participating (Godskesen, Nygren, Nordin, Hansson, & Kihlbom, 2013; Jansen et al., 2011; Pawlowski, Malik, & Mahalingam, 2015; Pentz et al., 2012; Schutta & Burnett, 2000). This belief has been labelled a "therapeutic misconception" (TM). The concept of a TM has been defined in various ways. It may be seen as a misunderstanding of the purpose of research: "[W]hen individuals do not understand that the defining purpose of clinical research is to produce generalisable knowledge, regardless of whether the subjects enrolled in the trial benefit from the intervention under study or other aspects of the clinical trial"(Henderson et al., 2007 p.325). This definition allows for situations where phase I clinical cancer trial patients could hope for a therapeutic benefit without the presence of a TM—as long as the purpose of the research is properly understood. In another explanation of the concept, a TM is thought to arise when a "research subject fails to appreciate the distinction between the imperatives of clinical research and standard care, and therefore inaccurately attributes therapeutic intent to research procedures"(Lidz & Appelbaum, 2002, p.55). Here, the misunderstanding occurs when the patient believes that the research is being performed *in order to treat*, which follows from an inability to distinguish between care and research.

1.3 | Research information

One reason for the development of TMs or other misunderstandings is the lack of good information on trials. However, provision of online information on trials does not appear to have decreased misunderstandings. Previous research on online trial information has shown that the documents are not adequately providing patients with relevant information, mainly because of poor readability and the use of difficult terminology (Abel, Cronin, Earles, & Gray, 2015; Atkinson et al., 2008).

When patients are deciding whether to participate in a trial, first impressions gained from reading and digesting online information can influence and possibly override information provided later in the trial process. Investigation of the information provided online is thus an important first step. The online platforms researched in previous studies were predominantly English language based, and users were directed to the official sites mentioned above for further information. However, not all Nordic citizens are fluent in English, so analysis of Nordic sites is relevant and necessary. To our knowledge, this has not previously been done.

TABLE 1 The 19 phase I cancer trials studied

1.	MAT 02	NCT01946373	https://www.cancercentrum.se
2.	HuMax®-TF-ADC	NCT02001623	https://www.cancercentrum.se
3.	HuMax®-TF-ADC	NCT02001623	https://www.skaccd.org
4.	LYMRIT-3701	NCT01796171	https://www.helsenorge.no
5.	LYMRIT-3701	NCT01796171	https://www.cancercentrum.se
6.	54767414MMY1004	NCT02519452	https://www.skaccd.org
7.	BP29435 Combo	NCT02304393	https://www.skaccd.org
8.	Keynote-173	NCT02130466	https://www.skaccd.org
9.	BrAKT1	NCT01226316	https://www.skaccd.org
10.	P[R]EBEN	NCT02678299	https://www.skaccd.org
11.	VINSOR	NCT01844947	https://www.skaccd.org
12.	VINSOR	NCT01844947	https://www.cancercentrum.se
13.	Anti-LAG-3	NCT01968109	https://www.skaccd.org
14.	Anti-LAG-3	NCT01968109	https://www.helsenorge.no
15.	Modufolin®	NCT02244632	https://www.helsenorge.no
16.	BGB324	NCT02488408	https://www.helsenorge.no
17.	Vaccine	NCT01197625	https://www.helsenorge.no
18.	LTX-315	NCT01986426	https://www.helsenorge.no
19.	CINC280A2108	NCT02925104	https://www.cancercentrum.se

The aim of this study was to assess the quality and readability of online information on phase I clinical cancer trials from sites intended for public use in Sweden, Denmark and Norway. The research questions were as follows: Is the information provided (a) complete (i.e., does it include the purpose, important adverse effects, disadvantages and risks of treatment); (b) misleading; and (c) easily readable?

2 | METHODS

2.1 | Selection of sites and research terms

The study examined patient-oriented information about 19 trials; the information was publicly available on websites set up by national authorities in Sweden, Denmark and Norway. The most accessible and widely used site from each country was chosen (Table 1). Of the 19 trials studied, 26% (5/19) were Swedish, 32% (6/19) were Norwegian and 42% (8/19) were Danish. Four (21%) were multinational studies including two of the Nordic countries (none included all three countries).

We used the following search terms in the respective national languages: "Cancer," "Clinical trials" and "Phase I." First-in-human trials, classical dose-escalating studies of a single agent or trials assessing combinations of standard drugs with new drugs were included (Table 2). We excluded the following results of the search: clinical trials in children or involving stem cell transplantations, surgery, pain treatment, nutrition or physical training programmes. These trials were omitted because of the vastly different adverse effects and risks in comparison with those in typical cancer drug trials.

The Swedish site www.cancercentrum.se is the result of a national collaboration between six regional cancer centres in Sweden. It has several aims, one of which is to increase patient participation in clinical cancer research. The Danish site www.skaccd.org is the result of a similar collaboration between regional cancer centres in Denmark. The Norwegian national site www.kliniskestudier.helsenorge.no is a public health portal in Norway that gives an overview of all clinical trials performed at hospitals in Norway.

TABLE 2 Types of phase I cancer trials included

	Trial no.
Chemotherapy	
One investigational agent	–
Combination of agents	11, 12, 15
Immunotherapy	
One investigational agent	2, 3, 4,5, 9, 19
Combination of agents	1, 7,8, 18, 6, 10, 13, 14, 16
Vaccines	
One investigational agent	17†
Combination of agents	–

Note. 17† In combination with surgery.

2.2 | Quality analysis

All trial documents were read several times by the researchers. In the first step, we used content analysis to evaluate all the qualitative data. Two of the authors (TG and SE) independently assessed whether the trial information was accurate and understandable with respect to completeness, clarity of the message and lack of

ambiguity. For the information to be complete, it should include a clearly stated trial purpose and descriptions of any important adverse effects, disadvantages and risks associated with the trial. Texts that are ambiguous and unclear risk misleading readers. For this reason, we looked carefully for terms and expressions that invited a TM by suggesting that the trial could serve a therapeutic purpose rather than a scientific purpose (where TM was defined using either of the definitions above). As we found instances of such terminology, we returned to all the other trial information to see if similar or the same terminology had been used there (a kind of hermeneutic circle).

2.3 | Readability

Readability testing (assessed by JF) was conducted using The Flesch-Kincaid Grade Level, and the SMOG and LIX indices. The Flesch-Kincaid Grade Level is the most commonly used tool in this respect; its scores are presented in terms of equivalence to US school grade levels (Kincaid, Fischburne, Rogers, & Chisson, 1975). The SMOG index also estimates the years of education required to understand a text (McLaughlin, 1969). It aims for a higher level of (expected) comprehension than the Flesh-Kincaid Grade Level, gives consistent results and has been suggested as a good fit for healthcare-related information (Wang, Miller, Schmitt, & Wen, 2013). However, both these tools were developed for the English language. For this reason, we decided to also include LIX, a readability scale developed for the Swedish language, and widely used in both Denmark and Norway (in Norwegian known as liks), which provides scores in five categories that range from easy to very difficult (Björnsson, 1968). Together, these scoring methods were expected to give a clear indication of the level of readability.

2.4 | About readability levels

Literacy rates differ around the world. The Nordic countries are all listed among the world's top five (Norway second, Denmark fourth, Sweden fifth) with the US in seventh place (Miller, 2016). Despite these high literacy rates, producers of texts should take into account that relatively large proportions of the adult population have poor literacy, numeracy and problem-solving skills, and are not native speakers (Schleicher, Keese, & Encinas-Martin, 2012a, 2012b; SFI., 2014). What does this mean for readability? It has been estimated that almost half of the adult US population read below or at a "basic" level (Kirsch, Jungeblut, Jenkins, & Kolstad, 2002). For this reason, written information for patients with poor literacy should ideally be written at a US 5th grade reading level (or lower) and should possibly also be accompanied by oral information (Weiss et al., 1998). In a policy statement, the American Society of Clinical Oncology states that information for patients should be written at an 8th-grade reading level (Weber et al., 2017). Given that most people in the Nordic countries have completed nine years of schooling, we decided to use their recommendation for this study, although this does not mean that the information will be accessible to the entire population.

The results of readability testing can differ considerably depending on the software used (Wang et al., 2013). In this study, the SMOG index and the Flesch-Kincaid Grade Level scores were estimated using an online tool available at readable.io. LIX scores were tested using lix.se.

2.5 | Preparations for testing

The Swedish and Danish information is structured in tables, while the Norwegian content is in plain text. The Norwegian information is also organised under descriptive headings, while the Swedish and Danish headings, as a rule, are less informative. To ensure that the different structuring of the content did not conflate the scores, the following steps were taken: the original.html content was copied and pasted to a.docx file and final versions of the content were compared to the original to verify accuracy. The following table headings, phrases and words were removed to ensure they did not influence the readability scores: diagnosis; name of study; English name of study protocol; participating hospitals; trial ID number; phase; stage; short title; start date; primary investigator; and date of last revision. Because the Swedish texts were very short, we opted to keep the Swedish title (as otherwise study no. 2 (GEN 701) would not have had any text to test).

Sentences that did not end with a period, but were clearly visually set apart at the end of a paragraph, had a period added. In one case, a comma at the end of a paragraph was replaced with a period. When upper case was used inside a paragraph, no periods were added. Periods were deleted from abbreviations and URLs in order not to conflate the scores. Bullet point lists were transformed into sentences ending with a period. Consecutive bullet points consisting of only one word were grouped together as one sentence, with the items separated by commas and a period added at the end of the list.

3 | RESULTS

3.1 | Completeness

While the purpose was clearly stated in the information provided, the adverse effects, disadvantages and risks of participation appeared downplayed or were simply ignored.

3.1.1 | Purpose

The purpose was described in all the examined documents. However, in most Swedish texts, the purpose was only found in the study title, for example:

> A dose escalation study to evaluate the pharmacokinetics, safety, and tolerability of [the study compound] (no. 19)

Most of the Danish texts included an "overall aim" which presented the purpose clearly; for example:

> To assess the safety and tolerability, characterise the dose-limiting toxicities, and identify the maximum tolerated dose of [the study compound] alone and in combination …in subjects with selected advanced (metastatic and unresectable) solid tumours, and to provide preliminary information on the clinical benefits of the combination (no. 13)

3.1.2 | Adverse effects, disadvantages and risks

Possible adverse effects of the study compound and disadvantages associated with participation were only mentioned in six of the 19 (32%) examined texts, while almost 70% made no reference to any risks associated with phase I trials. In one study, no information was given about adverse effects and disadvantages, although the protocol at ClinicalTrials.gov stated that 26 hospital visits were required to get an injection of the drug, undergo both computed tomography and electrocardiograms, and have up to three biopsies taken (no. 18). Some Danish trials stood out positively by presenting brief explanatory passages about potential adverse effects or disadvantages, or by providing links to comprehensive information about adverse effects or disadvantages.

3.2 | Misleading language

Misleading language or information was found in 16 of the 19 examined texts (84%). Of the three texts that were found not to be misleading, two consisted of short, summary descriptions of the study essentials that made no attempt to convey meaningful information to any interested patients. This meant that, in reality, only one protocol description (5.3%; no. 17) met reasonable standards for accuracy. Comparison of the countries did not show any marked differences in terms of using accurate language.

The most frequently occurring issue in the examined texts was language suggesting that the study could be seen as *treatment* of cancer (14 of 19; 74%, or that it might be *effective* for treating cancer (10 of 19; 53%). There were also other types of misleading information found in several texts. The main types of misleading information are described and exemplified below.

3.2.1 | Treatment

This type of statement usually used the word treatment instead of study protocol, experiment, test or trial, sometimes even in the headings, which made the word stand out. One typical sentence was:

> If you are interested in the treatment … (no. 3)

This type of wording was often aligned with the use of "patient" to describe the study participants, which could reinforce the message that the patient reader is being offered treatment ("Patients in this study will be treated with …"). Sometimes the word treatment was linked with "experimental," which could possibly make the wording clearer for some readers. This was, however, usually undermined by the use of misleading language in other places. The language was rather suggestive at times:

> Therefore, this is a targeted treatment of the cancer itself (no. 4)

Treatment was often used in conjunction with *medicine*, as described below.

3.2.2 | Efficacy

The typical expressions exemplifying this type of misleading language were statements claiming that the study was concerned with investigating whether the study compound was effective, or what kind of effect the new drug had, sometimes aligned with "possibility." The experimental meaning of "effect" was not explained, so it could easily be understood as the effect on the disease as experienced by the participant (sometimes "effect on the disease" was used). Occasionally, the wording seemed to indicate a strong possibility of getting well:

> [The study tests whether the compound] battles the cancer effectively (no. 3)

Patients could easily interpret this as a study investigating whether they can become free of their cancer. In another notable instance, a typo in the original Norwegian (from the conditional "kan få" to a mixed present tense "kan får") could indicate to an unwary reader that:

> Advantages of study participation are that one gets [sic] good efficacy and fewer side effects… (no. 4)

Thus, the addition of the "r" could result in a misunderstanding that this is an actual assurance of getting a good therapeutic effect and fewer side effects.

3.2.3 | Medicine

In seven documents, words such as "medicine," "drug" or "therapy" were used for the experimental compound, thus possibly suggesting that participants were to get clinical medical treatment. The other documents commonly just used "substance," the experimental drug designation or a functional description (e.g., "antibody").

3.2.4 | Opportunity

Five documents talked about participating as an opportunity:

> If you have cancer … this experimental treatment might present an opportunity (no. 12)

In all five documents discussing opportunities, a common expression, which is apparently a standard phrase used in many information documents, was used:

> [Talk to your doctor to discuss] whether the treatment might be an opportunity for you.

It was never stated if it was an opportunity for participation that was meant (we presume this was the intended meaning) or an opportunity for becoming better or well (the meaning a patient might attach to it). In our opinion, the use of "treatment" in conjunction with "opportunity" strongly invites the latter interpretation.

3.2.5 | Benefit

Three of the documents used expressions that were highly suggestive in terms of participation giving a possible benefit. In one document, the expression "if you gain from the treatment" was used, along with information that the patient would be given the doses that the doctors found to be "working best" (no. 3). In another document, it was stated that the test would go on as long as "you benefit from it" (no. 6). Finally, one study used an arguably true statement to nevertheless suggest by implication that benefit was possible:

> For the moment it is not known whether [the study compound] will have a beneficial effect on the disease (no. 16)

3.3 | Readability

Results from all three readability tests showed a similar pattern: the Danish texts scored lowest (i.e., were most readable), the Swedish texts scored highest (i.e., were least readable) and the Norwegian texts fell between (Figure 2).

The analysis showed that, in general, the Danish texts had lower scores over all three measures than the other countries. The mean LIX, Flesch-Kincaid and SMOG scores were 42, 9.1 and 11.9 for Denmark; 51, 12.7 and 15.1 for Norway; and 66, 18 and 17.7 for Sweden. The Danish scores indicated that readers required between 9 and 12 years of schooling for comprehension. The Swedish texts scored significantly higher than both Danish and Norwegian; readers required the equivalent of a PhD to comprehend the text. The Norwegian scores indicated that readers needed to be doing undergraduate studies at university to understand the text. The scores correlated with the length of the texts: the Danish texts were by far the longest (on average 677.3 words, 53.4 sentences), followed by the Norwegian texts (274 words, 15.5 sentences) and then the Swedish texts (54.4 words in 3.4 sentences).

The LIX comparison test provided scores in five categories: <30 = very easy, 30–40 = easy, 40–50 = medium difficulty, 50–60 = difficult, and >60 = very difficult (Björnsson, 1968). Writers of text for the public should aim to have scores between 30 and 40. The Danish texts ranged between 40 and 44, which places them at the lower end of medium difficulty. The Norwegian texts ranged between 47 and 61, placing most of them in the difficult range. The Swedish texts ranged between 56 and 73, with all but one in the very difficult range, mirroring the results from the other tests (Figure 3).

To summarise, after testing readability using the Flesch-Kincaid Grade Level, and the LIX and SMOG indices, the only texts that came close to meeting an 8th-grade reading level were Danish. The Danish texts were clearly the most readable, regardless of the index score, while the Swedish texts were clearly the least readable. The Danish texts were also the longest, while the content of one Swedish document was just the name of the study: one sentence consisting of 32 words. The Norwegian texts varied more in length. The shortness of the Swedish documents does indicate that readability testing might not be meaningful in this case. However, we consider testing to be nonetheless useful as the scores lend support to the varying quality of the documents between the studied countries.

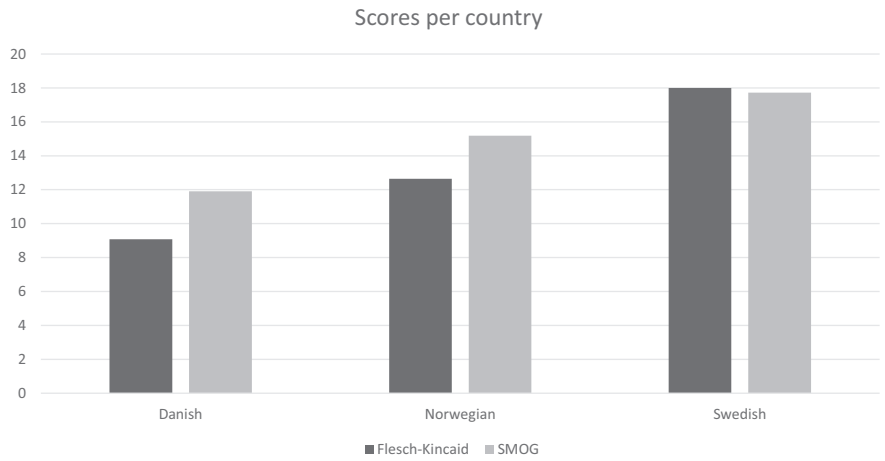

FIGURE 2 Flesch-Kincaid and SMOG scores per country (higher scores indicate poorer readability)

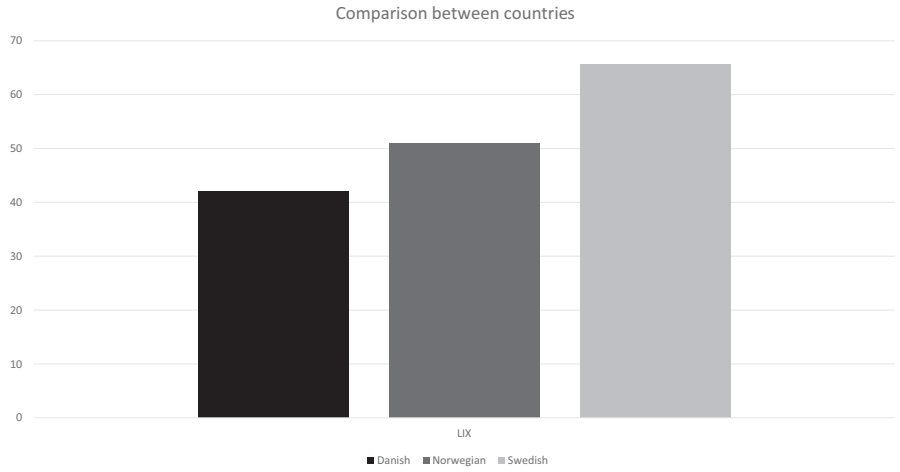

FIGURE 3 LIX score comparison between countries (higher scores indicate poorer readability)

4 | CONCLUSIONS

We found the information to be incomplete; barely any information on adverse effects was given. We also found that over 80% of the investigated cases contained misleading statements. Last, the readability overall was found to be poor.

The documents were difficult to read and understand, despite being written for patients who need clear, helpful information. The decision on whether to participate in a phase I trial should be based on *accessible* and *accurate* information. However, our results question whether this has been achieved in these public databases. The results from Sweden and Norway especially support and add to the findings of Monaco and Krills (2003) and Atkinson et al. (2008) who found that clinical trial-related websites use complex language and give minimal information (e.g., sometimes only providing the study title). As a result, patients may fail to understand and thus misinterpret what participation entails. Consequently, it is virtually impossible for patients to make an informed decision on whether to participate on this basis alone.

Benefit-related words like *treatment*, *medicine* and *efficacy* were frequently used in the information and may have created a skewed or biased picture of possible personal therapeutic benefit, although the primary endpoint of phase I trials is to assess the safety and not the efficacy of a new agent. Even though the information was assumed to be written in good faith and not to mislead people, some words are linked to a positive outcome. However, the results of this study fit with the findings of Godskesen et al. (2013) who found that participants in phase I trials had unrealistic expectations of therapeutic benefit and had a poor understanding of the purpose and scope of the studies.

If patients participate in a phase I clinical trial without an understanding of the purpose and scope of such trials, there is a serious ethical problem. The informed consent process includes both being given and understanding the information (Beauchamp & Childress, 2009). A research subject is not adequately informed until the information is understood. We acknowledge that the information on these sites is not directly a part of the informed consent procedure. Nonetheless, the information is meant to provide an accurate snapshot of ongoing trials and could, if the information was adequate and understandable, serve as an excellent tool for those who are considering participation. Therefore, these online descriptions of phase I trials should at least describe the nature and the scope of the trial, and not mislead the reader about what participation would entail. To do this, the potential adverse effects and risks of participation must be explained in a simple, clear manner which promotes true understanding (Weber et al., 2017).

Modern behavioural psychology of human decision-making can offer an interpretative, theoretical frame to explain why people might be misguided by the language we have labelled "misleading" and why there might be difficulties in correcting patients' misconceptions about the aims of phase I clinical trials in the informed consent process. When we are in unfamiliar situations with high-stake outcomes and limited time available, our reasoning relies heavily on intuition and we can easily be mistaken about various aspects of the situation (Kahneman, 2013). In most cases, this results in overly positive attitudes. We are, in a sense, programmed to believe the best and are cognitively susceptible to confirmation bias (Gilbert, Krulloch, & Malone, 1990). One aspect of this phenomenon is the well-known fact that our judgement of a person or a text is heavily influenced by our first impressions. If we first come across a positive value, we will often interpret a subsequent list of values or characteristics positively (Ash, 1946), also known as a halo effect (Fernan, Schuldt, & Niederdeppe, 2017). Another way of expressing this is by using the notion of *priming*, which is best explained as a memory effect where previous exposure to a stimulus influences later responses to another stimulus. We use the first stimulus as an *anchor* to judge the later one (Mussweiler & Strack, 2000). For example, a heading saying something about "treatment" (as we found in the material at hand) will likely influence readers to subsequently connect a word such as "effective" with treatment (which they then also want to believe is an "opportunity" for them). This also explains why there might be difficulties in correcting a misguided belief later in the informed consent process; whatever is stated in the informed consent information will be read in light of previous conceptions formed from reading the website information. This difficulty is reinforced by *affect heuristics*,

TABLE 3 Recommended phrases for replacing typical misleading phrases in phase I cancer trials

Typical phrase	Suggested replacement
If you are interested in the treatment	If you want to participate in the research
Patients will be treated with X	Participants will be given X
The study tests X's effect on cancer	The study evaluates [tumour] response to X
An advantage of study participation is that one	The study might lead to better treatment can get good efficacy for future patients
You will be administered a medicine/drug/therapy	You will be given a substance called X
This treatment could be an opportunity for you	You can participate in this study
For the moment it is not known whether [the study drug] will have a beneficial effect on the disease	Before the study has been done, we can't say whether it might be beneficial for you to participate

that is the tendency to give something positive (e.g., a treatment) high marks for usefulness and utility, while at the same time downplaying the negative sides and risks. This makes it easier for us to make decisions; the difficult balancing of benefits and costs is replaced by a focus on the positive—and the risks disappear from sight as we take the easier route (Gilovich, Griffin, & Kahneman, 2002). It is, then, no surprise that a dying patient might be clutching at straws. Kahneman states in his seminal work that when we are exposed to difficult questions (and how to spend the final days of one's life must surely be one), we clutch at whatever straw we can find—and a phase I trial is a highly feasible candidate. The downside, however, is our tendency to be unaware of the hidden power of suggestion.

4.1 | Implications for practice: A suggestion on how to improve trial information

As the quality of online information on phase I clinical cancer trials in Sweden, Denmark and Norway was poor as they contained misleading statements, lacked most information on adverse effects and had poor readability overall, we suggest that these sources of information could be improved by exchanging highly suggestive expressions for more accurate, neutral expressions (Table 3).

4.2 | Limitations

There are several limitations to this study. Firstly, the results are not generalisable to all web-based trial information, as our sampling frame was limited to phase I clinical cancer trials conducted in Sweden, Denmark and Norway. It could be that a sample of trial information from other countries in the Nordic region (such as Finland and Iceland) would yield different results. There are reasons to believe, however, that other phase I documents in a Nordic context are similar to those studied here, as similar regulations, laws and ethical norms are in place. It should be noted that there is a second Swedish website, www.kliniskastudier.se, created as a collaboration between the Swedish Research Council and Sweden's six healthcare regions. This partnership aims to integrate clinical trials into health care and to ensure that there are clear incentives for patients, medical staff, the academic community and industries to participate in research. This project was started in 2015 and will be completed by the end of 2017. As the kliniskastudier website was only available in a rudimentary form when this study was begun, it was decided to exclude it from the study.

Secondly, the sample size (19) is small. Nevertheless, this analysis provides a snapshot of phase I cancer trials in Sweden, Denmark and Norway between 15 February and 2 March 2017. Even if the Swedish websites are not yet well developed, this study provides an overview of the Nordic clinical trial landscape and is thus representative of what a person looking to participate in a clinical trial is likely to encounter. Since phase I trials are few, the small sample size might actually be more representative than seems at first glance. However, it is possible that a larger sample would have given different results. We therefore welcome more studies that attempt to replicate ours.

Thirdly, readability testing is a blunt tool. Readability and comprehension are different things. Both the Flesch-Kincaid Grade Level and the SMOG index use the occurrences of polysyllabic words to calculate scores. This could conflate results for Norwegian, Danish and Swedish, as words that are separated in English are often joined in these languages. Also, readers either know the definition of short words or not, while it is sometimes possible to make informed guesses about the meaning of more morphologically complex words (Bailin & Grafstein, 2001).

Fourthly, and last, our use of behavioural psychology to hypothesise about the impact of online information on later informed

consent is based on solid empirical work. Because of this, it is feasible to suggest that such a connection exists. This, however, remains to be tested empirically.

5 | CONCLUSION

The development of government-based public platforms on clinical trials in the Nordic countries is a promising way of providing trial information to patients searching for clinical trials in which to participate. However, the information provided on phase I clinical trials, particularly in Sweden and Norway, is of poor quality, gives misleading information, provides minimal information about adverse effects and has poor readability scores. At worst, this might invite TMs and encourage patients to participate for the wrong reasons. There is therefore a need for further development of the strategies employed for disseminating trial information to the public. This study has highlighted the problem and we propose that some ways of describing studies can be replaced with less suggestive language, that we should be more careful to inform about adverse effects, and that readability testing could be a helpful tool for improving texts, and making information easier to read and, by extension, also easier to understand. The ongoing work on the national platforms for patient information could greatly benefit from this realisation.

ORCID

Tove E. Godskesen http://orcid.org/0000-0001-6011-6740

REFERENCES

Abel, G. A., Cronin, A. M., Earles, K., & Gray, S. W. (2015). Accessibility and Quality of Online Cancer-Related Clinical Trial Information for Naive Searchers. *CancerEpidemiology, Biomarkers & Prevention : A Publication of the American Association for Cancer Research, Cosponsored by the American Society of Preventive Oncology*, *24*, 1629–1631. https://doi.org/10.1158/1055-9965.EPI-15-0274

Andreassen, H. K., Bujnowska-Fedak, M. M., Chronaki, C. E., Dumitru, R. C., Pudule, I., Santana, S., … Wynn, R. (2007). European citizens' use of E-health services: A study of seven countries. *BMC Public Health*, *7*, 53. https://doi.org/10.1186/1471-2458-7-53

Arkenau, H. T., Olmos, D., Ang, J. E., Barriuso, J., Karavasilis, V., Ashley, S., … Kaye, S. (2008). 90-Days mortality rate in patients treated within the context of a phase-I trial: How should we identify patients who should not go on trial? *European Journal of Cancer*, *44*, 1536–1540. https://doi.org/10.1016/j.ejca.2008.04.017

Ash, S. E. (1946). Forming impressions of personality. *Journal of Abnormal and Social Psychology*, *41*, 258–290. https://doi.org/10.1037/h0055756

Atkinson, N. L., Saperstein, S. L., Massett, H. A., Leonard, C. R., Grama, L., & Manrow, R. (2008). Using the Internet to search for cancer clinical trials: A comparative audit of clinical trial search tools. *Contemporary Clinical Trials*, *29*, 555–564. https://doi.org/10.1016/j.cct.2008.01.007

Bailin, A., & Grafstein, A. (2001). The linguistic assumptions underlying readability formulae. *Language & Communication*, *21*, 285–301. https://doi.org/10.1016/S0271-5309(01)00005-2

Beauchamp, T. L., & Childress, J. F. (2009). *Principles of biomedical ethics*, 6th ed. New York, NY: Oxford University Press.

Björnsson, C. H. (1968). *Läsbarhet*. Stockholm: Bokförlaget Liber.

Dolinsky, C. M., Wei, S. J., Hampshire, M. K., & Metz, J. M. (2006). Breast cancer patients' attitudes toward clinical trials in the radiation oncology clinic versus those searching for trial information on the Internet. *The Breast Journal*, *12*, 324–330. https://doi.org/10.1111/j.1075-122X.2006.00270.x

Emanuel, E. J. (2008). *The Oxford textbook of clinical research ethics*. New York, NY: Oxford University Press, Oxford.

Fernan, C., Schuldt, J. P., & Niederdeppe, J. (2017). Health halo effects from product titles and nutrient content claims in the context of "protein" bars. *Health Communication*, *33*, 1425–1433. https://doi.org/10.1080/10410236.2017.1358240

Gilbert, D. T., Krulloch, D. S., & Malone, P. S. (1990). Unbelieving the unbelievable: Some problems in the rejection of false information. *Journal of Personality and Social Psychology*, *59*, 601–613. https://doi.org/10.1037/0022-3514.59.4.601

Gilovich, T., Griffin, D. W., & Kahneman, D. (2002). *Heuristics and biases : The psychology of intuitive judgment*. New York, NY, Cambridge, UK: Cambridge University Press.

Godskesen, T., Nygren, P., Nordin, K., Hansson, M., & Kihlbom, U. (2013). Phase 1 clinical trials in end-stage cancer: Patient understanding of trial premises and motives for participation. *Supportive Care in Cancer*, *21*, 3137–3142. https://doi.org/10.1007/s00520-013-1891-7

Henderson, G. E., Churchill, L. R., Davis, A. M., Easter, M. M., Grady, C., Joffe, S., … Zimmer, C. R. (2007). Clinical trials and medical care: Defining the therapeutic misconception. *PLoS Med*, *4*, e324. https://doi.org/10.1371/journal.pmed.0040324

Jansen, L. A., Appelbaum, P. S., Klein, W. M., Weinstein, N. D., Cook, W., Fogel, J. S., & Sulmasy, D. P. (2011). Unrealistic optimism in early-phase oncology trials. *IRB*, *33*, 1–8.

Kahneman, D. (2013). *Thinking, fast and slow*, 1st pbk. ed. New York, NY: Farrar, Straus and Giroux.

Kincaid, P. J., Fischburne, R. P. J., Rogers, R. L., & Chisson, B. S. (1975). *Derivation of new readability formulas (Automated Readability Index, Fog Count, and Flesch Reading Ease Formula) for Navy enlisted personnel. Research Branch Report. Naval Air Station Memphis - Millingon* 8–75.

Kirsch, I. S., Jungeblut, A., Jenkins, L., & Kolstad, A. (2002). Adult literacy in America: A first look at the findings of the national adult literacy survey. Retrieved from https://nces.ed.gov/pubsearch/pubsinfo.asp?pubxml:id=93275

Lidz, C. W., & Appelbaum, P. S. (2002). The therapeutic misconception: Problems and solutions. *Medical Care*, *40*, V55–V63. https://doi.org/10.1097/00005650-200209001-00008

Mclaughlin, G. H. (1969). SMOG grading: A new readability formula. *Journal of Reading*, *12*, 639–646.

Miller, J. W. (2016). *World's most literate nations*. Retrieved from https://www.ccsu.edu/wmln/rank.html

Monaco, V., & Krills, S. K. (2003). *On-line information about cancer clinical trials: Evaluating the Web sites of comprehensive cancer centers*. AMIA Annu Symp Proc,470–474.

Mussweiler, T., & Strack, F. (2000). The use of category and exemplar knowledge in the solution of anchoring tasks. *Journal of Personality and Social Psychology*, *78*, 1038–1052. https://doi.org/10.1037/0022-3514.78.6.1038

Pawlowski, J., Malik, L., & Mahalingam, D. (2015). Advanced cancer patients' understanding and perceptions of phase I clinical trials. *Cancer Investigation*, *33*, 490–495. https://doi.org/10.3109/07357907.2015.1069833

Pentz, R. D., White, M., Harvey, R. D., Farmer, Z. L., Liu, Y., Lewis, C., … Khuri, F. R. (2012). Therapeutic misconception, misestimation, and optimism in participants enrolled in phase 1 trials. *Cancer*, *118*, 4571–4578. https://doi.org/10.1002/cncr.27397

Schleicher, A., Keese, M., & Encinas-Martin, M.(2012a). *Country Note: Survey of Adult Skills First Results - Norway*. Retrieved from https://www.aft.org/issues/

Schleicher, A., Keese, M., & Encinas-Martin, M. (2012b). *Country note: Survey of adult skills first results - SWEDEN*. Retrieved from https://www.aft.org/issues/

Schutta, K. M., & Burnett, C. B. (2000). Factors that influence a patient's decision to participate in a phase I cancer clinical trial. *Oncology Nursing Forum*, *27*, 1435–1438.

Sfi. (2014). *Survey of Adult Skills - Denmark Summary of Danish PIAAC results*.

Wang, L. W., Miller, M. J., Schmitt, M. R., & Wen, F. K. (2013). Assessing readability formula differences with written health information materials: Application, results, and recommendations. *Research in Social & Administrative Pharmacy:RSAP*, *9*, 503–516. https://doi.org/10.1016/j.sapharm.2012.05.009

Weber, J. S., Levit, L. A., Adamson, P. C., Bruinooge, S. S., Burris 3rd, H. A., Carducci, M. A., … Schuchter, L. M. (2017). Reaffirming and clarifying the American society of clinical oncology's policy statement on the critical role of phase I trials in cancer research and treatment. *Journal of Clinical Oncology*, *35*, 139–140. https://doi.org/10.1200/JCO.2016.70.4692

Weiss, B., Coyne, D., Michielutte, R., Davis, T., Meade, C., Doak, L., & Furnas, S. (1998). Communicating with patients who have limited literacy skills: Report of the national work group on literacy and health. *Journal of Family Practice*, *46*, 168–176.

How to cite this article: Godskesen TE, Fernow J, Eriksson S. Quality of online information about phase I clinical cancer trials in Sweden, Denmark and Norway. *Eur J Cancer Care*. 2018;27:e12937. https://doi.org/10.1111/ecc.12937